ঔষধ নিয়ন্ত্রণ কমিটির ১৮ ফেব্রুয়ারী, ২০২১ তারিখে অনুষ্ঠিত ২৫২ তম সভার কার্যবিবরণী

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্বাস্থ্য সেবা বিভাগের সচিব জনাব মো. আবদুল মান্নান এর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৫২ তম সভা বিগত ১৮ ফেব্রুয়ারী ২০২১ তারিখ সকাল ১২.৩০ ঘটিকায় মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

সভায় কমিটির নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জেষ্ঠ্যতার ক্রমানুসারে নয়) ঃ

১. মেজর জেনারেল মোঃ মাহবুবুর রহমান, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর।
২. অধ্যাপক আবুল বাসার মোহাম্মদ খুরশীদ আলম, মহাপরিচালক, স্বাস্থ্য অধিদপ্তর।
৩. জনাব মোঃ এনামুল হক, অতিরিক্ত সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা।
৪. ড. ফেরদৌসী কাদরী, সিনিয়র সাইন্টিস্ট, আইসিডিডিআর, বি।
৫. অধ্যাপক ডাঃ মোঃ ইসমাইল খান, উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয়, চট্টগ্রাম।
৬. ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, উপদেষ্টা চিকিৎসা বিশেষজ্ঞ এবং মেডিক্যাল অনকোলজিস্ট, সি এম এইচ, ঢাকা।
৭. অধ্যাপক ড. এস. এম. আবদুর রহমান, ডীন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়।
৮. প্রফেসর ড. মোঃ ইলিয়াস আল-মামুন, চেয়ারম্যান, ডিপার্টমেন্ট অব ফার্মাসিউটিক্যালস টেকনোলজি, ঢাকা বিশ্ববিদ্যালয়।
৯. অধ্যাপক ডাঃ জাকির হোসাইন গালিব, চর্ম ও যৌন রোগ বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
১০. ডাঃ শক্তি দাস, অধ্যাপক, গাইনি বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
১১. ডাঃ মোঃ টিটো মিঞা, চেয়ারম্যান, ঢাকা মেডিকেল কলেজ, ঢাকা।
১২. ডাঃ মুহাম্মদ রফিকুল আলম, বিএসএমএমইউ।
১৩. ডাঃ জামাল উদ্দিন চৌধুরী, কার্যকরী পরিষদ সদস্য, বিএমএ।
১৪. জনাব মোঃ রিয়াজুল হক, সদস্য, বাংলাদেশ ইম্পোটার্স এসোসিয়েশন।
১৫. আ. খ. মাহবুবুর রহমান, সদস্য, বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড, ইউনানী।
১৬. কবিরাজ শ্রী কৃষ্ণকান্ত রায়, সদস্য, বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড, আয়ুর্বেদিক।
১৭. ডাঃ মোঃ ফরহাদ হোসেন, ডিরেক্টর, রিসার্স ট্রেনিং এন্ড ইভাল্যুয়েশন, ডিএলএস।
১৮. জনাব মুহাম্মদ মাহবুবুল হক, সচিব, বাংলাদেশ ফার্মেসী কাউন্সিল।
১৯. অধ্যাপক ড. মোঃ আনোয়ার উল ইসলাম, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ফার্মাসিউটিক্যাল সোসাইটি, ঢাকা।

পর্যবেক্ষক ঃ

১. এস, এম, শফিউজ্জামান, মহাসচিব, বাংলাদেশ ঔষধ শিল্প সমিতি।
২. জনাব রাব্বুর রেজা, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং সিওও, মেসার্স বেক্সিমকো ফার্মাসিউটিক্যালস লিঃ।
৩. জনাব মোঃ আবদুর রাজ্জাক, বাংলাদেশ ঔষধ শিল্প সমিতি কর্তৃক মনোনীত মেডিকেল ডিভাইস বিশেষজ্ঞ এবং ব্যবস্থাপনা পরিচালক, জেএমআই সিরিঞ্জেস এন্ড মেডিকেল ডিভাইসেস লিঃ, কুমিল্লা ।

সভায় আলোচ্য বিষয়সমূহ :

১. ঔষধ নিয়ন্ত্রণ কমিটির ২৭ ফেব্রুয়ারী, ২০২০ তারিখে অনুষ্ঠিত ২৫১ তম সভার কার্যবিবরণী নিশ্চিতকরণ প্রসঙ্গে ।
২. স্থানীয়ভাবে উৎপাদনের জন্য ৪৩৮ টি হিউম্যান ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৩. আমদানীর জন্য ৪৮ টি হিউম্যান ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৪. স্থানীয়ভাবে উৎপাদনের জন্য ৪ টি হিউম্যান ভ্যাক্সিনের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৫. স্থানীয়ভাবে উৎপাদনের জন্য ৫৮ টি ভেটেরিনারি ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৬. আমদানীর জন্য ৫৫ টি ভেটেরিনারি ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৭. স্থানীয়ভাবে উৎপাদনের জন্য ১১৩ টি হারবাল ঔষধের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৮. আমদানীর জন্য ১৬ টি মেডিক্যাল ডিভাইসের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
৯. স্থানীয়ভাবে উৎপাদনের জন্য ০৪ টি মেডিক্যাল ডিভাইসের আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।
১০. কোভিড-১৯ সংক্রান্ত ঔষধ ও হ্যান্ড সেনিটাইজার এর আবেদনের বিষয়ে সিদ্ধান্ত গ্রহণ।

১১. বিবিধ আলোচনা।

সভার আলোচনা ও সিদ্ধান্ত ঃ

সভাপতি উপস্থিত সকলকে স্বাগত জানিয়ে সভার কার্যক্রম শুরু করেন। তিনি ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক মেজর জেনারেল মোঃ মাহবুবুর রহমানকে সভার আলোচ্যসূচী উপস্থাপনের জন্য অনুরোধ করেন। তিনি সভার আলোচ্যসূচী উপস্থাপন করেন।

তিনি উল্লেখ করেন যে, ইতোমধ্যে ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভায় উপস্থাপনের লক্ষ্যে নিম্নবর্ণিত মোট ০৬ টি টেকনিক্যাল সাব কমিটির সভা অনুষ্ঠিত হয়েছে।

- ডিসিসি এর টেকনিক্যাল সাব কমিটির (হিউম্যান মেডিসিন ও ভ্যাক্সিন) সভা ০৩ টিঃ ০৪.০৬.২০২০ ও ২০.১০.২০২০ ও ১১.০১.২০২১ তারিখে অনুষ্ঠিত হয়।
- মেডিক্যাল ডিভাইস ও সার্জিক্যাল ইকুইপমেন্টের ডিসিসি এর টেকনিক্যাল সাব কমিটির সভা ০২ টিঃ ২৪.০৬.২০২০, ও ২৯.১০.২০২০ তারিখে অনুষ্ঠিত হয়।
- হার্বাল এডভাইজরি কমিটির (ডিসিসি এর টেকনিক্যাল সাব কমিটি) সভা ০১ টিঃ ০৮.১২.২০২০ তারিখে অনুষ্ঠিত হয়।

ড্রাগ কন্ট্রোল কমিটির ২৫১ তম সভার কার্যবিবরণী নিশ্চিতকরণঃ

তিনি প্রথমেই ড্রাগ কন্ট্রোল কমিটির ২৫১ তম সভার কার্যবিবরণী নিশ্চিতকরণ সংক্রান্ত বিষয়াদি উপস্থাপন করেন। সভায় নিম্নবর্ণিত সিদ্ধান্ত সহকারে ড্রাগ কন্ট্রোল কমিটির ২৫১ তম সভার কার্যবিবরণী নিশ্চিত করা হয়।

(ক) নিম্নবর্ণিত দুইটি পদের বিষয়ে সাইক্রিয়াটিস্ট এর মতামত গ্রহন করার জন্য সিদ্ধান্ত গৃহীত হয় ঃ

পদসমূহঃ

(ধ) চরঃড়ষরঃধহঃ যু ফৎড়ঁপষড়ৎরফব্বয়ঁরাধষব হঃ ঃড় চরঃড়ষরঃধহঃ ৪.৪৫ সম ঞঃঁষবঃ,

(ন) চরঃড়ষরঃধহঃ যু ফৎড়ঁপষড়ৎরফব্বয়ঁরাধষব হঃ ঃড় চরঃড়ষরঃধহঃ ১৭.৮ সম ঞঃঁষবঃ

(খ) নিম্নবর্ণিত পদের বিষয়ে ইউরোলজিস্ট এর মতামত গ্রহন করার জন্য সিদ্ধান্ত গৃহীত হয় ঃ

পদটিঃ

(ধ)ঞরড়ঢ়ৎড়হরহ ১০০ সম ফব্ষধু বফ ৎব্ষবধৎব ঃধনষঃ

(গ) ড্রাগ কন্ট্রোল কমিটির ২৫১ তম সভায় বাতিল ও বহালকৃত ভিটামিন ও মিনারেল কম্বিনেশন প্রোডাক্টের বিষয়ে Annex- J মোতাবেক সংশোধন পূর্বক পুনঃ সিদ্ধান্ত গৃহীত হয়।

ড্রাগ কন্ট্রোল কমিটির ২৫২ তম সভায় টেকনিক্যাল সাব কমিটির সভাসমূহের সুপারিশসমূহের বিষয়ে সিদ্ধান্ত ঃ

১. স্থানীয়ভাবে উৎপাদনের জন্য ৪৩৮ টি হিউম্যান ঔষধের আবেদনের মধ্যে -

ক) ২৪১ টি পদের আবেদন অনুমোদন করা হয়;
খ) ১৯৬ টি পদের আবেদন নামঞ্জুর করা হয়;
গ) ১ টি পদের বিষয়ে সাইক্রিয়াটিস্টের মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়।

(Annex- A)

১. আমদানীর জন্য ৪৮ টি হিউম্যান ঔষধের আবেদনের মধ্যে-

ক) ২৮ টি পদের আবেদন অনুমোদন করা হয়;
খ) ২০ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- B)

২. **স্থানীয়ভাবে উৎপাদনের জন্য ৪ টি হিউম্যান ভ্যাক্সিনের আবেদন অনুমোদন করা হয়। (Annex- C)**

৩. **আমদানীর জন্য ১ টি হিউম্যান ভ্যাক্সিনের আবেদন নামঞ্জুর করা হয়। (Annex- C)**

৪. **স্থানীয়ভাবে উৎপাদনের জন্য ১ টি এনিম্যাল ভ্যাক্সিন ও ১ টি ডাইলুয়েন্টের আবেদন অনুমোদন করা হয়।(Annex- D)**

৫. **স্থানীয়ভাবে উৎপাদনের জন্য ৫৮ টি ভেটেরিনারি ঔষধের আবেদনের মধ্যে -**

ক) ৩০ টি পদের আবেদন অনুমোদন করা হয়;

খ) ২৮ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- E)

৬. **আমদানীর জন্য ৫৫ টি ভেটেরিনারি ঔষধের আবেদনের মধ্যে -**

ক) ৪৭ টি পদের আবেদন অনুমোদন করা হয়;

খ) ০৮ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- F)

৭. **স্থানীয়ভাবে উৎপাদনের জন্য ১১৩ টি হারবাল ঔষধের আবেদনের মধ্যে -**

ক) ৫২ টি পদের আবেদন অনুমোদন করা হয়;

খ) ৬১ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- G)

৮. **আমদানীর জন্য ১৬ টি মেডিক্যাল ডিভাইসের আবেদনের মধ্যে -**

ক) ০৩ টি পদের আবেদন অনুমোদন করা হয়;

খ) ১৩ টি পদের আবেদন নামঞ্জুর করা হয়;

(Annex- H)

৯. **স্থানীয়ভাবে উৎপাদনের জন্য ০৪ টি মেডিক্যাল ডিভাইসের বিষয়ে সিদ্ধান্ত গৃহীত হয়। (Annex- H)**

১০. কোভিড-১৯ সংক্রান্ত ০৫ টি ঔষধ ও ড ঐঙ এর ফর্মুলা মোতাবেক ০৩ টি হ্যান্ড সেনিটাইজার পোস্ট অ্যাপ্রুভাল করা হয়। **(Annex- I)**

১১. বিবিধ আলোচনা। **(Annex- J)**

অন্য কোন আলোচ্য বিষয় না থাকায় সভাপতি মহোদয় উপস্থিত সকলকে ধন্যবাদ জ্ঞাপন করে সভার সমাপ্তি ঘোষণা করেন।

মেজর জেনারেল মোঃ মাহবুবুর রহমান
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ও
সদস্য সচিব
ঔষধ নিয়ন্ত্রণ কমিটি

মো. আবদুল মান্নান
সচিব, স্বাস্থ্য সেবা বিভাগ
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
ও
সভাপতি
ঔষধ নিয়ন্ত্রণ কমিটি

Annex-A: Proposed product for locally manufacture (Human)

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Edoxaban 15 mg tablet	Edoxaban INN 15 mg	**Therapeutic Class**: Anticoagulants and Fibrinolytic Drug **Therapeutic Code:**012	Reduces the risk of Stroke, Systemic Embolism, Deep vein Thrombosis	**Contraindications:** Active pathological Bleeding. **Side effects:** Bleeding and Anemia **Precautions & warnings:** Bleeding: Serious and potentially fatal bleeding. Promptly evaluate signs and symptoms of blood loss, Mechanical heart valves or moderate to severe mitral stenosis: Use is not recommended	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
2.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Edoxaban 30 mg tablet	Edoxaban INN 30 mg	**Therapeutic Class**: Anticoagulants and Fibrinolytic Drug **Therapeutic Code:**012	Reduces the risk of Stroke, Systemic Embolism, Deep vein Thrombosis	**Contraindications:** Active pathological Bleeding. **Side effects:** Bleeding and Anemia **Precautions & warnings:** Bleeding: Serious and potentially fatal bleeding. Promptly evaluate signs and symptoms of blood loss, Mechanical heart valves or moderate to severe mitral stenosis: Use is not recommended	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
3.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Edoxaban 60 mg tablet	EdoxabanINN 60 mg	**Therapeutic Class**: Anticoagulants and Fibrinolytic Drug **Therapeutic Code:**012	Reduces the risk of Stroke, Systemic Embolism, Deep vein Thrombosis	**Contraindications:** Active pathological Bleeding. **Side effects:** Bleeding and Anemia **Precautions & warnings:** Bleeding: Serious and potentially fatal bleeding. Promptly evaluate signs and symptoms of blood loss, Mechanical heart valves or moderate to severe mitral stenosis: Use is not recommended	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
4.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Clevidipine 0.5mg/ml injection	Clevidipine INN 0.5mg/ml	Therapeutic Class: Antihypertensive Therapeutic code: 022	Hypertension	**Contraindications**: Defective lipid Metabolism, Severe Aortic stenosis **Side effects:** Nausea and Vomiting **Precautions & warnings:** Maintain aseptic technique.Discard unused portion 12 hours after stopper puncture. (5.1) • Hypotension and reflex tachycardiaare potential consequences of rapid upward titration of Cleviprex. (5.2) • Dihydropyridine calcium channel blockers can produce negative inotropic effects and exacerbate heart failure. Monitor heart	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						failure patients carefully(5.4) • Cleviprex gives no protection against the effects of abrupt beta-blocker withdrawal. (5.5) • Patients who receive prolonged Cleviprex infusions and are not transitioned to other antihypertensive therapies should be monitored for the possibility of rebound hypertension for at least 8 hours after the infusion is stopped.				
5.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Vitamin D3 1000 IU + Vitamin K2 25 mcg Oral Spray	Vitamin D3 BP 1000 IU + Vitamin K2 Ph. Gr 25 mcg	**Therapeutic Class**: Antiplatelete **Therapeutic Code:**026	It supports normal blood clotting, a normal immune system, Maintains normal bones and teeth & Tooth-kind formulation.	**Contraindication:** Hypersensitivity to any elements of the preparation& Should discontinue this product with anti-coagulants (blood thinners). **Side Effects:** Constipation, Intense Abdominal Pain, Nausea etc.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
6.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Cinitapride 1 mg tablet	Cinitapride USP 1 mg	**Therapeutic Class**: Antiemetic **Therapeutic Code:** 018	It is indicated to treat gastrointestinal disorders associated with motility disturbances like gastroesophageal reflux disease (GERD), non-ulcer dyspepsia and delayed gastric emptying.	**Contraindications:** Cinitapride should not be administered to patients with Hemorrhages, obstructions or perforations with stimulating gastric motility could be harmful. Proven tardive dyskinesia to neuroleptic drugs. **Side effects:** None **Precautions & Warnings:** it should not be taken this medicine during pregnancy, because the safety of this medicine for use during pregnancy has not been established. Gastrointestinal bleeding, partial or complete blockage in intestine, gastrointestinal perforation, movement disorders is the common warnings	New Molecule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
7.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Cinitapride 3 mg tablet	Cinitapride USP 3 mg	**Therapeutic Class**: Antiemetic **Therapeutic Code:** 018	It is indicated to treat gastrointestinal disorders associated with motility disturbances like gastroesophageal reflux disease (GERD), non-ulcer dyspepsia and delayed gastric emptying.	**Contraindications:** Cinitapride should not be administered to patients with Hemorrhages, obstructions or perforations with stimulating gastric motility could be harmful. Proven tardive dyskinesia to neuroleptic drugs. **Side effects:** None **Precautions & Warnings:** it should not be taken this medicine during pregnancy, because the safety of this	New Molecule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						medicine for use during pregnancy has not been established. Gastrointestinal bleeding, partial or complete blockage in intestine, gastrointestinal perforation, movement disorders is the common warnings				
8.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Calcium (Algae Source) 600 mg + Vitamin D3 200 IU + Vitamin K2 as Menaquinone 75 mcg tablet	Calcium (Algae Source) USP 600 mg + Vitamin D3 BP 200 IU + Vitamin K2 as Menaquinone Ph. Gr 75 mcg	**Therapeutic Class**: Vitamins & combinations **Therapeutic Code:** 078	Any type of Calcium deficiency like low bone density, Osteoporosis, Osteomalacia, Tetany, Hypoparathyroidism & Osteogenesis. Moreover improves heart health & reduces bone loss.	**Contraindications:** hypercalceamia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D over dosage. In severe renal failure. Hypersensitivity to any of the tablet ingredients. Relative contra-indications are osteoporosis due to prolonged immobilization, renal stones, and severe hypercalciuria. **Precautions & Warnings:** Not Found	New Molecule	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
9.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Iota-carrageenan 1.2 mg/ml nasal spray	Iota-carrageenan Ph Gr. 1.2 mg/ml	**Therapeutic Class**: Ear & Nose preparation **Therapeutic Code:** 050	Used to treat the symptoms of common cold	Not found. **Precautions & Warnings:** For hygienic reasons and to avoid transmission of pathogens, one spray bottle should be used by one and the same person only.	New Molecule	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
10.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Atlantic Cod Trypsin 1% + Glycerol 1% Mouth Spray	Atlantic Cod Trypsin USP 1% + Glycerol BP 1%	**Therapeutic Class**: Throat preparations, Mouth washes and gargles **Therapeutic Code:** 073	Used to treat the symptoms of common cold	Not found. **Precautions & Warnings:** Precautions & Warnings: Do not use if you are hypersensitive/allergic to any of its ingredients. No specific data found.	New Molecule	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
11.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Ferric derisomaltose IV injection (100 mg iron/mL)	Ferric derisomaltose IV injection (100 mg iron/mL)	Drug used in anemia and other blood disorders **Code:**045	Iron deficiency anemia in adult patients	Serious hypersensitivity to ferric derisomaltose injection or any of its components **Precautions & Warnings:** Hypersensitivity Reactions: Monitor patients for signs and symptoms of hypersensitivity during and after Ferric derisomaltose administration for at least 30 minutes and until clinically stable following completion of the infusion. • Iron Overload: Do not administer Ferric derisomaltose to patients with iron overload.	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
12.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Lofexidine 0.18 mg Tablet	Lofexidine INN 0.18 mg	Opioid antagonist **Code:**065	Mitigation of opioid withdrawal symptoms	**Contraindication:** None **Side Effects:** Most common adverse reactions (incidence ≥ 10% and notably more frequent than placebo) are orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, and dry mouth." **Precautions & Warnings:** Risk of Hypotension, Bradycardia, and Syncope: May cause a decrease in blood pressure, a decrease in pulse, and syncope.	New Molecule	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
13.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Osilodrostat 1 mg Tablet	Osilodrostat INN 1 mg	Adrecortical steroid antagonist **Code:**002	Osilodrostat is indicated for the treatment of adult patients with Cushing's disease	**Contraindication:** None **Side Effects:** Most common adverse reactions (incidence > 20%) are adrenal insufficiency, fatigue, nausea, headache, edema. **Precautions & Warnings:** QTc Prolongation: Perform electrocardiogram in all patients Use with caution in patients with risk factors for QTc prolongation.	New Molecule	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
14.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Osilodrostat 5 mg Tablet	Osilodrostat INN 5 mg	Adrecortical steroid antagonist **Code:**002	Osilodrostat is indicated for the treatment of adult patients with Cushing's disease	**Contraindication:** None **Side Effects:** Most common adverse reactions (incidence > 20%) are adrenal insufficiency, fatigue, nausea, headache, edema. **Precautions & Warnings**: QTc Prolongation: Perform electrocardiogram in all patients Use with caution in patients with risk factors for QTc prolongation.	New Molecule	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
15.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Osilodrostat 10 mg Tablet	Osilodrostat INN 10 mg	Adrecortical steroid antagonist **Code:**002	Osilodrostat is indicated for the treatment of adult patients with Cushing's disease	**Contraindication:** None **Side Effects:** Most common adverse reactions (incidence > 20%) are adrenal insufficiency, fatigue, nausea, headache, edema. **Precautions & Warnings**: QTc Prolongation: Perform electrocardiogram in all patients Use with caution in patients with risk factors for QTc prolongation.	New Molecule	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
16.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Ozanimod 0.46 mg Capsule	Ozanimod INN 0.46 mg	Neuromuscular blocking agent **Code:**063	Ozanimod is indicated for the treatment of relapsing forms of multiple sclerosis	**Contraindication:** In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure • Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker• Severe untreated sleep apnea • Concomitant use of a monoamine oxidase inhibitor **Side Effects:** Upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension. **Precautions & Warnings**: • Infections: OZANIMOD may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 3 months after discontinuation. Do not start OZANIMOD in patients with active infections • Bradyarrhythmia and Atrioventricular Conduction Delays: OZANIMOD may result in transient decrease in heart rate; titration is required for treatment initiation. Check an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting OZANIMOD. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart • Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating OZANIMOD • Fetal Risk: Women of childbearing potential should use effective contraception during	New Molecule	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						treatment and for 3 months after stopping OZANIMOD • Increased Blood Pressure (BP): Monitor BP during treatment • Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated • Macular Edema: A prompt ophthalmic evaluation is recommended if there is any change in vision while taking OZANIMOD. Diabetes mellitus and uveitis increase the risk of macular edema; patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation.				
17.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Ozanimod 0.92 mg Capsule	Ozanimod INN 0.92 mg	Neuromuscular blocking agent **Code:**063	Ozanimod is indicated for the treatment of relapsing forms of multiple sclerosis	**Contraindication:** In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure • Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker• Severe untreated sleep apnea • Concomitant use of a monoamine oxidase inhibitor **Side Effects:** Upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension. **Precautions & Warnings**: • Infections: OZANIMOD may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 3 months after discontinuation. Do not start OZANIMOD in patients with active infections • Bradyarrhythmia and Atrioventricular Conduction Delays:	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						OZANIMOD may result in transient decrease in heart rate; titration is required for treatment initiation. Check an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting OZANIMOD. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart • Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating OZANIMOD • Fetal Risk: Women of childbearing potential should use effective contraception during treatment and for 3 months after stopping OZANIMOD • Increased Blood Pressure (BP): Monitor BP during treatment • Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated • Macular Edema: A prompt ophthalmic evaluation is recommended if there is any change in vision while taking OZANIMOD. Diabetes mellitus and uveitis increase the risk of macular edema; patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation.				
18.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Siponimod 0.25 mg Tablet	Siponimod INN 0.25 mg	Neuromuscular blocking agent **Code:**063	Siponimod is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	**Contraindications:** In the last 6 months, experienced myocardial infarction, unstable angina, stroke, decompensated heart failure requiring hospitalization, or Class III/IV heart failure • Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker. **Side-effects:** Most common adverse reactions (incidence greater than 10%)	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						are headache, hypertension, and transaminase increases." **Precautions & Warnings:** Infections: SIPONIMOD may increase the risk. Obtain a complete blood count (CBC) before initiating treatment. Monitor for infection during treatment. Do not start in patients with active infection • Macular Edema: An ophthalmic evaluation is recommended before starting treatment and if there is any change in vision while taking SIPONIMOD. Diabetes mellitus and uveitis increase the risk • Bradyarrhythmia and Atrioventricular Conduction Delays: SIPONIMOD may result in a transient decrease in heart rate; titration is required for treatment initiation. Consider resting heart rate with concomitant betablocker use; obtain cardiologist consultation before concomitant use with other drugs that decrease heart rate • Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated • Liver Injury: Obtain liver enzyme results before initiation. Closely monitor patients with severe hepatic impairment. Discontinue if significant liver injury occurs. • Increased Blood Pressure (BP): Monitor BP during treatment. • Fetal Risk: Women of childbearing potential should use effective contraception during and for 10 days after stopping SIPONIMOD.				
19.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Siponimod 2 mg Tablet	Siponimod INN 2 mg	Neuromuscular blocking agent **Code:**063	Siponimod is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	**Contraindications:** In the last 6 months, experienced myocardial infarction, unstable angina, stroke, decompensated heart failure requiring hospitalization, or Class III/IV heart failure • Presence of Mobitz type II second-degree, third-degree AV block, or sick	New Molecule	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						sinus syndrome, unless patient has a functioning pacemaker. **Side-effects:** Most common adverse reactions (incidence greater than 10%) are headache, hypertension, and transaminase increases." **Precautions & Warnings:** Infections: SIPONIMOD may increase the risk. Obtain a complete blood count (CBC) before initiating treatment. Monitor for infection during treatment. Do not start in patients with active infection • Macular Edema: An ophthalmic evaluation is recommended before starting treatment and if there is any change in vision while taking SIPONIMOD. Diabetes mellitus and uveitis increase the risk. • Bradyarrhythmia and Atrioventricular Conduction Delays: SIPONIMOD may result in a transient decrease in heart rate; titration is required for treatment initiation. Consider resting heart rate with concomitant betablocker use; obtain cardiologist consultation before concomitant use with other drugs that decrease heart rate) • Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated. • Liver Injury: Obtain liver enzyme results before initiation. Closely monitor patients with severe hepatic impairment. Discontinue if significant liver injury occurs. • Increased Blood Pressure (BP): Monitor BP during treatment. • Fetal Risk: Women of childbearing potential should use effective contraception during and for 10 days after stopping SIPONIMOD.				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
20.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Famotidine 10 mg/ml USP Injection	Famotidine USP 10 mg/ml	H2 Receptor Blocking **Code:**055	Famotidine is useful in promoting the healing of stomach and duodenal ulcers and in reducing ulcer pain. Famotidine has been effective in preventing recurrence of ulcers when given in low doses for prolonged periods of time. Famotidine also is used for treating heartburn and in healing ulceration and inflammation of the esophagus (esophagitis) resulting from acid (gastroesophageal reflux disease or GERD).	**Contraindication:** Hypersensitivity to any component of these products. Cross sensitivity in this class of compounds has been observed. Famotidine should not be administered to patients with a history of hypersensitivity to other H2-receptor antagonists. **Precautions & Warnings:** General Symptomatic response to therapy with Famotidine does not preclude the presence of gastric malignancy. Patients with Severe Renal Insufficiency Longer intervals between doses or lower doses may need to be used in patients with severe renal insufficiency (creatinine clearance	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
21.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Unoprostone Isopropyl 0.15gm/100ml (Sterile Eye Drops)	Unoprostone Isopropyl INN 0.15gm/100ml	Eye Preparations **Code:**052	Intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive to another intraocular pressure lowering medication.	**Contraindications:** Known hypersensitivity to unoprostone isopropyl, benzalkonium chloride or any other ingredients in this product. **Side effects:** In clinical studies, the most common ocular adverse events were burning/stinging, burning/stinging upon drug instillation, dry eyes, itching, increased length of eyelashes and injection. These were reported in approximately 10-25% of patients. Approximately 10-14% of patients were observed to have an increase in the length of eyelashes (≥ 1 mm) at 12 months, while 7% of patients were observed to have a decrease in the length of eyelashes. **Precautions & Warnings:** Unoprostone may gradually change eye color, increasing the amount of brown pigment in the iris. The long-term effects and the consequences of potential injury to the eye are currently unknown. The change in iris color occurs slowly and may not be noticeable for months to several years. Patients should be informed of the possibility of iris color change. General:	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface (see Information for Patients).				
22.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Verteporfin 2 mg/ml (Intravenous injection)	Verteporfin USP 2 mg/ml	Eye Preparations **Code:**052	Indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia or presumed ocular histoplasmosis.	**Contraindication:** contraindicated for patients with porphyria or a known hypersensitivity to any component of this preparation. **Side effects:** Most common adverse reactions (incidence >10%) are: injection site reactions, visual disturbances **Precautions & Warnings:** Extravasation: If extravasation occurs, the infusion should be stopped immediately. The extravasation area must be thoroughly protected from direct light until swelling and discoloration have faded in order to prevent the occurrence of local burn.● Following injection with verteporfin for injection, care should be taken to avoid exposure of skin or eyes to direct sunlight or bright indoor light for 5 days.	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
23.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Levobetaxolol hydrochloride 0.5gm/100 ml (Sterile Ophthalmic Suspension)	Levobetaxolol hydrochloride INN 0.5gm/100 ml	Eye Preparations **Code:**052	Indicated for lowering intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	**Contraindication:** Sinus bradycardia, greater than a first degree atrioventricular block, cardiogenic shock, or overt cardiac failure. **Side effects:** Most common adverse reaction is transient ocular discomfort upon instillation. **Precautions & Warnings:** Same adverse reactions found with systemic administration of beta-adrenergic receptor inhibitors may occur with topical ophthalmic administration • Treatment with Levobetaxolol should be discontinued at the first signs of	New Molecule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						cardiac failure • Caution should be exercised in the treatment of glaucoma patients with excessive restriction of pulmonary function. • Beta-adrenergic receptor inhibitors may mask certain clinical signs (e.g. tachycardia) or hyperthyroidism .				
24.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Terbinafine 187.5 mg Granules for Suspension	Terbinafine INN 187.5 mg	Anti-Fungal **Code:**020	Indicated for the treatment of tinea capitis in patients 4 years of age and older	**Contraindication:** It is contraindicated in individuals with a history of allergic reaction to oral terbinafine because of the risk of anaphylaxis. **Side effects:** headache, fever, vomiting, upper respiratory tract infection, abdominal pain, diarrhea, nausea, and itching etc. Serious side effects on the liver, including death and liver transplant, have occurred in people taking terbinafine. Because of the potential for liver damage, people with liver disease should not take Terbinafine Oral Granules. **Precautions & Warnings:** Liver failure, sometimes leading to liver transplant or death, has occurred with the use of oral terbinafine. Obtain pretreatment serum transaminases. Prior to initiating treatment and periodically during therapy, assess liver function tests. Discontinue TERBINAFINE Tablets if liver injury develops. • Taste disturbance, including taste loss, has been reported with the use of TERBINAFINE Tablets. Taste disturbance can be severe, may be prolonged, or may be permanent. Discontinue TERBINAFINE Tablets if taste disturbance occurs. • Smell disturbance, including loss of smell, has been reported with the use of TERBINAFINE Tablets. Smell disturbance may be prolonged, or may be permanent. Discontinue TERBINAFINE Tablets if smell		রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						disturbance occur • Depressive symptoms have been reported with terbinafine use. Prescribers should be alert to the development of depressive symptoms. • Severe neutropenia has been reported. If the neutrophil count is less than or equal to 1000 cells/mm3 , TERBINAFINE Tablets should be discontinued. • Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, exfoliative dermatitis, bullous dermatitis, and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome have been reported with oral terbinafine use. If signs or symptoms of drug reaction occur, treatment with TERBINAFINE Tablets should be discontinued.				
25.	**Opsonin Pharma Limited,** Rupatali, Barishal.	Ichthammol 20% cream	Ichthammol USP 20%	Skin & mucous membrane preparations **Code:**071	It is indicated to draw splinetrs (Like wood or glass), treat boils, curbuncle, abscesses, draw pus, treat painful insect bites or stings and many inflammatory infections.	**Contraindication:** N/A Side Effects: **Precautions & Warnings:** • For external use only • Do not use in eyes • Ask a doctor before use if you have deep puncture wounds or serious burns • Stop use and ask doctor if redness, irritation, swelling or pain persists If swallowed, get medical help or contact a Poison Control Center immediately. Before using any medication, read all label directions. Keep this carton, it contains important information.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
26.	**Beximco Pharma Limited**, Tongi Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Molnupiravir 200 mg Tablet	Molnupiravir INN 200 mg	Therapeutic Class: Antiviral Therapeutic code: 032	Molnupiravir is an under **investigating drug** which activity against a number of viral infections including influenza, MERS-CoV, and **SARS-CoV-2** has been observed in clinical trials	Not known	New	নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝঋ উ অ কর্তৃক অনুমোদন/ ঊটঅ প্রাপ্তির পর	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝঋ উ অ কর্তৃক নিবন্ধন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে নিবন্ধন/ ঊটঅ প্রদানের বিষয়ে সিদ্ধান্ত গৃহীত হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
									পদটির অনুকূলে ঊটঅ প্রদানের সুপারিশ করা হয়।	
27.	**Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna**	Molnupiravir 200 mg Capsule	Molnupiravir INN 200 mg	Therapeutic Class: Antiviral Therapeutic code: 032	Molnupiravir is an under **investigating drug** which activity against a number of viral infections including influenza, MERS-CoV, and **SARS-CoV-2** has been observed in clinical trials.	Not known	New	নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝখ উ অ কর্তৃক অনুমোদন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে ঊটঅ প্রদানের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝখ উ অ কর্তৃক নিবন্ধন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে নিবন্ধন/ ঊটঅ প্রদানের বিষয়ে সিদ্ধান্ত গৃহীত হয়।
28.	**Beximco Pharma Limited**, Tongi Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Molnupiravir 400 mg Tablet	Molnupiravir INN 400 mg	Therapeutic Class: Antiviral Therapeutic code: 032	Molnupiravir is an under **investigating drug** which activity against a number of viral infections including influenza, MERS-CoV, and **SARS-CoV-2** has been observed in clinical trials.	Not known	New	নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝখ উ অ কর্তৃক অনুমোদন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে ঊটঅ প্রদানের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝখ উ অ কর্তৃক নিবন্ধন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে নিবন্ধন/ ঊটঅ প্রদানের বিষয়ে সিদ্ধান্ত গৃহীত হয়।
29.	**Beximco Pharma Limited**, Tongi Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Molnupiravir 800 mg Tablet	Molnupiravir INN 800 mg	Therapeutic Class: Antiviral Therapeutic code: 032	Molnupiravir is an under **investigating drug** which activity against a number of viral infections including influenza, MERS-CoV, and **SARS-CoV-2** has been observed in clinical trials.	Not known	New	নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝখ উ অ কর্তৃক অনুমোদন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে ঊটঅ প্রদানের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়। তবে পদটির ক্লিনিক্যাল ট্রায়াল চলছে এবং পদটি টঝখ উ অ কর্তৃক নিবন্ধন/ ঊটঅ প্রাপ্তির পর পদটির অনুকূলে নিবন্ধন/ ঊটঅ প্রদানের বিষয়ে সিদ্ধান্ত গৃহীত হয়।
30.	**Beximco Pharma Limited**, Tongi Gazipur	Olopatadine hydrochloride 600mcg + mometasone furoate monohydrate 25mcg Nasal spray	Olopatadine hydrochloride USP 665 mcg equivalent to 600 mcg olopatadine base and mometasone furoate monohydrate BP equivalent to 25mcg	Therapeutic Class: Antihistamine Therapeutic code: 021	Indicated for the treatment of symptoms associated with allergic rhinitis and rhinoconjunctivitis in patients 12 years of age and older.	**Contrindication:** Patients with known hypersensitivity to olopatadine hydrochloride, mometasone furoate, or any ingredients • Severe nasal infection, especially candidiasis	New	TGA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			mometasone furoate per spray.			• Persons with haemorrhagic diathesis or with a history of recurrent nasal bleeding. Side effects: More common side effects include: unpleasant taste, nosebleeds and nasal discomfort. Other less common side effects include sleepiness or drowsiness, nasal problems such as crusting in the nose or nosebleeds				
31.	**Ziska Pharmaceuticals Ltd.**	Hydroxy Propyl Methyl Cellulose 89.9% Powder for Nasal Spray	Hydroxy Propyl Methyl Cellulose BP 89.9%	Antihistamine Therapeutic Code: 021	It is indicated for use as a protective mechanical barrier against allergens, pollens, bacteria and viruses within the nasal cavity.	**Contraindications:** • Contraindicated in individuals who are hypersensitive to Hydroxy Propyl Methyl Cellulose. **Side effects:** Very few cases of allergic reactions to this product have been reported. Most reports received have been blocked nose, runny nose, sneezing, sore throat.	New	USFDA (Generally Regarded As Safe)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
32.	Ziska Pharmaceuticals Ltd.	Micronized Progesterone 100 mgFilm-Coated Tablet	Micronized Progesterone USP 100 mg	Hormone **Therapeutic Code:** 056	It is indicated for use in the prevention of endometrial hyperplasia in non-hysterectomized postmenopausal women who are receiving conjugated estrogens tablets. They are also indicated for use in secondary amenorrhea. Secondary Amenorrhea - Progesterone may be given as a single daily dose of 400 mg in the evening for 10 days.	**Contraindications:** • Known or suspected pregnancy, thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or patients with a past history of these conditions. Severe liver dysfunction or disease. Known or suspected malignancy of breast or genital organs. Undiagnosed vaginal bleeding. Missed abortion. As a diagnostic test for pregnancy. **Side effects:** Nausea, bloating, breast tenderness, headache, change in vaginal discharge, mood swings, blurred vision, dizziness, or drowsiness may occur.	Progesterone USP 100 mg	নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
33.	Ziska Pharmaceuticals Ltd.	Micronized Progesterone 200 mgFilm-Coated Tablet	Micronized Proges terone USP 200 mg	Hormone **Therapeutic Code:** 056	It is indicated for use in the prevention of endometrial hyperplasia in non-hysterectomized postmenopausal women who are receiving conjugated estrogens tablets. They are also indicated for use in secondary amenorrhea.	**Contraindications:** • Known or suspected pregnancy, thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or patients with a past history of these conditions. Severe liver dysfunction or disease. Known or suspected malignancy of breast or genital organs. Undiagnosed vaginal bleeding. Missed	Progesterone USP 200 mg	নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Secondary Amenorrhea - Progesterone may be given as a single daily dose of 400 mg in the evening for 10 days.	abortion. As a diagnostic test for pregnancy. **Side effects:** Nausea, bloating, breast tenderness, headache, change in vaginal discharge, mood swings, blurred vision, dizziness, or drowsiness may occur.				
34.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ascorbic Acid 1000mg, Elemental Zinc 10mg and Cholecalciferol 400 IU Effervescent Tablet	Ascorbic Acid USP 1000mg + Zinc Citrate Trihydrate INN 32mg (E.q. to 10mg of Elemental Zinc) + Dry Vitamin D3 USP 4.00mg (Eq. to Cholecalciferol 400 IU)	Therapeutic Class: Vitamins and Combinations Therapeutic code: 078	Treatment of vitamin C and Zinc deficiency.	**SIDE EFFECTS:** • Gastrointestinal disorders • Immune System Disorders **CONTRAINDICATIONS:** • Hypersensitivity to any of the active substances or to any of the excipients listed • Patients suffering from or having a history of Nephrolitiasis must not take this product. • Patients suffering from oxalate urolithiasis or oxaluria must not take this product. • Patients suffering from severe renal insufficiency or renal failure must not take the product. • This includes patients on dialysis. • Patients suffering from Hemochromatosis must not take this product. **WARNINGS AND PRECAUTIONS:** • Patients with rare hereditary problems of fructose intolerance should not take this medicine • Patients suffering from renal insufficiency Patients suffering from glucose-6-phosphatase deficiency	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
35.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Suvorexant 5mg Tablet	Suvorexant INN 5mg	Therapeutic Class: **Antidepressants** Therapeutic code: 014	Suvorexant is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	**SIDE EFFECTS:** • Dizziness, headache • Diarrhoea, • Abnormal dreams • Dry mouth **CONTRAINDICATIONS:** Contraindicated in patients with narcolepsy **WARNINGS AND PRECAUTIONS:** • CNS Depressant Effects and Daytime Impairment: Risk of impaired alertness and motor coordination, including impaired driving; risk increases with dose; caution patients taking 20 mg against next-day driving and other activities requiring complete mental alertness. • Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur. Risk increases with dose. Immediately evaluate any new behavioral changes. Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days of treatment.	**New**	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
36.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Suvorexant 15mg Tablet	Suvorexant INN 15mg	Therapeutic Class: **Antidepressants** Therapeutic code: 014	Suvorexant is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	**SIDE EFFECTS:** • Dizziness, headache • Diarrhoea, • Abnormal dreams • Dry mouth **CONTRAINDICATIONS:** Contraindicated in patients with narcolepsy. **WARNINGS AND PRECAUTIONS:** • CNS Depressant Effects and Daytime Impairment: Risk of impaired alertness and motor coordination, including impaired driving; risk increases with dose; caution patients taking 20 mg against next-day driving and other	**New**	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						activities requiring complete mental alertness. • Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur. Risk increases with dose. Immediately evaluate any new behavioral changes. Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days of treatment.				
37.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Diphenhydramine Hydrochloride 14.00mg, Ammonium Chloride 135.00mg and Levomenthol 1.10mg per 5mL syrup.	Diphenhydramine Hydrochloride BP 14.00mg + Ammonium Chloride BP 135.00mg + Levomenthol BP 1.10mg	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic code: 031	For the oral symptomatic relief of common coughs (such as dry or tickly, or troublesome cough) associated with upper respiratory tract congestion and aids restful sleep.	**SIDE EFFECTS:** CNS effects such as nervous drowsiness, paradoxical stimulation, Antimuscarinic effects such as urinary retensoin, dry mouth, blurred vision, hypotension, tremor, palpitation. **CONTRAINDICATIONS:** Hypersensitivity to any of the ingredients.	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
38.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ambroxol Hydrochloride 30mg/5mL syrup	Ambroxol Hydrochloride BP 30mg/5mL	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic code: 031	AMBROXOL is indicated to aid in the treatment of catarrhal inflammation of bronchi and the upper respiratory tract in horses and dogs. Specific indications include: Chest Infections: acute and chronic bronchopneumonia, catarrhal rhinitis, strangles, post-viral cough Uterine Infections: pyometron, mucometron Ocular Infections: purulent Conjunctivitis, hypopion.	**SIDE EFFECTS:** Gastrointestinal side effects may occur occasionally with Ambroxol and a transient rise in serum aminotransferase values has been reported. Other reported adverse effect includes sweating, allergic reactions. **CONTRAINDICATIONS:** Ambroxol Hydrochloride solution is contraindicated for use in animals with known hypersensitivity or idiosyncratic reaction to Ambroxol Hydrochloride (or any of the other ingredients in the product).	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
39.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Dextromethorphan Hydrobromide 30mg/5mL Extended Release Suspension.	Dextromethorphan Hydrobromide USP 30mg/5mL.	Therapeutic Class: Antitussives, Expectorants and Mucolytic Therapeutic code: 031	It is used for temporary relief of coughs without phlegm that are caused by certain infections of the air passages (e.g., sinusitis, common cold). This product should not usually be used for an ongoing cough from smoking or long-term breathing	**SIDE EFFECTS:** • Dizziness, • Nausea • Vomiting **CONTRAINDICATIONS:** Taking certain MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid	**New** Dextromethorphan Polistirex 0.8gm/100 ml Extended Release	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					problems (e.g., chronic bronchitis, emphysema) unless directed doctor. Dextromethorphan is a cough suppressant that works by decreasing the feeling of needing to cough.	taking isocarboxazid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, or tranylcypromine during treatment with this medication	Suspension			
40.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olmesartan Medoxomil 20mg and S-Amlodipine 2.5mg (As S-Amlodipine Besylate) film coated tablet	Olmesartan Medoxomil BP 20mg and S-Amlodipine Besylate INN 2.5mg INN	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is a dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents.	**SIDE EFFECTS:** • dizziness • peripheral edema • headache • fatigue **CONTRAINDICATIONS:** Anuria, Hypersensitivity to sulfonamide-derived drugs. **WARNINGS AND PRECAUTIONS:** Hypotension in volume- or salt-depleted patients with treatment initiation may occur. Start treatment under close supervision. Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.	**New** Amlodipine BP 5mg + Olmesartan Medoxomil 20mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
41.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Olmesartan Medoxomil 40mg and S-Amlodipine 2.5mg Film Coated Tablets	Olmesartan Medoxomil BP 40mg + S-Amlodipine INN 2.5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	It is a dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents.	**SIDE EFFECTS:** • dizziness, • peripheral edema, • headache, • fatigue, **CONTRAINDICATIONS:** Anuria, Hypersensitivity to sulfonamide-derived drugs. **WARNINGS AND PRECAUTIONS:** Hypotension in volume- or salt-depleted patients with treatment initiation may occur. Start treatment under close supervision. Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.	**New** Amlodipine BP 5mg + Olmesartan Medoxomil 20mg Tablet Amlodipine BP 10mg + Olmesartan Medoxomil 20mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
42.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Sodium Bicarbonate 1.76g, Sodium Citrate(Anhydrous) 0.63g, Anhydrous Citric Acid 0.72g, Tartaric Acid 0.89g Effervescent Powder in Sachet.	Sodium Bicarbonate BP 1.76g + Sodium Citrate(Anhydrous) USP 0.63g + Anhydrous Citric Acid BP 0.72g + Tartaric Acid BP 0.89g	Therapeutic Class: Antacid,Adsorbent Therapeutic code: 007	Urinary alkalization where indicated as an adjunct therapy for urinary tract infection to relieve dysuria and enhance the action of certain antibiotics, anti-urolithic that reduces and prevents the crystallization of uric acid, cysteine and calcium oxalate stones, also for symptomatic treatment of gastric hyperacidity.	**SIDE EFFECTS:** Laxative effect, systemic alkalosis or hypernatraemia. **CONTRAINDICATIONS:** Renal failure or hypernatraemia, overt and occult cardiac failure.	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
43.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lidocaine Hydrochloride 4% (w/w) Lotion	Lidocaine Hydrochloride USP 40mg/ml	Therapeutic Class: Anaesthetics Therapeutic code: 004	It is indicated for pruritus, pruritic eczemas, abrasions, minor burns, insect bites, pain, soreness and discomfort due to pruritus ani, pruritus vulvae, hemorrhoids, anal fissures and similar conditions of the skin and mucous membranes.	**SIDE EFFECTS:** Erythema or edema, Abnormal sensation. **CONTRAINDICATIONS:** Traumatized mucosa, Secondary bacterial infection, known hypersensitivity.	**New** Lidocaine 2% Gel Lidocaine 1% Solution Lidocaine 4% Injection	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
44.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Montelukast 5mg and Levocetirizine Dihydrochloride 2.5mg Film Coated Tablet	Montelukast USP 5mg + Levocetirizine Dihydrochloride INN 2.5mg	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic code: 044	It is indicated for Asthma, Exercise induced Bronchospasm, Allergic Rhinitis, Urticaria, Seasonal and perennial allergic rhinitis, Uncomplicated skin manifestations of chronic idiopathic urticaria.	**SIDE EFFECTS:** Calcium Orotate is generally well tolerated. **CONTRAINDICATIONS:** Hypersensitivity.	**New** Montelukast 5mg, 10mg Tablet Levocetirizine 5mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
45.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Montelukast 10mg and Fexofenadine Hydrochloride 120mg Tablet	Montelukast Sodium USP 10mg + Fexofenadine Hydrochloride USP 120mg	Therapeutic Class: Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic code: 044	It is indicated for Asthma, Allergic rhinitis	**SIDE EFFECTS:** Headache, divines, cough and fever. **CONTRAINDICATIONS:** Hypersensitivity	**New** Montelukast 10mg Tablet Fexofenadine 120mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
46.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lurasidone Hydrochloride 60mg Film coated Tablet.	Lurasidone Hydrochloride INN 60mg	Therapeutic Class: Antipsychotic Therapeutic code: 028	It is an atypical antipsychotic indicated for the treatment of: • Schizophrenia in adults and adolescents (13 to 17 years) • Depressive episode associated with Bipolar I Disorder (bipolar depression) • In adults and pediatric patients (10 to 17 years) as monotherapy Depressive episode associated with Bipolar I Disorder (bipolar depression) In adults as adjunctive therapy with lithium or valproate	**SIDE EFFECTS:** Somnolence, Akathisia, Nausea, Parkinsonism, Agitation. **CONTRAINDICATIONS:** • Contraindicated in any patient with a known hypersensitivity to Lurasidone or any components in the formulation. • Angioedema has been observed with Lurasidone. • Lurasidone is contraindicated with strong CYP3A4 inhibitors (e.g., Ketoconazole) and strong CYP3A4 Inducers.	**New** Lurasidone Hydrochloride 20/40mg Tablet	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
47.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ceftriaxone 1gm, Tazobactam 125mg Powder for Injection	Ceftriaxone Sodium BP 1gm + Tazobactam INN 125mg	Therapeutic Class: Anti-infective Therapeutic code: 023	It is indicated to reduce the development of drug-resistance bacteria and maintain the effectiveness of this injection; it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	**SIDE EFFECTS:** Rash, pruritus, fever or chills. **CONTRAINDICATIONS:** Hypersensitivity	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
48.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Phenazopyridine Hydrochloride 100 mg Film Coated Tablet	Phenazopyridine Hydrochloride USP 100 mg	Therapeutic Class: Analgesics and Antipyretics Therapeutic code: 006	It is indicated for the symptomatic relief of pain, burning, urgency, frequency, and other discomforts resulting from irritation of the mucosa of the lower urinary tract caused by infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters. It is compatible with antimicrobial therapy and can help relieve pain and discomfort during the interval before an antimicrobial therapy controls the infection.	**SIDE EFFECTS:** • Gastrointestinal: nausea, vomiting and diarrhea. • Nervous System: headache, aseptic meningitis. **CONTRAINDICATIONS:** • Patients with renal insufficiency or any liver disease. Patients who are hypersensitive to the drug or its ingredients.	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
49.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Telmisartan 20mg and S-Amlodipine 2.5mg Tablet	Telmisartan USP 20mg + S-Amlodipine INN (S-Amlodipine besilate) 2.5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	This combination is indicated as initial therapy in patients likely to need multiple antihypertensive	**SIDE EFFECTS:** Most common side effects of Telmisartan are-	**New** Telmisartan 4 mg +	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					agents to achieve their blood pressure goals.	Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) Pharyngitis (1%). **CONTRAINDICATIONS:** • Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. Do not co-administer aliskiren with Telmisartan and amlodipine combination in patients with diabetes.	Amlodipine 5mg Tablet Telmisartan 80mg + Amlodipine 5mg Tablet Telmisartan 20mg, 40mg & 80mg Tablet. Amlodipine 5 mg Tablet Telmisartan 40mg + Amlodipine 10mg Tablet Telmisartan 80mg + Amlodipine 10mg Tablet			
50.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Telmisartan 40mg and S-Amlodipine 2.5mg Tablet	Telmisartan USP 40mg + S-Amlodipine INN (S-Amlodipine besilate) 2.5mg	Therapeutic Class: Antihypertensive Therapeutic code: 022	This combination is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	**SIDE EFFECTS:** Most common side effects of Telmisartan are- Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) Pharyngitis (1%). **CONTRAINDICATIONS:**	**New** Telmisartan 4 mg + Amlodipine 5mg Tablet Telmisartan 80mg + Amlodipine 5mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, amlodipine or any other component of this product. Do not co-administer aliskiren with Telmisartan and amlodipine combination in patients with diabetes.	Telmisartan 20mg, 40mg & 80mg Tablet. Amlodipine 5 mg Tablet Telmisartan 40mg + Amlodipine 10mg Tablet Telmisartan 80mg + Amlodipine 10mg Tablet			
51.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bisoprolol Fumarate 20mg film coated Tablet	Bisoprolol Fumarate USP 20mg	**Therapeutic Class:** Antihypertensive **Therapeutic code**: 022	Bisoprolol is used with or without other medications to treat high blood pressure (hypertension). Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. This medication belongs to a class of drugs known as beta blockers. It works by blocking the action of certain natural chemicals in your body such as epinephrine on the heart and blood vessels. This effect lowers the heart rate, blood pressure, and strain on the heart. **WARNINGS AND PRECAUTIONS:** This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: certain types of heart rhythm problems	**SIDE EFFECTS:** • Dizziness, • Diarrhea • Reduce blood flow **CONTRAINDICATIONS:** Patients with a history of hypersensitivity reaction to Bisoprolol or to any of its components.	**New** Bisoprolol Fumarate 1.25mg, 2.5mg, 5mg & 10mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					(such as a slow heartbeat, second- or third-degree atrioventricular block), severe heart failure					
52.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Tamsulosin Hydrochloride 0.4mg and Solifenacin Succinate 6mg modified Release film coated tablet	Tamsulosin Hydrochloride 0.4mg INN + Solifenacin Succinate BP 6mg	**Therapeutic Class:** Drug used in obstratics and Gentiourinary disease **Therapeutic code:** 049	It is used for the treatment of moderate to severe storage symptoms (urgency, increased maturation frequency) and voiding symptoms associates with benign prostatic hyperplasia in men.	**SIDE EFFECTS:** Constipation, dyspepsia, dizziness, vision blurred fatigue. **CONTRAINDICATIONS:** Hypersensitivity, patients undergoing Hemodialysis, hepatic impairment, renal impairment.	**New** Dutasteride 500mcg + Tamsulosin Hydrochloride 400mcg Capsule.	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
53.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Aliskiren 150mg and Amlodipine 10mg film coated tablet	Aliskiren Hemifumarate INN 150mg + Amlodipine besilate BP 10mg	**Therapeutic Class:** Antihypertensive **Therapeutic code:** 022	It is a combination of aliskiren, a rennin inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension, to lower blood pressure: • As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. • In patients not adequately controlled with monotherapy. As a substitute for its titrated components. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**SIDE EFFECTS:** The most common adverse event (Incidence ≥2% and more common than with placebo) is peripheral edema. **CONTRAINDICATIONS:** Do not use with angiotensin receptor blockers (ARBs) or angiotensin converting enzyme inhibitors (ACEIs) in patients with diabetes. Known hypersensitivity to any of the components.	**New** Aliskiren 150mg Tablet Aliskiren 300mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
54.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Aliskiren 300mg and amlodipine 10mg film coated tablet	Aliskiren Hemifumarate INN 300mg + Amlodipine besilate BP 10mg	**Therapeutic Class:** Antihypertensive **Therapeutic code:** 022	It is a combination of aliskiren, a rennin inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of	**SIDE EFFECTS:** The most common adverse event (Incidence ≥2% and more common than with placebo) is peripheral edema. **CONTRAINDICATIONS:**	**New** Aliskiren 150mg Tablet	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					hypertension, to lower blood pressure: • As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. • In patients not adequately controlled with monotherapy. As a substitute for its titrated components. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	Do not use with angiotensin receptor blockers (ARBs) or angiotensin converting enzyme inhibitors (ACEIs) in patients with diabetes. Known hypersensitivity to any of the components.	Aliskiren 300mg Tablet			
55.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Aliskiren 300mg and amlodipine 5mg film coated tablet	Aliskiren Hemifumarate INN 300mg + Amlodipine besilate BP 5mg	**Therapeutic Class:** Antihypertensive **Therapeutic code:** 022	It is a combination of aliskiren, a rennin inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension, to lower blood pressure: • As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. • In patients not adequately controlled with monotherapy. As a substitute for its titrated components. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**SIDE EFFECTS:** The most common adverse event (Incidence ≥2% and more common than with placebo) is peripheral edema. **CONTRAINDICATIONS:** Do not use with angiotensin receptor blockers (ARBs) or angiotensin converting enzyme inhibitors (ACEIs) in patients with diabetes. Known hypersensitivity to any of the components.	**New** Aliskiren 150mg Tablet Aliskiren 300mg Tablet	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
56.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Prulifloxacin 600mg film coated tablet	Prulifloxacin INN 600mg	**Therapeutic Class:** Anti-infective **Therapeutic code:** 023	Indicated for the treatment of • Acute uncomplicated lower urinary tract infections (simole cystitis) • Complicated Lower urinary tract infections	**SIDE EFFECTS:** • Epigastralgia, • Nausea • Pruritus, • Skin rash.	**New**	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					• Acute exacerbation of chronic bronchitis	**CONTRAINDICATIONS:** • Hypersensitivity to Prulifloxacin, to other quinolones antibacterial agents or to any of the excipients. • Pre-pubertal children or adolescents below the age of 18 years with uncomplicated skeletal development. Patients with anamnesis of tendon diseases related to the administration of quinolones Pregnancy and lactation. **WARNINGS AND PRECAUTIONS:** It should not be used in pregnant women or if you are planning for pregnancy must be used by breastfeeding mothers only if it is necessary. No research indicates that it may be harmful if taken with alcohol.				
57.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Progesterone 100mg SR Tablet	Progesterone BP 100mg	**Therapeutic Class:** Hormone **Therapeutic code:** 056	Progesterone is a progesterone indicated to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women	**SIDE EFFECTS:** • Vomiting • Tiredness • Constipation • Upset Stomach **CONTRAINDICATIONS:** Previous allergic reactions to progesterone or any of the ingredients of Endometrin Vaginal Insert Known missed abortion or ectopic pregnancy **WARNINGS AND PRECAUTIONS:** Life-threatening arterial or venous thromboembolic disorders may occur during hormone treatment, including treatment with Endometrin. Discontinue Endometrin if any of these are suspected. Observe patients with a history of depression closely. Consider discontinuation if symptoms worsen	**New** Progesterone 100mg, 200mg Soft Gelatin Capsule.	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
58.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Esomeprazole Magnesium 40mg Powder for Suspension	Esomeprazole USP 40mg	**Therapeutic Class**: Proton Pump inhibitor **Therapeutic code:** 067	It is a proton pump inhibitor indicated for the following: • Treatment of gastroesophageal reflux disease (GERD). • Risk reduction of NSAID-associated gastric ulcer. • H. pylori eradication to reduce the risk of duodenal ulcer recurrence. • Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.	**SIDE EFFECTS:** Most common adverse reactions: • Adults (≥ 18 years) (incidence >1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth. • Pediatric (1 to 17 years) (incidence >2%) are headache, diarrhea, abdominal pain, nausea, and somnolence. • Pediatric (1 month to less than 1 year) (incidence 1%) are abdominal pain, regurgitation, tachypnea, and increased ALT. **CONTRAINDICATIONS:** Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred). **WARNINGS AND PRECAUTIONS:** Acute Tubulointerstitial Nephritis	**New** Esomeprazole USP 20mg, 40mg Tablet, Capsule and 40mg Injection & 20mg Sachet.	**USFDA**	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
59.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	S-Amlodipine Besylate 2.5mg Tablet	S-Amlodipine INN 2.5mg	**Therapeutic Class**: Antihypertensive **Therapeutic code**: 022	It is a calcium channel blocker and may be used alone or in combination with other antihypertensive and anti-anginal agents for the treatment of: ➢ Hypertension • Indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. ➢ Coronary Artery Disease	**SIDE EFFECTS:** Most common adverse reaction to amlodipine is edema which occurred in a dose related manner. Other adverse experiences not dose related but reported with an incidence >1.0% are fatigue, nausea, abdominal pain, and somnolence. **CONTRAINDICATIONS:** Known sensitivity to amlodipine. **WARNINGS AND PRECAUTIONS:** • Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely. • Worsening angina and acute myocardial infarction can develop after starting or increasing the dose, particularly in patients with severe	**NEW** **USFDA** Amlodipine Besylate 2.5mg, 5mg & 10mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	পদটির প্রয়োজন রয়েছে বিধায় অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					• Chronic Stable Angina • Vasospastic Angina (Prinzmetal's or Variant Angina) Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%.	obstructive coronary artery disease. Titrate slowly in patients with severe hepatic impairment				
60.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	S-Amlodipine Besylate 1.25mg Tablet	S-Amlodipine INN 1.25mg	**Therapeutic Class:** Antihypertensive **Therapeutic code**: 022	It is a calcium channel blocker and may be used alone or in combination with other antihypertensive and anti-anginal agents for the treatment of: ➢ **Hypertension** Indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. ➢ **Coronary Artery Disease** Chronic Stable Angina Vasospastic Angina (Prinzmetal's or Variant Angina) Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%.	**SIDE EFFECTS:** Most common adverse reaction to amlodipine is edema which occurred in a dose related manner. Other adverse experiences not dose related but reported with an incidence >1.0% are fatigue, nausea, abdominal pain, and somnolence. **CONTRAINDICATIONS:** Known sensitivity to amlodipine. **WARNINGS AND PRECAUTIONS:** • Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely. • Worsening angina and acute myocardial infarction can develop after starting or increasing the dose, particularly in patients with severe obstructive coronary artery disease. Titrate slowly in patients with severe hepatic impairment.	**NEW** **USFDA** Amlodipine Besylate 2.5mg, 5mg & 10mg Tablet	**নাই -**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
61.	**Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna** **Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area. Gazipur, Bangladesh**.	Vibegron INN 75mg Tablet	Vibegron INN 75mg	Therapeutic Class: Adreneroic Therapeutic Code: 001	It is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults colic.	**Side effect:** The most common side effects of Vibegron include: • urinary tract infection • nasal congestion, sore throat or runny nose • nausea • headache • upper respiratory tract infection • diarrhea	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Contra-Indication: Do not use if prior hypersensitivity reaction to vibegron or any components of the product. **Warnings and Precautions**: Urinary Retention: Monitor for urinary retention, especially in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medications for OAB, in whom the risk of urinary retention may be greater. If urinary retention develops, discontinue Vibegron.				
62.	**Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna**	(Thiamine Hydrochloride BP 100gm + Pyridoxine Hydrochloride BP 5mg + Cyanocobalamin BP 50mg)/ 5ml Syrup	(Thiamine Hydrochloride 100gm + Pyridoxine Hydrochloride 5mg + Cyanocobalamin 50mg)/ 5ml	Therapeutic Class: Vitamins and Combinations Therapeutic Code: 078	1) It provides support in various conditions (as in growth, physiologic stress, decreased resistance to infection and chronic illnesses, metabolic disorders and in certain diseases of the digestive tract and nervous system). 2) It is indicated for the prevention and treatment of deficiency disorders arising from poor dietary intake, impaired B-complex vitamins absorption or utilization of B group vitamins 3) It can also be given before and after surgical procedures. 4) A nutritional supplement to promote appetite and weight gain.	**Side effect:** The most common side effects of Vibegron include: Pruritus, Urticaria, Weakness, Sweating, Nausea, Restlessness, Tightness of the throat, Hemorrhage, Paresthesia, Somnolence, Low serum folic acid levels, Pulmonary edema, Congestive heart failure, Polycythemia vera, Diarrhea, Itching **Contra-Indication:** Do not use if prior hypersensitivity reaction to any components of the product. **Warnings and Precautions**: B vitamins are generally safe for most people to use. The vitamins dissolve in water and do not build up in the tissues very well. This means that the body can easily remove any excess vitamins in the urine. Because of this, B vitamins are generally nontoxic, with very little risk of causing harm. However, taking a very high dose can be dangerous and cause side effects.	Cyanocobalamin 200mcg + Pyridoxine Hydrochloride 200mg + Vitamin B1 100mg Tablet	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
63.	Renata Limited **Mirpur, Dhaka**	Levomilnacipran Pellets 20.00% w/w Pharma Grade 200mg contain Levomilnacipran Hydrochloride INN 45.92 equivalent to Levomilnacipran 40mg Extended Release Capsule	Levomilnacipran Hydrochloride INN 45.92 equivalent to Levomilnacipran 40mg Extended Release Capsule	**Therapeutic Class:** Antidepressants **Therapeutic Code: 014**	It is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of Major Depressive Disorder. Limitation of Use:	Contraindications: Hypersensitivity to levomilnacipran, milnacipran HCl, or any excipient in the formulation. Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with Levomilnacipran or within 7 days of stopping treatment with Levomilnacipran. Do not use Levomilnacipran within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Levomilnacipran in a patient who is being treated with linezolid or intravenous methylene blue	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
64.	Renata Limited **Mirpur, Dhaka**	Levomilnacipran Pellets 20.00% w/w Pharma Grade 400mg contain Levomilnacipran Hydrochloride INN 91.84 equivalent to Levomilnacipran 80mg Extended Release Capsule	Levomilnacipran Pellets 20.00% w/w Pharma Grade 400mg contain Levomilnacipran Hydrochloride INN 91.84 equivalent to Levomilnacipran 80mg Extended Release Capsule	**Therapeutic Class:** Antidepressants **Therapeutic Code: 014**	It is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of Major Depressive Disorder. Limitation of Use:	Contraindications: Hypersensitivity to levomilnacipran, milnacipran HCl, or any excipient in the formulation. Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with Levomilnacipran or within 7 days of stopping treatment with Levomilnacipran. Do not use Levomilnacipran within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Levomilnacipran in a patient who is being treated with linezolid or intravenous methylene blue	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
65.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Meropenem 500 mg+ Vaborbactam 500 mg per vial of injection	Meropenem INN 500 mg + Vaborbactam INN 500 mg / Vial	**Therapeutic Class:** Anti-infective **Therapeutic Code**: 023	Meropenem and Vaborbactam is a combination of Meropenem, a penem antibacterial, and Vaborbactam, a beta - lactamase inhibitor, indicated for the treatment of patients 18years and older with complicated urinary tract infections (CUTI) including pyelonephritis caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintainthe	**Contraindication** This medication is contraindicated in patients with known hypersensitivity to any components of (Meropenem and Vaborbactam), or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactam antibacterial drugs **Side-effects:** Hypersensitivity Reactions Seizure Potential Clostridiumdifficile-associated Diarrhea	Meropenem 2.0 gm + Vaborbactam 2.0 gm / Vial Powder for Injection (DCC 249)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					effectiveness of this medication and other antibacterial drugs, it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	Risk of Breakthrough Seizures Due to Drug Interaction with Valproic Acid Thrombocytopenia Potential for Neuromata Impairment				
66.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cellulose & Citric acid Hydrogels 0.75gm Capsule	Cellulose & Citric Acid (Superabsorbent hydrogel Particles) INN 750mg	**Therapeutic Class:** Other Classification **Therapeutic Code**: 075	Indicated to aid in weight management in overweight and obese adults with a Body Mass Index (BMI) of 25-40 kg/m2, when used in conjunction with diet and exercise.	**Contraindication:** contraindicated in the following conditions: Pregnancy History of allergic reaction to cellulose, citric acid, sodium stearyl fumarate, gelatin, or titanium oxide **Side-effects:** Bloating Abdominal distension	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
67.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Linzagolix 100 mg tablet	Linzagolix INN 100 mg	**Therapeutic Class:** Hormone **Therapeutic Code**: 056	Linzagolix for the treatment of uterine fibroids, endometriosis and adenomyosis.	**Contraindication** No data available **Side-effects:** Incidence of hot flushes, insomnia, mood change.	New	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
68.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Linzagolix 200 mg tablet	Linzagolix INN 200 mg	**Therapeutic Class:** Hormone **Therapeutic Code**: 056	Linzagolix for the treatment of uterine fibroids, endometriosis and adenomyosis.	**Contraindication** No data available **Side-effects:** Incidence of hot flushes, insomnia, mood change.	New	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
69.	Incepta Pharmaceuticals Ltd (Dhamrai Unit). Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Relugolix 120 mg tablet	Relugolix INN 120 mg	**Therapeutic Class:** Hormone **Therapeutic Code**: 056	This drug is a gonadotropin-releasing hormone antagonist (GnRH antagonist) medication and has been used in the treatment of Endometriosis, Prostate Cancer, Uterine Fibroids, and Androgen	**Contraindication** No data available **Side-effects** Hot flush,Glucose increased, Triglycerides increased,Musculoskeletal	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Deprivation Treatment-naïve Nonmetastatic Prostate Cancer.	pain,Hemoglobin decreased,Fatigue, Diarrhea,Constipation				
70.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Trastuzumab 420 mg/ml vial as lyophilized powder/cake for solution for infusion	Trastuzumab ready to fill sterile bulk INN 8.0000 per ml eqv.to Trastuzumab 420 mg per ml	Anticancer Therapeutic Code: 010	Trastuzumab is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high-risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel with docetaxel and carboplatin as a single agent following multi-modality anthracycline based therapy. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.	**Contraindication:** None **Side-effects:** The following adverse reactions are discussed in greater detail in other sections of the label: Cardiomyopathy Infusion reactions Embryo-fetal Toxicity chemotherapy-induced neutropenia	Trastuzumab INN 440 mg/Vial (DCC 239) Trastuzumab 150 mg/vial Injection (DCC 241)	BNF 80 (Page 935-937) USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
71.	Popular Pharmaceuticals Limited Ziska Pharmaceuticals Ltd., Gazipur.	**Progesterone USP (Natural Micronized) 200 mg SR Tablet**	Progesterone USP (Natural Micronized) 200 mg SR	Hormone Replacement Therapy	• Maintenance of pregnancy in case of Threatened/Recurrent abortion & IUGR • Premenstrual syndrome • Menstrual irregularities through dysovulation or anovulation • Menopause (in addition to oestrogen treatment) to significantly reduce the risk of endometrial hyperplasia and carcinoma. • Dysfunctional uterine bleeding (DUB) • Luteal support during assisted reproductive techniques (ART) • Luteal support in in luteal phase defect	**Contraindication:** Micronized progesterone sustained-release tablets should not be used in women with any of the following conditions: • In patients with a known hypersensitivity to its ingredients. • Undiagnosed abnormal genital bleeding. • Known, suspected, or a history of breast cancer • Active arterial thromboembolic disease (e.g. stroke and myocardial infarction), or a history of these conditions. • Known liver dysfunction or disease. **Side-effects:** **Some of the warning signs of serious side effects include:** •	**1.** Progesterone USP 100 mg Soft gelatin Capsule **Approved By DCC 240** **2.** Progesterone USP 200 mg Soft gelatin Capsule **Approve**	**Progesterone 200 and 100 mg Capsule** **Approved By USFDA and BNF-78**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Changes in vision or speech • Sudden new severe headaches • Severe pains in your chest or legs with or without shortness of breath, weakness and fatigue • Dizziness and faintness • Vomiting Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptoms that concern you. **Less serious but common side effects include:** • Headaches • Breast pain • Irregular vaginal bleeding or spotting • Stomach or abdominal cramps, bloating • Nausea and vomiting • Hair loss • Fluid retention • Vaginal yeast infection	**d By DCC 240**			
72.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	S-Amlodipine Besylate 5mg Tablet	S-Amlodipine INN 5mg	Anti-hypertensive	It is a calcium channel blocker and may be used alone or in combination with other antihypertensive and anti-anginal agents for the treatment of: Hypertension Indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Coronary Artery Disease Chronic Stable Angina Vasospastic Angina (Prinzmetal's or Variant Angina) Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%. **WARNINGS AND PRECAUTIONS:** Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis.	**SIDE EFFECTS:** Most common adverse reaction to amlodipine is edema which occurred in a dose related manner. Other adverse experiences not dose related but reported with an incidence >1.0% are fatigue, nausea, abdominal pain, and somnolence. **CONTRAINDICATIONS:** Known sensitivity to amlodipine.	**NEW**	**USFDA** Amlodipine Besylate 2.5mg, 5mg & 10mg Tablet	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুরের করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					However, acute hypotension is unlikely. Worsening angina and acute myocardial infarction can develop after starting or increasing the dose, particularly in patients with severe obstructive coronary artery disease. • Titrate slowly in patients with severe hepatic impairment.					
73.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Pralsetinib INN 100 mg Capsule	Pralsetinib INN 100.00 mg	Anticancer	Pralsetinib is indicated for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Pralsetinib or any other components of this product. **Precaution:** Caution should be exercised when using Pralsetinib in patients with Hypertension, Hepatotoxicity, Interstitial Lung Disease/Pneumonitis, Hamorrhagic, Risk of Impaired Wound Healing , Embryo-Fetal Toxicity. **Warning:** Included as part of the "Precaution" Section. **Side effects:** The most common side effects are tiredness ,constipation, muscle and joint pain high blood pressure, decreased white blood cell and red blood cell counts, decreased levels of phosphate in the blood, decreased levels of body salt (sodium) in the blood, decreased levels of calcium in the blood, abnormal liver function blood tests.	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
74.	**One Pharma Ltd., Bogura**	Metronidazole 400 mg+Diloxanide Furoate 500 mg Tablet	Metronidazole USP 400 mg+Diloxanide Furoate USP 500 mg	Anti-protozoal	Gastrointestinal amebiasis, Giradiassis, and Liver and brain abscesses	**Contra-indications:** Hypersensitivity to any of the components of this drug. **Side-effect:** The common side effects are nausea, headaches, loss of appetite, vomiting and rash.	New	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
75.	**One Pharma Ltd., Bogura**	Metronidazole 4 gm+Diloxanide Furoate 5	Metronidazole USP 4 gm+Diloxanide	Anti-protozoal	Gastrointestinal amebiasis, Giradiassis, and Liver and brain abscesses	**Contra-indications:** Hypersensitivity to any of the components of this drug.	New	**নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
		gm/100 ml Powder for Suspension	Furoate USP 5 gm/100ml			**Side-effect:** The common side effects are nausea, headaches, loss of appetite, vomiting and rash.				
76.	**Team Pharmaceuticals Ltd. BSCIC, Rajshahi**	Efinaconazole topical 10% solution	Efinaconazole INN 10% solution	Antifungal	Efinaconazole topical solution, 10% is an azole antifungal indicated for the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes.	**Contra-indication:** None. **Side effects:** ngrown toenail,redness,itching,swelling,burning ,stinging,blisters, and pain.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
77.	Ziska Pharmaceuticals Ltd. **Gazipur.**	Bromelain 50 mg + Trypsin 1 mg Tablet	Bromelain 50 mg+ Trypsin 1 mg	Enzymes	Bromelain & Trypsin is indicated for inflammatory pains, soft tissue inflammation, edema associated with trauma and surgery such as in gynaecological conditions, breast engorgement, fractures, sprains, injuries, hemorrhoid, anal prolapse	**Contraindications:** Hypersensitivity **Side effects:** Trypsin seems to be safe when used by healthcare professionals for wound cleaning and healing. It can cause side effects such as pain and burning. Not enough is known about the safety of trypsin for its other uses **Warnings and Precautions:** Allergies: If you are allergic to pineapple, latex, wheat, celery, papain, carrot, fennel, cypress pollen, or grass pollen, you might have an allergic reaction to bromelain. Surgery: Bromelain might increase the risk of bleeding during and after surgery. Stop using bromelain at least 2 weeks before a scheduled surgery	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
78.	**General Pharmaceutical Ltd., Unit-2 Gazipur**	Papaverine Hydrochloride USP 60mg/2ml IM/IV Injection	Papaverine Hydrochloride (injectable Grade) USP 60mg/2ml IM/IV Injection	Coronary Vasodilatory Drugs **Therapeutic Code:** 040	Papaverine is recommended in various conditions accompanied by spasm of smooth muscle, such as vascular spasm associated with acute myocardial infarction (coronary occlusion), angina pectoris, peripheral and pulmonary embolism, peripheral vascular disease in which there is a vasospastic element, or certain cerebral angiospastic states; and visceral spasm, as in ureteral, biliary, or gastrointestinal colic.	**Contra-Indication:-** Intravenous injection of papaverine is contraindicated in the presence of complete atrioventricular heart block. When conduction is depressed, the drug may produce transient ectopic rhythms of ventricular origin, either premature beats or paroxysmal tachycardia. Papaverine Hydrochloride is not indicated for the treatment of impotence by intracorporeal injection. The intracorporeal injection of papaverine hydrochloride has been reported to have resulted in persistent	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						priapism requiring medical and surgical intervention. **Warnings and Precautions**: **General** Papaverine Hydrochloride Injection, USP, should not be added to Lactated Ringer's Injection, because precipitation would result. Papaverine Hydrochloride should be used with caution in patients with glaucoma. The medication should be discontinued if hepatic hypersensitivity with gastrointestinal symptoms, jaundice, or eosinophilia becomes evident or if liver function test values become altered. **Pregnancy** Pregnancy Category C - No teratogenic effects were observed in rats when papaverine hydrochloride was administered subcutaneously as a single agent. It is not known whether papaverine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Papaverine Hydrochloride should be given to a pregnant woman only if clearly needed. **Nursing Mothers** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when papaverine hydrochloride is administered to a nursing woman. **Pediatric Use** Safety and effectiveness in children have not been established.				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
79.	**General Pharmaceutical Ltd., Unit-2 Gazipur**	(Tropicamide (Injectable Grade) BP 0.120 mg + Phenylephrine Hydrochloride (Injectable Grade) USP 1.860 mg + Lidocaine Hydrochloride (Injectable Grade) BP 6.000 mg) Injection / 0.6ml Ampoule	(Tropicamide (Injectable Grade) BP 0.120 mg + Phenylephrine Hydrochloride (Injectable Grade) USP 1.860 mg + Lidocaine Hydrochloride (Injectable Grade) BP 6.000 mg) Injection / 0.6ml Ampoule	Eye Preparations **Therapeutic Code:** 052	Tropicamide + Phenylephrine Hydrochloride + Lidocaine Hydrochloride injection is indicated for cataract surgery to obtain mydriasis and intraocular anaesthesia during thesurgical procedure. It is indicated in adults only	**Contraindications:** Cataract Surgery Combined with vitrectomy. History of acute, narrow-angle glaucoma. Shallow anterior chamber. • **Side Effect*:*** • **Allergy and Cross- Sensitivity:** Contra-indicated in patients with known hypersensitivity to amide-type anesthetics or atropine derivatives. • **Pregnancy:** Manufacture advise avoid (systemic Uptake after administration cannot be excluded) - insufficient data available for phenylephrine and tropicamide in pregnancy; Lidocaine cross the placenta but is not known to be harmful in animal studies. • **Breast Feeding:** Manufacturer advises avoid- no data available for phenylephrine or tropicamide;Lidocaine present in milk in small amount. • **Pre-treatment screening:**Manufacturer advises patients must have demonstrated, at a previous visit, satisfactory pupil dilation with topical mydriatic treatment. **Patient and Carer Advice:** Driving and Skilled tasks**:** Manufacturer advises patients should be counselled about the effects on driving and skilled tasks.	New	**BNF 76 Page-1142**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
80.	**General Pharmaceutical Ltd., Unit-2 Gazipur**	Ceftazidime Pentahydrate and Avibactam Sodium (Sterile powder) Ph.Gr. 1.7128 gm (Equivalent to 1.000 gm Ceftazidime USP & 0.250 gm Avibactam INN) Powder for IV Injection	Ceftazidime Pentahydrate and Avibactam Sodium (Sterile powder) Ph.Gr. 1.7128 gm (Equivalent to 1.000 gm Ceftazidime USP & 0.250 gm Avibactam INN)/Vial	Anti-infective **Therapeutic Code:023**	For the treatment of patients 18 years or older with following infections caused by the susceptible microorganisms. 1. Complicated intra-abdominal infections (cIAI), used in combination with metronidazole. 2. Complicated Urinary Tract Infections (cUTI) including Pyelonephritis.	**Contraindications:** Known serious hypersensitivity to ceftazidime, avibactam or other members of the cephalosporin class. **Warnings and Precautions:** Decreased efficacy in patients with baseline CrCL of 30 to 50 mL/ min. Monitor CrCL at least daily in patients with changing renal function and adjust the dose of Ceftazidime Pentahydrate and Avibactam Sodium accordingly.	Ceftazidime 2 gm + Avibactam 0.5 gm/Vial Sterile powder for solution for Infusion	USDFA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Hypersensitivity reactions: Includes anaphylaxis and serious skin reactions. Cross-hypersensitivity may occur in patients with a history of penicillin allergy. If an allergic reaction occurs, discontinue Ceftazidime Pentahydrate and Avibactam Sodium. • Clostridium difficile-associated diarrhea: Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including Ceftazidime Pentahydrate and Avibactam Sodium. Evaluate if diarrhea occurs. • Central Nervous System Reactions: Seizures and other neurologic events may occur, especially in patients with renal impairment. Adjust dose in patients with renal impairment. **Side Effects:** Most common adverse reactions (incidence of > 10% in either indication) are vomiting, nausea, constipation, and anxiety.				
81.	**General Pharmaceutical Ltd., Unit-2 Gazipur**	Ceftazidime Pentahydrate and Avibactam Sodium (Sterile powder) Ph. Gr. 1.2873 gm (Equivalent to 0.750 gm Ceftazidime USP & 0.190 gm Avibactam INN) Powder for IV Injection	Ceftazidime Pentahydrate and Avibactam Sodium (Sterile powder) Ph. Gr. 1.2873 gm (Equivalent to 0.750 gm Ceftazidime USP & 0.190 gm Avibactam INN)/Vial	Anti-infective **Therapeutic Code:023**	For the treatment of patients 18 years or older with following infections caused by the susceptible microorganisms. 1. Complicated intra-abdominal infections (cIAI), used in combination with metronidazole. 2. Complicated Urinary Tract Infections (cUTI) including Pyelonephritis.	**Contraindications:** Known serious hypersensitivity to ceftazidime, avibactam or other members of the cephalosporin class. **Warnings and Precautions:** Decreased efficacy in patients with baseline CrCL of 30 to 50 mL/ min. Monitor CrCL at least daily in patients with changing renal function and adjust the dose of Ceftazidime Pentahydrate and Avibactam Sodium accordingly. • Hypersensitivity reactions: Includes anaphylaxis and serious skin reactions. Cross-hypersensitivity may occur in patients with a history of penicillin allergy. If an allergic reaction occurs, discontinue Ceftazidime Pentahydrate and Avibactam Sodium.	Ceftazidime 2 gm + Avibactam 0.5 gm/Vial Sterile powder for solution for Infusion	USDFA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Clostridium difficile-associated diarrhea: Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including Ceftazidime Pentahydrate and Avibactam Sodium. Evaluate if diarrhea occurs. • Central Nervous System Reactions: Seizures and other neurologic events may occur, especially in patients with renal impairment. Adjust dose in patients with renal impairment. **Side Effects:** Most common adverse reactions (incidence of > 10% in either indication) are vomiting, nausea, constipation, and anxiety.				
82.	**General Pharmaceutical Ltd., Unit-2 Gazipur**	Poly-L-Lactic Acid (Lyophilized Sterile Powder) Ph. Gr. 367.500 mg (Equivalent to 150.000 mg Poly-L-Lactic Acid) Powder for IV Injection	Poly-L-Lactic Acid (Lyophilized Sterile Powder) Ph. Gr. 367.500 mg (Equivalent to 150.000 mg Poly-L-Lactic Acid)/Vial	Skin and Mucos Membrane Preparation **Therapeutic Code:071**	Poly-L-Lactic Acid Injection is suitable for increasing the volume of depressed areas, particularly to correct skin depressions, such as in skin creases, wrinkles, folds, scars and for skin aging. SCULPTRA is also suitable for large volume corrections of the signs of facial fat loss (lipoatrophy). Injection techniques: The depth of injection and quantity of Poly-L-Lactic Acid Injection used depend on the area to be treated and the result expected. Over-corrections should be avoided, but if they occur, the area concerned should be thoroughly massaged to ensure proper distribution of the product. Limited correction of the treatment area allows for the gradual improvement of the depressed area over several	**Contraindications:** Poly-L-Lactic Acid Injection should not be used in any person who has hypersensitivity to any of the components of the product **WARNINGS** Use of Poly-L-Lactic Acid Injection in any person with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled. Do not overcorrect (overfill) a contour deficiency because the depression should gradually improve within several weeks as the treatment effect of Poly-L-Lactic Acid Injection occurs (see INSTRUCTIONS FOR USE). Injection procedure reactions to Poly-L-Lactic Acid Injection have been observed consisting mainly of hematoma, bruising, edema, discomfort, inflammation, and erythema. The most common device related adverse effect was the delayed	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					weeks as the treatment effect occurs.	occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable, asymptomatic and nonvisible. Refer to ADVERSE REACTIONS for details. Special care should be taken to avoid injection into the blood vessels. An introduction into the vasculature may occlude the vessels and could cause skin infarction or embolism. Do not inject into the red area of the lip (vermillion). The long term efficacy and safety of SCULPTRA has not been established in the red area of the lip. **PRECAUTIONS** Poly-L-Lactic Acid Injection should only be used by health care providers with expertise in the correction of volume deficiencies after fully familiarizing themselves with the product, the product educational materials, and the entire instruction leaflet. Poly-L-Lactic Acid Injection vials are for single patient and single session use only. Do not reuse or resterilize the vial. Discard immediately after use. Do not use if package or vial is opened or damaged. Long-term safety and effectiveness of Poly-L-Lactic Acid Injection beyond two years have not been studied in controlled clinical trials. Poly-L-Lactic Acid Injection should be used in the deep dermis or subcutaneous layer. Avoid superficial injections in order to avoid the appearance of early papules or nodules at the injection site, which could be suggestive of improper injection techniques (superficial placement, excessive amount of product, incorrect reconstitution). In addition, massaging the treatment area to ensure proper distribution of the				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						product may also minimize the appearance of papules or nodules. Special care must be taken when using Poly-L-Lactic Acid Injection in areas of thin skin, such as the periorbital area. An increased risk of papules and nodules in the periorbital area has been reported . Refer to the INSTRUCTIONS FOR USE regarding injection techniques. As with all transcutaneous procedures, Poly-L-Lactic Acid Injection carries a risk of infection. Standard precautions associated with injectable materials should be followed. As with all injections, patients treated with anti-coagulants may run the risk of a hematoma or localized bleeding at the injection site. The safety of Poly-L-Lactic Acid Injection for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established. No studies of interactions of Poly-L-Lactic Acid Injection with drugs or other substances or implants have been made. The safety of using Poly-L-Lactic Acid Injection in patients with susceptibility to keloid formation and hypertrophic scarring has not been established. Poly-L-Lactic Acid Injection should not be used in patients with known history of or susceptibility to keloid formation or hypertrophic scarring. The patient should be informed that he or she should minimize exposure of the treatment area to excessive sun and avoid UV lamp exposure until any initial swelling and redness has resolved. If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						treatment with SCULPTRA, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if Poly-L-Lactic Acid Injection is administered before the skin has healed completely after such a procedure.				
83.	**General Pharmaceutical Ltd., Gazipur**	Ethanol 96% BP 72.920gm/100gm (w/w) Hand & Skin Sanitizer Gel	Ethanol 96% BP 72.920gm/100gm (w/w)	Antiseptic and Disinfectants Therapeutic Code:029	Ethanol 96% Hand & Skin Sanitizers a broad-spectrum Sanitizer with efficacy proven across a wide range of bacteria.	**Contra-Indication:-** No Specific Contraindications were found. **Warnings and Precautions**: Patients with skin disorders should closely be monitored. Since Ethanol 70% has directly activity, it should be used with caution in patients.		**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
84.	**General Pharmaceutical Ltd., Gazipur**	Isopropyl Alcohol BP 70.00gm/100gm (w/w) Hand & Skin Sanitizer Gel	Isopropyl Alcohol BP 70.00gm/100gm (w/w)	Antiseptic and Disinfectants Therapeutic Code:029	Isopropyl Alcohol 70% Hand & Skin Sanitizers a broad-spectrum Sanitizer with efficacy proven across a wide range of bacteria.	**Contra-Indication:-** No Specific Contraindications were found. **Warnings and Precautions**: Patients with skin disorders should closely be monitored. Since Isopropyl Alcohol 70% has directly activity, it should be used with caution in patients.		**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
85.	**General Pharmaceutical Ltd., Gazipur**	Astaxanthin 2mg (as 4% Powder) USP Chewable Tablet	Astaxanthin 2mg (as 4% Powder) USP	Other Classification Therapeutic Code:075	Strong antioxidant Improves cardiovascular health (Atherosclerosis, reduce cholesterol).Improves immune function.Improves condition of skin. Protects skin from damage caused by sun (Reduce wrinkles, pimples and other signs of aging). Improves recovery from central nervous system injuries. Protects from Parkinson 's disease, Dementia and Alzheimer's. Protects eyes from cataracts and macular degeneration. Reduces inflammation (Arthritis). Reduces risk of infertility	Contraindication: No clear data found Side effect: No clear data found.	Astaxanthin 2mg, 4mg soft gelatin capsule (DCC-251 এ হার্বাল হিসাবে অনুমোদন আছে।)	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Also Astaxnthin effectively reduce oxidative damage to DNA, decrease the risk for many types of cancer and stabilize blood sugar.					
86.	**General Pharmaceutical Ltd., Gazipur**	Astaxanthin 4mg (as 4% Powder) USP Chewable Tablet	Astaxanthin 4mg (as 4% Powder) USP	Other Classification Therapeutic Code:075	Strong antioxidant Improves cardiovascular health (Atherosclerosis, reduce cholesterol).Improves immune function.Improves condition of skin. Protects skin from damage caused by sun (Reduce wrinkles, pimples and other signs of aging). Improves recovery from central nervous system injuries. Protects from Parkinson 's disease, Dementia and Alzheimer's. Protects eyes from cataracts and macular degeneration. Reduces inflammation (Arthritis). Reduces risk of infertility Also Astaxnthin effectively reduce oxidative damage to DNA, decrease the risk for many types of cancer and stabilize blood sugar.	Contraindication: No clear data found Side effect: No clear data found.	Astaxanthin 2mg, 4mg soft gelatin capsule (DCC-251 এ হার্বাল হিসাবে অনুমোদন আছে।)	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
87.	**General Pharmaceutical Ltd., Gazipur**	Astaxanthin 6mg (as 4% Powder)USP Chewable Tablet	Astaxanthin 6mg (as 4% Powder) USP	Other Classification Therapeutic Code:075	Strong antioxidant Improves cardiovascular health (Atherosclerosis, reduce cholesterol).Improves immune function.Improves condition of skin. Protects skin from damage caused by sun (Reduce wrinkles, pimples and other signs of aging). Improves recovery from central nervous system injuries. Protects from Parkinson 's disease, Dementia and Alzheimer's. Protects eyes from cataracts	Contraindication: No clear data found Side effect: No clear data found.	Astaxanthin 2mg, 4mg soft gelatin capsule	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					and macular degeneration. Reduces inflammation (Arthritis). Reduces risk of infertility Also Astaxnthin effectively reduce oxidative damage to DNA, decrease the risk for many types of cancer and stabilize blood sugar.					
88.	**General Pharmaceutical Ltd., Gazipur** Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka. Navana Pharmaceuticals Limited	Lumateperone tosylate INN 60 mg (Equivalent to 42 mg Lumateperone) Capsule	Lumateperone tosylate INN 60 mg (Equivalent to 42 mg Lumateperone)	Antipsychotic Therapeutic Code: 028	Lumateperane is an atypical antipsychotic indicated for the treatment of schizophrenia in adults.	**Contra-Indication:** Known hypersensitivity to lumateperone or any components of Lumateperone. **Warnings and Precautions:** Cerebrovascular Adverse Reactions in Elderly Patients with DementiaRelated Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke and transient ischemic attack). • Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. Tardive Dyskinesia: Discontinue treatment if clinically appropriate. (5.4) • Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain. • Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing Lumateperane if clinically significant decline in WBC occurs in absence of other causative factors. • Orthostatic Hypotension and Syncope: Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope.	New	USFDA	পদটির বিষয়ে সিদ্ধান্ত স্থগিত রাখা হয়।	সাইক্রেটিস্ট এর মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Seizures: Use cautiously in patients with a history of seizure or with conditions that lower seizure threshold. • Potential for Cognitive and Motor Impairment: Use caution when operating machinery. **Side-effects:** Most common adverse reactions in clinical trials (incidence > 5% and greater than twice placebo) were somnolence/sedation and dry mouth.				
89.	**General Pharmaceutical Ltd., Gazipur**	(Fluocinolone Acetonide USP 0.025 gm + Clioquinol USP 3.000 gm)/100gm Ointment	(Fluocinolone Acetonide USP 0.025 gm + Clioquinol USP 3.000 gm)/100gm	Steroidal Anti Inflammatory Therapeutic Code: 072	Fluocinolone Acetonide & Clioquinol combines the effective topical corticosteroid with the effective antibacterial and antifungal agent clinoquinol. It is indicated for inflammatory dermatoses - including eczema, dermatitis, seborrhoea and intertrigo where secondary bacterial and/or fungal infection is present or likely to occur.	**Contraindications:** Fluocinolone Acetonide & Clioquinol preparations are contra-indicated in primary infections of the skin caused by bacteria, fungi or viruses and in rosacea, acne, perioral dermatitis and napkin eruptions. Fluocinolone Acetonide & Clioquinol preparations should not be used in patients that are hypersensitive to any of the ingredients. Fluocinolone Acetonide & Clioquinol preparations are not advised in the treatment of children under one year of age. **Side-effects:** The following side effects have also been reported but how often they occur is unknown: • An allergic (itchy) reaction to the cream. • Irritation where the cream has been applied. • A worsening of acne, rosacea and dermatitis around the mouth (see section 2). • Patches of pale skin (depigmentation). • localised increased hair growth.	(Fluocinolone Acetonide USP 0.025 gm + Clioquinol USP 3.000 gm)/100gm Cream	**BNF-76 Page-1216**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
90.	**General Pharmaceutical Ltd., Gazipur** Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cenobamate INN 12.5 mg Tablet	Cenobamate INN 12.5 mg	Drug used in Epilepsy Therapeutic Code: 046	Cenobamate is indicated for the treatment of partial-onset seizures in adult patients. :	**Contraindications:** • Hypersensitivity to cenobamate or any of the inactive ingredients. • Familial Short QT syndrome. **WARNINGS AND PRECAUTIONS:** Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/ Multi-Organ Hypersensitivity: Discontinue if no alternate etiology. • QT Shortening: Use caution when administering Cenobamate with other drugs that shorten the QT interval • Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. • Neurological Adverse Reactions: Monitor for somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on Cenobamate. Concomitant use with other CNS depressants or alcohol may have additive effects. **Side-effects:** The most common adverse reactions in patients receiving Cenobamate (at least 10% for Cenobamate and more frequently than placebo) include somnolence, dizziness, fatigue, diplopia, and headache.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
91.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cenobamate 25 mg Tablet	Cenobamate INN 25 mg	Drug used in Epilepsy Therapeutic Code: 046	Cenobamate is indicated for the treatment of partial-onset seizures in adult patients. :	**Contraindications:** • Hypersensitivity to cenobamate or any of the inactive ingredients. • Familial Short QT syndrome. **WARNINGS AND PRECAUTIONS:** Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/ Multi-Organ Hypersensitivity: Discontinue if no alternate etiology.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• QT Shortening: Use caution when administering Cenobamate with other drugs that shorten the QT interval • Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. • Neurological Adverse Reactions: Monitor for somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on Cenobamate. Concomitant use with other CNS depressants or alcohol may have additive effects. **Side-effects:** The most common adverse reactions in patients receiving Cenobamate (at least 10% for Cenobamate and more frequently than placebo) include somnolence, dizziness, fatigue, diplopia, and headache.				
92.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cenobamate 50 mg Tablet	Cenobamate INN 50 mg	Drug used in Epilepsy Therapeutic Code: 046	Cenobamate is indicated for the treatment of partial-onset seizures in adult patients. :	**Contraindications:** • Hypersensitivity to cenobamate or any of the inactive ingredients. • Familial Short QT syndrome. **WARNINGS AND PRECAUTIONS:** Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/ Multi-Organ Hypersensitivity: Discontinue if no alternate etiology. • QT Shortening: Use caution when administering Cenobamate with other drugs that shorten the QT interval • Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. • Neurological Adverse Reactions: Monitor for	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on Cenobamate. Concomitant use with other CNS depressants or alcohol may have additive effects. **Side-effects:** The most common adverse reactions in patients receiving Cenobamate (at least 10% for Cenobamate and more frequently than placebo) include somnolence, dizziness, fatigue, diplopia, and headache.				
93.	**General Pharmaceutical Ltd., Gazipur**	Cenobamate INN 100 mg Tablet	Cenobamate INN 100.00mg	Drug used in Epilepsy Therapeutic Code: 046	Cenobamate is indicated for the treatment of partial-onset seizures in adult patients. :	**Contraindications:** • Hypersensitivity to cenobamate or any of the inactive ingredients. • Familial Short QT syndrome. **WARNINGS AND PRECAUTIONS:** Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/ Multi-Organ Hypersensitivity: Discontinue if no alternate etiology. • QT Shortening: Use caution when administering Cenobamate with other drugs that shorten the QT interval • Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. • Neurological Adverse Reactions: Monitor for somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on Cenobamate. Concomitant use with other CNS depressants or alcohol may have additive effects. **Side-effects:**	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						The most common adverse reactions in patients receiving Cenobamate (at least 10% for Cenobamate and more frequently than placebo) include somnolence, dizziness, fatigue, diplopia, and headache.				
94.	**General Pharmaceutical Ltd., Gazipur**	Cenobamate INN 200 .00 mg Tablet	Cenobamate INN 200.00mg	Drug used in Epilepsy Therapeutic Code: 046	Cenobamate is indicated for the treatment of partial-onset seizures in adult patients. :	**Contraindications:** • Hypersensitivity to cenobamate or any of the inactive ingredients. • Familial Short QT syndrome. **WARNINGS AND PRECAUTIONS:** Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/ Multi-Organ Hypersensitivity: Discontinue if no alternate etiology. • QT Shortening: Use caution when administering Cenobamate with other drugs that shorten the QT interval • Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. • Neurological Adverse Reactions: Monitor for somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on Cenobamate. Concomitant use with other CNS depressants or alcohol may have additive effects. **Side-effects:** The most common adverse reactions in patients receiving Cenobamate (at least 10% for Cenobamate and more frequently than placebo) include somnolence, dizziness, fatigue, diplopia, and headache.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
95.	**General Pharmaceutical Ltd., Gazipur**	Hyaluronic Acid INN 5.000 mg + Glucosamine Sulfate potaasium chloride USP 663.000 mg (equivalent to 500mg Glucosamine Sulfate) + Condroitin Sulfate Sodium USP 200.000 mg Tablet	Hyaluronic Acid INN 5.000 mg + Glucosamine Sulfate potaasium chloride USP 663.000 mg (equivalent to 500 mg Glucosamine Sulfate) + Condroitin Sulfate Sodium USP 200.000 mg	Nonsteroidal Antiinflamatory Therapeutic Code: 064	Osteoarthritis (OA), Rheumatoid arthritis (RA), Degenerative change in bone and joint. Prophylaxis of muscle and tendon injury.	**Contra-indication:** It is safe in recommended dose but caution should be taken in Diabetes, Glucose-6-phosphate dehydrogenase deficiency (G6PD deficiency), Iron-related disorders such as hemochromatosis, thalassemia or anemia and sickle cell disease. **Side effect:** A traditional and widely consumed food, the rosehip showed considerable safety. In very rare case acid regurgitation, diarrhea and constipation may occur.	New	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
96.	**General Pharmaceutical Ltd., Gazipur**	Calcium Carbonate BP 750.00 mg + Heavy Magnesium Oxide BP 82.900 mg + Betacarotene (as 20%) Ph. Gr. 36.000 mg + Vitamin C (Ascorbic Acid) BP 60.000 mg + Vitamin D_3: Dried Vitamin D_3 (Cholecalciferol) Ph. Gr. 4.000 mg + Vitamin E: Dry Vitamin E Acetate [Alpha Tocopheryl Acetate Concentrate (Powder form)] 50% Ph. Gr. 40.200 mg + Thiamine Mononitrate USP 1.700 mg + Riboflavin(Vitamin B_2) BP 2.000 mg + Niacin (Nicotinic Acid) USP 20.000 mg + Pyridoxine Hydrochloride (Vitamin B_6) BP 2.500 mg + Folic Acid BP 0.800 mg + Cyanocobalamin (Vitamin B_{12}) 0.1% Ph. Gr. 1.920 mg + Biotin BP 0.300 mg + Calcium Pantothenate BP10.000 mg + Iron (as Ferrous Fumarate) BP 28.000 mg +	Calcium Carbonate BP 750.00 mg + Heavy Magnesium Oxide BP 82.900 mg + Betacarotene (as 20%) Ph. Gr. 36.000 mg + Vitamin C (Ascorbic Acid) BP 60.000 mg + Vitamin D_3: Dried Vitamin D_3 (Cholecalciferol) Ph. Gr. 4.000 mg + Vitamin E: Dry Vitamin E Acetate [Alpha Tocopheryl Acetate Concentrate (Powder form)] 50% Ph. Gr. 40.200 mg + Thiamine Mononitrate USP 1.700 mg + Riboflavin(Vitamin B_2) BP 2.000 mg + Niacin (Nicotinic Acid) USP 20.000 mg + Pyridoxine Hydrochloride (Vitamin B_6) BP 2.500 mg + Folic Acid BP 0.800 mg + Cyanocobalamin	Vitamins and Combinations Therapeutic Code: 078	This medication is a multivitamin product used to treat or prevent vitamin deficiency due to poor diet, certain illnesses, or during pregnancy. Vitamins are important building blocks of the body and help keep you in good health.	**Contraindications:** Iron metabolism disorder causing increased iron storage. An overload of iron in the blood. A type of blood disorder where the red blood cells burst. An ulcer from too much stomach acid. A type of stomach irritation called gastritis. Ulcerative colitis. An inflammatory condition of the intestines. Several blood transfusions. **Side-effect:** Constipation, diarrhea, or upset stomach may occur. These effects are usually temporary and may disappear as your body adjusts to this medication. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. If your doctor has prescribed this drug, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling	অনুরূপ কম্বিনেশন রয়েছে	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
		Povidone Iodine USP 0.150 mg + Zinc Oxide BP 15.000 mg + Copper (ii) Oxide Ph. Gr. 2.504 mg Tablet	(Vitamin B_{12}) 0.1% Ph. Gr. 1.920 mg + Biotin BP 0.300 mg + Calcium Pantothenate BP10.000 mg + Iron (as Ferrous Fumarate) BP 28.000 mg + Povidone Iodine USP 0.150 mg + Zinc Oxide BP 15.000 mg + Copper (ii) Oxide Ph. Gr. 2.504 mg			(especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. .				
97.	Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited	**Diethylpropion HCl 75mg ER Tablet.**	**Diethylpropion HCl 75mg**	Anticonvulsants Therapeutic Code: 013	Indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m2 or higher and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.	Contraindications: Pulmonary hypertension, advanced arteriosclerosis, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma, severe hypertension, Agitated states, Patients with a history of drug abuse, Use in combination with other anorectic agents is contraindicated. During or within 14 days following the administration of monoamine oxidase inhibitors, hypertensive crises may result. Side Effects: Cardiovascular: Precordial pain, arrhythmia (including ventricular), ECG changes, tachycardia, elevation of blood pressure, palpitation and rare reports of pulmonary hypertensionCNS: Dyskinesia, blurred vision, overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, mydriasis, drowsiness, malaise, headache, and cerebrovascular accident, Gastrointestinal: Vomiting, diarrhea, abdominal discomfort, dryness of the mouth, unpleasanttaste, nausea, constipation, other gastrointestinal disturbancesAllergic:	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Urticaria, rash, ecchymosis, erythema Endocrine: Impotence, changes in libido, gynecomastia, menstrual upset Hematopoietic System: Bone marrow depression, agranulocytosis, leukopenia				
98.	**General Pharmaceutical Ltd., Gazipur**	**Omega-3 Acid Ethyl Esters (From fish Oil) (Combination of DHA & EPA) USP 223.000 mg (Eq. to DHA 200mg & EPA 23mg)+ Oleic Acid USP 6.690 mg + Sodium Alginate BP 6.690 mg + Medium-Chain Triglyceride (Miglyol 812) BP 8.620 mg Soft Gel Capsule**	**Omega-3 Acid Ethyl Esters (From fish Oil) (Combination of DHA & EPA) USP 223.000 mg (Eq. to DHA 200mg & EPA 23mg)+ Oleic Acid USP 6.690 mg + Sodium Alginate BP 6.690 mg + Medium-Chain Triglyceride (Miglyol 812) BP 8.620 mg**	Maltivitamins and Minerals Code:0078	Omega 3 fatty acids, principally EPA and DHA, indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia (HTG). (1) Limitations of Use: • The effect of Omega 3 fatty acids on the risk for pancreatitis has not been determined. • The effect of Omega 3 fatty acids on cardiovascular mortality and morbidity has not been determined.	**Contraindications:** Omega 3 fatty acids is Contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Omega 3 fatty acids or any of its components. **Adverse Reaction:** The most common adverse reactions (incidence >3% and greater than placebo) were eructation, dyspepsia, and taste perversion	Omega-3 Acid Ethyl Esters 1gm Soft Gel Capsule	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
99.	**General Pharmaceutical Ltd., Gazipur**	Sumatriptan Succinate 10mg+Naproxen Sodium 60 mg Tablet	Sumatriptan Succinate BP 14.000 mg (Equivalent to 10.000 mg Sumatriptan)+ Naproxen Sodium BP 60 mg	Analgesics and Antipyretics Therapeutic Code: 006	It is a combination of sumatriptan, a serotonin (5-HT) 1b/1d receptor agonist (triptan), and naproxen sodium, a non-steroidal antiinflammatory drug, indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. Not indicated for the prophylactic therapy of migraine attacks. Not indicated for the treatment of cluster headache.	**Contraindications:** History of coronary artery disease or coronary vasospasm. History of coronary artery bypass graft surgery.(Wolff-Parkinson-White syndrome or other cardiac accessory conduction, pathway disorders. History of stroke, transient ischemic attack, or hemiplegic or basilar migraine. Peripheral vascular disease. Ischemic bowel disease. Uncontrolled hypertension. **<u>WARNINGS AND PRECAUTIONS:</u>** • Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.	Naproxen 250, 500 mg Tablet Sumatriptan 50mg Tablet	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• It is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. **Side Effects:** Dizziness, drowsiness, Somnolence, Paresthesia, Nausea, Dyspepsia, dry mouth, chest pain or pressure, tight feeling in neck or jaw, pain spreading to arm or shoulder, sudden numbness or weakness, confusion, problems with vision, speech, or balance, bloody or tarry stools.				
100.	**Acme Laboratories Ltd., Dhamrai, Dhaka** Navana Pharmaceuticals Limited	Opicapone INN 25mg Hard Gelatin s Capsule	Opicapone INN 25mg Hard Gelatin s Capsule	Antiparkinsonism Therapeutic Code: 025	It is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.	**Contraindications:** • Concomitant use of non-selective monoamine oxidase (MAO) inhibitors. • History of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms. **Side Effects:** Most common adverse reactions (≥4% and > placebo): dyskinesia, constipation, blood creatine kinase increased, hypotension/syncope, and weight decreased. **WARNINGS AND PRECAUTIONS:** • Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT): May cause arrhythmias, increased heart rate, and excessive	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						changes in blood pressure. Monitor patients when treated concomitantly with products metabolized by COMT. • Falling Asleep During Activities of Daily Living: Advise patients prior to treatment. • Hypotension/Syncope: If occurs, consider discontinuing Opicapone or adjusting dosage of other medications that can lower blood pressure. • Dyskinesia: May cause or exacerbate dyskinesia; consider levodopa or dopaminergic medication dose reduction. • Hallucinations and Psychosis: Consider stopping Opicapone if occurs. • Impulse Control/Compulsive Disorders: Consider stopping Opicapone if occurs. • Withdrawal-Emergent Hyperpyrexia and Confusion: When discontinuing Opicapone, monitor patients and consider adjustment of other dopaminergic therapies as needed.				
101.	**Acme Laboratories Ltd., Dhamrai, Dhaka** Navana Pharmaceuticals Limited	Opicapone INN 50mg Hard Gelatin s Capsule	Opicapone INN 50mg Hard Gelatin s Capsule	Antiparkinsonism Therapeutic Code: 025	It is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.	**Contraindications:** • Concomitant use of non-selective monoamine oxidase (MAO) inhibitors. • History of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms. **Side Effects:** Most common adverse reactions (≥4% and > placebo): dyskinesia, constipation, blood creatine kinase increased, hypotension/syncope, and weight decreased. **WARNINGS AND PRECAUTIONS:** • Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT): May cause arrhythmias,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						increased heart rate, and excessive changes in blood pressure. Monitor patients when treated concomitantly with products metabolized by COMT. • Falling Asleep During Activities of Daily Living: Advise patients prior to treatment. • Hypotension/Syncope: If occurs, consider discontinuing Opicapone or adjusting dosage of other medications that can lower blood pressure. • Dyskinesia: May cause or exacerbate dyskinesia; consider levodopa or dopaminergic medication dose reduction. • Hallucinations and Psychosis: Consider stopping Opicapone if occurs. • Impulse Control/Compulsive Disorders: Consider stopping Opicapone if occurs. • Withdrawal-Emergent Hyperpyrexia and Confusion: When discontinuing Opicapone, monitor patients and consider adjustment of other dopaminergic therapies as needed.				
102.	Navana Pharmaceuticals Limited Beacon Pharmaceuticals Ltd, Valuka, Mymanshing.	Remimazolam INN 20mg IV Inj.	Remimazolam INN 20mg IV Inj.	Hypnotics,Sedatives& Anxiolitic Therapeutic Code: 057	Remimazolam for injection is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.	Contraindications: Hypersensitivity to dextran 40. **<u>Side Effects:</u>** The most common adverse reactions (>10%) in patients receiving Remimazolam for procedural sedation are hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension. **<u>Warnings and precautions:</u>** Hypersensitivity Reactions: Hypersensitivity reactions including anaphylaxis may occur. Neonatal Sedation: Benzodiazepine use during pregnancy can result in neonatal sedation. Observe newborns	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						for signs of sedation and manage accordingly. Pediatric Neurotoxicity: In developing animals, exposures greater than 3 hours cause neurotoxicity. Weigh benefits against potential risks when considering elective procedures in children under 3 years old.				
103.	Navana Pharmaceuticals Limited	Alogliptin 6.25 mg Tablet	Alogliptin 6.25 mg	Antidiabetes Therapeutic Code: 015	It is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of Use: Not for treatment of type 1 diabetes or diabetic ketoacidosis.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin-containing products, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. **Side effects:** Common adverse reactions (reported in ≥4% of patients treated with Alogliptin 25 mg and more frequently than in patients who received placebo) are: nasopharyngitis, headache, and upper respiratory tract infection. **WARNINGS AND PRECAUTIONS:** Acute pancreatitis: There have been postmarketing reports of acute pancreatitis. If pancreatitis is suspected, promptly discontinue Alogliptin. • Hypersensitivity: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with Alogliptin such as anaphylaxis, angioedema and severe cutaneous adverse reactions. In such cases, promptly discontinue Alogliptin, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment for diabetes. • Hepatic effects: Postmarketing reports of hepatic failure, sometimes fatal. Causality cannot be excluded. If liver injury is detected, promptly interrupt Alogliptin and assess patient for probable cause, then treat cause if	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						possible, to resolution or stabilization. Do not restart Alogliptin if liver injury is confirmed and no alternative etiology can be found. • Hypoglycemia: When an insulin secretagogue (e.g. sulfonylurea) or insulin is used in combination with Alogliptin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia. • Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Alogliptin or any other antidiabetic drug.				
104.	Navana Pharmaceuticals Limited	Alogliptin 12.5 mg Tablet	Alogliptin 12.5 mg	Antidiabetes Therapeutic Code: 015	It is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of Use: Not for treatment of type 1 diabetes or diabetic ketoacidosis.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin-containing products, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. **Side effects:** Common adverse reactions (reported in ≥4% of patients treated with Alogliptin 25 mg and more frequently than in patients who received placebo) are: nasopharyngitis, headache, and upper respiratory tract infection. **WARNINGS AND PRECAUTIONS:** Acute pancreatitis: There have been postmarketing reports of acute pancreatitis. If pancreatitis is suspected, promptly discontinue Alogliptin. • Hypersensitivity: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with Alogliptin such as anaphylaxis, angioedema and severe cutaneous adverse reactions. In such cases, promptly discontinue Alogliptin, assess for other potential causes,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						institute appropriate monitoring and treatment, and initiate alternative treatment for diabetes. • Hepatic effects: Postmarketing reports of hepatic failure, sometimes fatal. Causality cannot be excluded. If liver injury is detected, promptly interrupt Alogliptin and assess patient for probable cause, then treat cause if possible, to resolution or stabilization. Do not restart Alogliptin if liver injury is confirmed and no alternative etiology can be found. • Hypoglycemia: When an insulin secretagogue (e.g. sulfonylurea) or insulin is used in combination with Alogliptin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia. • Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Alogliptin or any other antidiabetic drug.				
105.	Navana Pharmaceuticals Limited Acme Laboratories Ltd., Dhamrai, Dhaka	Alogliptin 25 mg Tablet	Alogliptin 25 mg	Antidiabetes Therapeutic Code: 015	It is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of Use: Not for treatment of type 1 diabetes or diabetic ketoacidosis.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin-containing products, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. **Side effects:** Common adverse reactions (reported in ≥4% of patients treated with Alogliptin 25 mg and more frequently than in patients who received placebo) are: nasopharyngitis, headache, and upper respiratory tract infection. **WARNINGS AND PRECAUTIONS:** Acute pancreatitis: There have been postmarketing reports of acute pancreatitis. If pancreatitis is	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						suspected, promptly discontinue Alogliptin. • Hypersensitivity: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with Alogliptin such as anaphylaxis, angioedema and severe cutaneous adverse reactions. In such cases, promptly discontinue Alogliptin, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment for diabetes. • Hepatic effects: Postmarketing reports of hepatic failure, sometimes fatal. Causality cannot be excluded. If liver injury is detected, promptly interrupt Alogliptin and assess patient for probable cause, then treat cause if possible, to resolution or stabilization. Do not restart Alogliptin if liver injury is confirmed and no alternative etiology can be found. • Hypoglycemia: When an insulin secretagogue (e.g. sulfonylurea) or insulin is used in combination with Alogliptin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia. • Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Alogliptin or any other antidiabetic drug.				
106.	**General Pharmaceutical Ltd., Gazipur** Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Pregabalin BP 330mg CR Tablet	Pregabalin BP 300mg	Drug used in Epilepsy Therapeutic Code: 046	is indicated for the management of: •Neuropathic pain associated with diabetic peripheral neuropathy Postherpetic neuralgia Efficacy of pregabalin has not been established for the management of fibromyalgia or	**CONTRAINDICATIONS :** Known hypersensitivity to pregabalin or any of its components. **WARNINGS AND PRECAUTIONS:** Angioedema: Angioedema (e.g., swelling of the face, mouth (tongue, lips, and gums) and neck (throat and larynx)) can occur and may be	Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg Capsule	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					as adjunctive therapy for adult patients with partial onset seizur	associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue pregabalin immediately in patients with these symptoms. Hypersensitivity reactions: Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur. Discontinue pregabalin immediately in these patients. Suicidal Behavior and Ideation: Antiepileptic drugs, including pregabalin, the active ingredient in pregabalin, increase the risk of suicidal thoughts or behavior. Peripheral Edema: May cause peripheral edema. Monitor patients for the development of edema when co-administering pregabalin and thiazolidinedione antidiabetic agents. Dizziness and Somnolence: May cause dizziness and somnolence and impair patients ability to drive or operate machinery. Increased seizure frequency may occur in patients with seizure disorders if pregabalin is rapidly discontinued. Withdraw pregabalin gradually over a minimum of 1 week. **Side Effects:** Most common adverse reactions reported in greater than or equal to 4% of patients treated with LYRICA CR are dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain.				
107.	Beximco Pharmaceuticals Ltd	Pregabalin 330 mg Extended release tablet.	Pregabalin USP 330 mg	Drug used in Epilepsy Therapeutic Code: 046	It is indicated for the management of: •Neuropathic pain associated with diabetic peripheral neuropathy Postherpetic neuralgia	**CONTRAINDICATIONS :** Known hypersensitivity to pregabalin or any of its components. **WARNINGS AND PRECAUTIONS:** Angioedema: Angioedema (e.g., swelling of the face, mouth (tongue,	Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg Capsule	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Efficacy of pregabalin has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizur	lips, and gums) and neck (throat and larynx)) can occur and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue pregabalin immediately in patients with these symptoms. Hypersensitivity reactions: Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur. Discontinue pregabalin immediately in these patients. Suicidal Behavior and Ideation: Antiepileptic drugs, including pregabalin, the active ingredient in pregabalin, increase the risk of suicidal thoughts or behavior. Peripheral Edema: May cause peripheral edema. Monitor patients for the development of edema when co-administering pregabalin and thiazolidinedione antidiabetic agents. Dizziness and Somnolence: May cause dizziness and somnolence and impair patients ability to drive or operate machinery. Increased seizure frequency may occur in patients with seizure disorders if pregabalin is rapidly discontinued. Withdraw pregabalin gradually over a minimum of 1 week. **Side Effects:** Most common adverse reactions reported in greater than or equal to 4% of patients treated with LYRICA CR are dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain.				
108.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Bosutinib INN 400 mg Tablet	Bosutinib Monohydrate INN413.60 mg (Eq. to 400.0 mg Bosutinib)	Anticancer Therapeutic Code: 010	It is indicated for the treatment of adult patients with: **i)** Newly diagnosed chronic phase (CP) Philadelphia	**Contraindication:** Hypersensitivity to Bosutinib. **Warnings and Precautions:**	Bosutinib INN 100 mg, 500 mg Tablet.	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka				chromosome-positive Chronic Myelogenous Leukemia (Ph+ CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial. **ii)** Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy.	**Gastrointestinal toxicity:** Monitor and manage as necessary. Withhold, dose reduce, or discontinue Bosutinib. **Myelosuppression:** Monitor blood counts and manage as necessary**.** **Hepatic toxicity:** Monitor liver enzymes at least monthly for the first three months and as needed. Withhold, dose reduce, or discontinue Bosutinib. **Fluid retention:** Monitor patients and manage using standard of care treatment. Withhold, dose reduce, or discontinue Bosutinib. **Embryofetal toxicity:** May cause fetal harm. Females of reproductive potential should avoid becoming pregnant while being treated with Bosutinib. **Side effects:** Most common adverse reactions (incidence greater than 20%) are diarrhea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anemia, pyrexia, and fatigue.				
109.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Ripretinib INN 50 mg Tablet	Ripretinib INN 50.00 mg	Anticancer Therapeutic Code: 010	It is indicated for the treatment of adult patients with Advanced Gastrointestinal Stromal Tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including Imatinib.	**Contraindication:** None. **Warnings and Precautions:** Palmar-Plantar Erythrodysesthesia Syndrome: Based on severity, withhold Ripretinib and resume at same or reduced dose. • New Primary Cutaneous Malignancies: Perform dermatologic evaluations when initiating Ripretinib and routinely during treatment. • Hypertension: Do not initiate Ripretinib in patients with uncontrolled hypertension and monitor blood pressure during treatment. Based on severity, withhold Ripretinib and then resume at same or reduced dose or permanently discontinue. • Cardiac Dysfunction: Assess ejection fraction by echocardiogram or MUGA	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						scan prior to initiating Ripretinib and during treatment, as clinically indicated. Permanently discontinue Ripretinib for Grade 3 or 4 left ventricular systolic dysfunction. • Risk of Impaired Wound Healing: Withhold Ripretinib for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks after major surgery and until adequate wound healing. The safety of resumption of Ripretinib after resolution of wound healing complications has not been established. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. **Side effects:** The most common side effects are Alopecia, Fatigue, Nausea, Abdominal pain, Constipation, Myalgia, Diarrhea, Decreased appetite, PalmarPlantar Erythrodysesthesia, and Vomiting.				
110.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur. **M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh**	Tucatinib INN 50 mg Tablet	Tucatinib INN 50.00 mg	Anticancer Therapeutic Code: 010	It is indicated in combination with Trastuzumab and Capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2- positive Breast Cancer, including patients with brain metastases, who have received one or more prior anti- HER2-based regimens in the metastatic setting.	**Contraindication:** None. **Warnings and Precautions:** **Diarrhea:** Severe diarrhea, including dehydration, acute kidney injury, and death, has been reported. Administer antidiarrheal treatment as clinically indicated. Interrupt dose, then dose reduce, or permanently discontinue Tucatinib based on severity. **Hepatotoxicity:** Severe hepatotoxicity has been reported on Tucatinib. Monitor ALT, AST and bilirubin prior to starting Tucatinib, every 3 weeks during treatment and as clinically indicated. Interrupt dose, then dose	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						reduce, or permanently discontinue Tucatinib based on severity. **Embryo-Fetal Toxicity:** Tucatinib can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. Also, refer to the Full Prescribing Information of trastuzumab and capecitabine for pregnancy and contraception information. **Side effects:** The most common side effects are Diarrhea, Hepatotoxicity, Palmar-plantar erytrodysesthesia, Nausea, Vomiting, Fatigue, Hepatotoxicity, Stomatitis, Decreased appetite, Abdomenal pain, Headache, Anemia, Rash.				
111.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur. **M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh**	Tucatinib INN 150 mg Tablet	Tucatinib INN 150.00 mg	Anticancer Therapeutic Code: 010	It is indicated in combination with Trastuzumab and Capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2- positive Breast Cancer, including patients with brain metastases, who have received one or more prior anti- HER2-based regimens in the metastatic setting.	**Contraindication:** None. **<u>Warnings and Precautions:</u>** **Diarrhea:** Severe diarrhea, including dehydration, acute kidney injury, and death, has been reported. Administer antidiarrheal treatment as clinically indicated. Interrupt dose, then dose reduce, or permanently discontinue Tucatinib based on severity. **Hepatotoxicity:** Severe hepatotoxicity has been reported on Tucatinib. Monitor ALT, AST and bilirubin prior to starting Tucatinib, every 3 weeks during treatment and as clinically indicated. Interrupt dose, then dose reduce, or permanently discontinue Tucatinib based on severity. **Embryo-Fetal Toxicity:** Tucatinib can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. Also, refer to the Full Prescribing Information of trastuzumab and capecitabine for pregnancy and contraception information.	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side effects: The most common side effects are Diarrhea, Hepatotoxicity, Palmar-plantar erytrodysesthesia, Nausea, Vomiting, Fatigue, Hepatotoxicity, Stomatitis, Decreased appetite, Abdomenal pain, Headache, Anemia, Rash.				
112.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Vandetanib INN 100 mg Tablet	Vandetanib INN 100.00 mg	Anticancer Therapeutic Code: 010	It is indicated for the treatment of symptomatic or progressive medullary Thyroid Cancer in patients with unresectable locally advanced or metastatic disease. It should be used in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Vandetanib.	**Contraindication:** It is contraindicated in patients with congenital long QT syndrome. **<u>Warnings and Precautions:</u>** • Prolonged QT Interval, Torsades de pointes, and sudden death have been reported. Monitor electrocardiograms and levels of serum potassium, calcium, magnesium and TSH at baseline, 2-4 weeks and 8-12 weeks after starting treatment with vandetanib, and every 3 months thereafter and following dose adjustments. Dose reduce as appropriate. • Stevens-Johnson syndrome resulting in death has been observed. Severe skin reactions may prompt permanent discontinuation of vandetanib. • Interstitial lung disease, resulting in death has been reported. Interrupt vandetanib and investigate unexplained dyspnea, cough, and fever. Appropriate measures should be taken for ILD. • Ischemic cerebrovascular events, hemorrhage, heart failure, diarrhea, hypothyroidism, hypertension, and reversible posterior leukoencephalopathy syndrome, have been observed. • Vandetanib can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid pregnancy while receiving	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						vandetanib and for four months following treatment. **Side effects:** The most common side effects are QT Prolongation and Torsades de Pointes, Severe Skin Reactions, Interstitial Lung Disease, Ischemic Cerebrovascular Events, Hemorrhage, Heart Failure, Diarrhea, Hypothyroidism, Hypertension, Reversible Posterior Leukoencephalopathy Syndrome, Embryo fetal Toxicity.				
113.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Vandetanib INN 300 mg Tablet	Vandetanib INN 300.00 mg	Anticancer Therapeutic Code: 010	It is indicated for the treatment of symptomatic or progressive medullary Thyroid Cancer in patients with unresectable locally advanced or metastatic disease. It should be used in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Vandetanib.	**Contraindication:** It is contraindicated in patients with congenital long QT syndrome. **<u>Warnings and Precautions:</u>** • Prolonged QT Interval, Torsades de pointes, and sudden death have been reported. Monitor electrocardiograms and levels of serum potassium, calcium, magnesium and TSH at baseline, 2-4 weeks and 8-12 weeks after starting treatment with vandetanib, and every 3 months thereafter and following dose adjustments. Dose reduce as appropriate. • Stevens-Johnson syndrome resulting in death has been observed. Severe skin reactions may prompt permanent discontinuation of vandetanib. • Interstitial lung disease, resulting in death has been reported. Interrupt vandetanib and investigate unexplained dyspnea, cough, and fever. Appropriate measures should be taken for ILD. • Ischemic cerebrovascular events, hemorrhage, heart failure, diarrhea, hypothyroidism, hypertension, and reversible posterior	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						leukoencephalopathy syndrome, have been observed. • Vandetanib can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid pregnancy while receiving vandetanib and for four months following treatment. **Side effects:** The most common side effects are QT Prolongation and Torsades de Pointes, Severe Skin Reactions, Interstitial Lung Disease, Ischemic Cerebrovascular Events, Hemorrhage, Heart Failure, Diarrhea, Hypothyroidism, Hypertension, Reversible Posterior Leukoencephalopathy Syndrome, Embryo fetal Toxicity.				
114.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur. **Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka**	Zanubrutinib INN 80 mg Capsule	Zanubrutinib INN 80.00 mg	Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the treatment of adult patients with Mantle Cell Lymphoma (MCL) who have received at least one prior therapy.	**Contraindication:** None. **<u>Warnings and Precautions:</u>** **Hemorrhage:** Monitor for bleeding and manage appropriately. **Infections:** Monitor patients for signs and symptoms of infection, including opportunistic infections, and treat as needed. **Cytopenias:** Monitor complete blood counts during treatment. Second Primary Malignancies: Other malignancies have occurred in patients including skin cancers. Advise patients to use sun protection. **Cardiac Arrhythmias:** Monitor for atrial fibrillation and atrial flutter and manage appropriately. **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise women of the potential risk to a fetus and to avoid pregnancy. **Side effects:**	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						The most common side effects are Hemorrhage, Infections, Cytopenias, Second Primary Malignancies, Cardiac Arrhythmias.				
115.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Capmatinib INN 150 mg Tablet	Capmatinib INN 150 mg	Anticancer Therapeutic Code: 010	It is indicated for the treatment of adult patients with metastatic Non- small Cell Lung Cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal- epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.	**Contraindication:** None. **Warnings and Precautions:** • Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Permanently discontinue Capmatinib in patients with ILD/pneumonitis. • Hepatotoxicity: Monitor liver function tests. Withhold, dose reduce, or permanently discontinue Capmatinib based on severity. • Risk of Photosensitivity: May cause photosensitivity reactions. Advise patients to limit direct ultraviolet exposure. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. **Side effects:** The most common side effects are ILD/ Pneumonitis, Hepatotoxicity, Peripheral edema, Nausea, Fatigue, Vomiting, Dyspnea, Decreased appetite.	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
116.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Capmatinib INN 200 mg Tablet	Capmatinib INN 200.00 mg	Anticancer Therapeutic Code: 010	It is indicated for the treatment of adult patients with metastatic Non- small Cell Lung Cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal- epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.	**Contraindication:** None. **Warnings and Precautions:** • Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Permanently discontinue Capmatinib in patients with ILD/pneumonitis. • Hepatotoxicity: Monitor liver function tests. Withhold, dose reduce, or	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						permanently discontinue Capmatinib based on severity. • Risk of Photosensitivity: May cause photosensitivity reactions. Advise patients to limit direct ultraviolet exposure. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. **Side effects:** The most common side effects are ILD/ Pneumonitis, Hepatotoxicity, Peripheral edema, Nausea, Fatigue, Vomiting, Dyspnea, Decreased appetite.				
117.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Selpercatinib INN 40 mg Capsule	Selpercatinib INN 40 mg	Anticancer Therapeutic Code: 010	**Metastatic RET Fusion-Positive Non- Small Cell Lung Cancer:** It is indicated for the treatment of adult patients with metastatic RET fusion- positive Non- Small Cell Lung Cancer (NSCLC). **RET- Mutant Medullary Thyroid Cancer:** It is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-Mutant Medullary Thyroid Cancer (MTC) who require systemic therapy. **RET Fusion-Positive Thyroid Cancer:** It is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET Fusion- Positive Thyroid Cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).	**Contraindication:** None. **Warnings and Precautions:** • Hepatotoxicity: Monitor ALT and AST prior to initiating Selpercatinib, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue Selpercatinib based on severity. • Hypertension: Do not initiate Selpercatinib in patients with uncontrolled hypertension. Optimize blood pressure (BP) prior to initiating Selpercatinib. Monitor BP after 1 week, at least monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue Selpercatinib based on severity. • QT Interval Prolongation: Monitor patients who are at significant risk of developing QTc prolongation. Assess QT interval, electrolytes and TSH at baseline and periodically during treatment. Monitor QT interval more frequently when Selpercatinib is concomitantly administered with strong	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						and moderate CYP3A inhibitors or drugs known to prolong QTc interval. Withhold and dose reduce or permanently discontinue Selpercatinib based on severity. • Hemorrhagic Events: Permanently discontinue Selpercatinib in patients with severe or life-threatening hemorrhage. • Hypersensitivity: Withhold Selpercatinib and initiate corticosteroids. Upon resolution, resume at a reduced dose and increase dose by 1 dose level each week until reaching the dose taken prior to onset of hypersensitivity. Continue steroids until patient reaches target dose and then taper. • Risk of Impaired Wound Healing: Withhold Selpercatinib for at least 7 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of Selpercatinib after resolution of wound healing complications has not been established. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the possible risk to the fetus and to use effective contraception. **Side effects:** The most common side effects are Hepatotoxicity, Hypertension, QT Interval Prolongation, Hemorrhagic Events, Hypersensitivity and Risk of Impaired Wound Healing.				
118.	Drug International Ltd (Unit-2) **Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.**	Selpercatinib INN 80 mg Capsule	Selpercatinib INN 80 mg	Anticancer Therapeutic Code: 010	**Metastatic RET Fusion-Positive Non- Small Cell Lung Cancer:** It is indicated for the treatment of adult patients with metastatic RET fusion- positive	**Contraindication:** None. **Warnings and Precautions:**	New	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Non- Small Cell Lung Cancer (NSCLC). **RET- Mutant Medullary Thyroid Cancer:** It is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-Mutant Medullary Thyroid Cancer (MTC) who require systemic therapy. **RET Fusion-Positive Thyroid Cancer:** It is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET Fusion- Positive Thyroid Cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).	• Hepatotoxicity: Monitor ALT and AST prior to initiating Selpercatinib, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue Selpercatinib based on severity. • Hypertension: Do not initiate Selpercatinib in patients with uncontrolled hypertension. Optimize blood pressure (BP) prior to initiating Selpercatinib. Monitor BP after 1 week, at least monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue Selpercatinib based on severity. • QT Interval Prolongation: Monitor patients who are at significant risk of developing QTc prolongation. Assess QT interval, electrolytes and TSH at baseline and periodically during treatment. Monitor QT interval more frequently when Selpercatinib is concomitantly administered with strong and moderate CYP3A inhibitors or drugs known to prolong QTc interval. Withhold and dose reduce or permanently discontinue Selpercatinib based on severity. • Hemorrhagic Events: Permanently discontinue Selpercatinib in patients with severe or life-threatening hemorrhage. • Hypersensitivity: Withhold Selpercatinib and initiate corticosteroids. Upon resolution, resume at a reduced dose and increase dose by 1 dose level each week until reaching the dose taken prior to onset of hypersensitivity. Continue steroids until patient reaches target dose and then taper. • Risk of Impaired Wound Healing: Withhold Selpercatinib for at least 7 days prior to elective surgery. Do not				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of Selpercatinib after resolution of wound healing complications has not been established. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the possible risk to the fetus and to use effective contraception. **Side effects:** The most common side effects are Hepatotoxicity, Hypertension, QT Interval Prolongation, Hemorrhagic Events, Hypersensitivity and Risk of Impaired Wound Healing.				
119.	Aristopharma Ltd. **Gachha, Gazipur Sadar, Gazipur**	Cyclosporine 0.1g/100 ml Ophthalmic Emulsion	Cyclosporine USP 0.1g/100 ml	Eye Preparations Therapeutic Code: 052	Cyclosporine is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.	**Contra-indication:** Cyclosporine is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation. **Side-effect:** The most common adverse reactions following the use of cyclosporine ophthalmic solution was instillation site pain (22%) and conjunctival hyperemia (6%). **WARNINGS AND PRECAUTIONS:** To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces.	Cyclosporine USP 500 mg/100 ml Ophthalmic Emulsion	BNF-79 (Page: 1201) EMA approved (April-2015)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
120.	Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur	Tarcrolimus 0.03g/100g Ophthalmic Ointment	Tarcrolimus USP 0.03g/100g	Eye Preparations Therapeutic Code: 052	Tacrolimus is an Immunomodulator agent, indicated for the treatment of allergic eye diseases like Vernal Keratoconjunctivitis (VKC) and Atopic Keratoconjunctivitis (AKC). Topical application of Tacrolimus ophthalmic ointment is an excellent alternative to anti-allergic and steroids eye drops	**Contra-indication:** Tacrolimus Ointment is contraindicated in patients with a history of hypersensitivity to tacrolimus or any other component of the ointment. **Side-effect:** None	Tacrolimus 0.03% Ointment	BNF-79 (Page: 1293)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					for the treatment of allergic conjunctivitis such as VKC and AKC.					
121.	Aristopharma Ltd. Gachha, Gazipur Sadar, Gazipur	Perfluorohexyloctane 100 ml/100 ml Eye Drops	Perfluorohexyloctane INN 100 ml/100 ml	Eye Preparations Therapeutic Code: 052	Perfluorohexyloctane Eye Drops is indicated for the symptoms associated with Evaporative Dry Eye (by lubricating the surface of the eye), reducing excessive tear evaporation and stabilizing the tear film.	**Contra-indication:** Perfluorohexyloctane Eye Drops is contraindicated in patients with a history of hypersensitivity to Perfluorohexyloctane. **Side-effect:** None	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
122.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Empagliflozin 10 mg + Linagliptin 5 mg + Metformin Hydrochloride 1000 mg Extended Release Tablet	Empagliflozin INN 10 mg + Linagliptin INN 5 mg + Metformin Hydrochloride BP 1000 mg	Antidiabetic Therapeutic Code: 015	I) This formulation is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor, linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl), a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. II) Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.	**Contraindication:** I) Severe renal impairment (eGFR less than 30 mL/min/1.73 m²), end-stage renal disease, or dialysis. II) Metabolic acidosis, including diabetic ketoacidosis. III) Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients. **Side-effect:** The most common adverse reactions associated with this drug (5% or greater incidence) were upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis. **WARNINGS AND PRECAUTIONS:** **LACTIC ACIDOSIS :** • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased	Empagliflozin 10, 25 mg Tablet, Empagliflozin 5 mg + Metformin 500 mg, Linagliptin 2.5 mg + Metformin 1000, Linagliptin 5 mg + Metformin 1000, Linagliptin 2.5 mg + Metformin 850	US FDA (Reference ID: 4551762)	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age ≥65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue it and institute general supportive measures in a hospital setting.				
123.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Acme Laboratories Ltd., Dhamrai, Dhaka	Budesonide 160 mcg + Glycopyrrolate 9 mcg + Formoterol Fumarate 4.8 mcg/Puff Metered Dose Inhaler	Budesonide BP 160 mcg + Glycopyrrolate USP 9 mcg + Formoterol Fumarate BP 4.8 mcg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	This fomulation is a combination of budesonide, an inhaled corticosteroid (ICS); glycopyrrolate, an anticholinergic; and formoterol fumarate, a long-acting beta-adrenergic agonist (LABA), indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitations of Use: Not indicated for the relief of acute bronchospasm or for the treatment of asthma.	**Contraindication:** Hypersensitivity to budesonide, glycopyrrolate, formoterol fumarate, or to any of the excipients. **Side-effect:** Most common adverse reactions (incidence ≥ 2%) are upper respiratory tract infection, pneumonia, back pain, oral candidiasis, influenza, muscle spasm, urinary tract infection, cough, sinusitis and diarrhea. **WARNINGS AND PRECAUTIONS:** • LABA as monotherapy (without an inhaled-corticosteroid) is associated with an increased risk of serious asthma-related events. • Do not initiate in acutely deteriorating COPD. Do not use to relieve acute symptoms. • Do not use in combination with an additional therapy containing a LABA because of the risk of overdose. • Candida albicans infection of the mouth and pharynx may occur. Monitor patients periodically. Advise the patient to rinse his/her mouth	New	US FDA (Reference ID: 4645600)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						with water without swallowing after inhalation to help reduce the risk. • Increased risk of pneumonia in patients with COPD. Monitor patients for signs and symptoms of pneumonia. • Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infections; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. • Risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to this drug. • Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, consider appropriate therapy. If paradoxical bronchospasm occurs, discontinue this drug and institute alternative therapy. • Use with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation. • Assess for decrease in bone mineral density initially and periodically thereafter. • Glaucoma and cataracts may occur with long-term use of ICS. Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur. Consider referral to an ophthalmologist in patients who				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						develop ocular symptoms or use this drug long term. • Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur. • Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis. • Be alert to hypokalemia and hyperglycemia.				
124.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Indacaterol 150 mcg+ Mometasone 80 mcg Dry powder inhaler (DPI) Capsule (Each delivered dose contains 125mcg of Indacaterol + 62.5mcg of Mometasone)	Indacaterol Acetate (Micronized) INN 173 mcg (eqv. to Indacaterol 150 mcg) + Mometasone Furoate (Micronized) BP 80mcg	COPD Therapeutic Code: 044	It is indicated as a maintanace treatment of asthma in adults and children aged 12 years and older whose asthma is not adequately controlled with inhaled corticosteroids and inhaled short acting beta-2 agonists.	**Contra-indication:** Hypersensitivity or intolerance to any component **Side-effect**: Worsening of asthma, nasopharyngitis, upper repiratory tract infection, headache	Indacaterol 75, 150, 300 mcg Inhalation Capsule Mometasone Furoate 50,110,220 mcg Inhalation Capsule	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
125.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Indacaterol 150 mcg+ Mometasone 160 mcg Dry powder inhaler (DPI) Capsule (Each delivered dose contains 125mcg of Indacaterol + 127.5mcg of Mometasone)	Indacaterol Acetate (Micronized) INN 173 mcg (eqv. to Indacaterol 150 mcg) + Mometasone Furoate (Micronized) BP 160 mcg	COPD Therapeutic Code: 044	It is indicated as a maintanace treatment of asthma in adults and children aged 12 years and older whose asthma is not adequately controlled with inhaled corticosteroids and inhaled short acting beta-2 agonists.	**Contra-indication:** Hypersensitivity or intolerance to any component **Side-effect**: Worsening of asthma, nasopharyngitis, upper repiratory tract infection, headache	Indacaterol 75, 150, 300 mcg Inhalation Capsule Mometasone Furoate 50,110,220 mcg Inhalation Capsule	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
126.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Glycopyrronium 50 mcg + Indacaterol 150 mcg + Mometasone 160 mcg Dry powder inhaler (DPI) Capsule (Each delivered dose contains 114mcg of Indacaterol + 46mcg of Glycopyrronium + 136mcg of Mometasone)	Glycopyrronium Bromide (Micronized) EP 63mcg (eqv. to Glycopyrronium 50 mcg) + Indacaterol Acetate (Micronized) INN 173 mcg (eqv. to Indacaterol 150 mcg) + Mometasone Furoate (Micronized) BP 160mcg	COPD Therapeutic Code: 044	It is used for maintenance (regular) treatment in adults whose asthma is not controlled well enough with inhaled long-acting beta-2 agonist together with a high dose of an inhaled corticosteroid. It should be used for patients who have had at least one asthma attack (exacerbation) in the last year.	**Contra-indication:** Hypersensitivity or intolerance to any component **Side-effect**: Worsening of asthma, nasopharyngitis, upper repiratory tract infection, headache	Indacaterol 75, 150, 300 mcg Inhalation Capsule Mometasone Furoate 50,110,220 mcg Inhalation Capsule Glycopyrronium 50 mcg Inhalation Capsule	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
127.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Indacaterol 150 mcg + Mometasone 320 mcg Dry powder inhaler (DPI) Capsule (Each delivered dose contains 125mcg of Indacaterol + 260mcg of Mometasone)	Indacaterol Acetate (Micronized) INN 173 mcg (eqv. to Indacaterol 150 mcg) + Mometasone Furoate (Micronized) BP 320mcg	COPD Therapeutic Code: 044	It is indicated as a maintanace treatment of asthma in adults and children aged 12 years and older whose asthma is not adequately controlled with inhaled corticosteroids and inhaled short acting beta-2 agonists.	**Contra-indication:** Hypersensitivity or intolerance to any component **Side-effect**: Worsening of asthma, nasopharyngitis, upper repiratory tract infection, headache	Indacaterol 75, 150, 300 mcg Inhalation Capsule Mometasone Furoate 50,110,220 mcg Inhalation Capsule	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
128.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Menthol 2gm + Eucalyptus Oil 10ml/100ml Suspension	Menthol BP 2gm + Eucalyptus Oil BP 10ml/100ml	Ear and Nose Preparations Therapeutic Code: 050	For relief of the symptoms of coughs, colds and blocked nose.	**Contra-indication:** Hypersensitivity or intolerance to any component **Side-effect**: Dermatitis, Apnoea	New	BNF-78 page-297	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
129.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ciprofibrate 100mg Tablet	Ciprofibrate BP 100mg	Lipid Lowering Therapeutic Code: 060	Severe hyperglyceridaemia, mixed hyperlipidaemia when a statin is contraindicated or not tolerated	**Contra-indication:** Galactose intolerance, lapp lactose deficiency, glucose-galactose malabsorption, patients with myalgia, impaired hepatic function, concomitant oral anticoagulant therapy **Side-effect**: Muscle aches or pains, indigestion, abdominal pain, nausea, headache, diarrhoea, vertigo, dizziness or tired, skin rash, urticaria	New	BNF-78 page-199	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
130.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Opsonin Pharma Limited, Rupatali, Barishal.	Terbinafine 125mg/ Sachet Oral Granules	Terbinafine Hydrochloride BP 140.625 mg (eqv. to Terbinafine 125.00 mg)	Antifungal Therapeutic Code: 020	For the treatment of tinea capitis in patients 4 years of age and older and also effective in other tinea infections especially in children	**Contra-indication:** allergic reaction to oral terbinafine because of the risk of anaphylaxis **Side-effect**: nasopharyngitis, headache, pyrexia, cough, vomiting, upper respiratory tract infection, upper abdominal pain, and diarrhea **WARNINGS AND PRECAUTIONS:** • Cases of liver failure, some leading to death or liver transplant, have occurred with the use of oral terbinafine. Pretreatment serum transaminase (ALT and AST) tests are advised for all patients before taking Terbinafine Hydrochloride. • Severe neutropenia has been reported. If the neutrophil count is < 1,000 cells/mm3, Terbinafine Hydrochloride should be discontinued. • Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported with oral terbinafine use. If	Terbinafin 125 mg, 250 mg tablet, 1% cream, 1gm/100 gm spray	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						progressive skin rash occurs, treatment with Terbinafine Hydrochloride should be discontinued.				
131.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna. Beximco Pharmaceuticals Ltd.	Pregabalin 2gm/100ml Oral Solution	Pregabalin EP 2gm/100ml	Drug used in Epilepsy Therapeutic Code: 046	Neuropathic pain associated with diabetic peripheral neuropathy (DPN), Post herpetic neuralgia (PHN), Adjunctive therapy for adult patients with partial onset seizures, Fibromyalgia	**Contra-indication:** Known hypersensitivity to pregabalin or any of its components **Side-effect**: Dizziness, somnolence, dry mouth, edema, blurred vision, weight gain and thinking abnormal (primarily difficulty with concentration/attention). **<u>WARNINGS AND PRECAUTIONS:</u>** • Angioedema (e.g. swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue Pregabalin immediately in these cases. • Hypersensitivity reactions (e.g. hives, dyspnea, and wheezing) can occur. Discontinue Pregabalin immediately in these patients. • Increased seizure frequency may occur in patients with seizure disorders if Pregabalin is rapidly discontinued. Withdraw Pregabalin gradually over a minimum of 1 week. • Antiepileptic drugs, including Pregabalin, increase the risk of suicidal thoughts or behavior. • Pregabalin may cause peripheral edema. Exercise	Pregabalin 25,50,75, 100,150, 300 mg Capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						caution when co-administering Pregabalin and thiazolidinedione antidiabetic agents. Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.				
132.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Glycerol 1gm Suppository	Glycerol BP 1gm	Laxatives Therapeutic Code: 060	For the relief of occasional constipation	**Contra-indication:** Sensitivity to the ingredients, liver problems, chronic kidney disese **Side-effect**: GI disorder, irritation, abdominal cramps	Glycerol 2.3, 1.035, 1.15 gm Suppository	BNF-78 page:63	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
133.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Glycerol 2 gm Suppository	Glycerol BP 2 gm	Laxatives Therapeutic Code: 060	For the relief of occasional constipation	**Contra-indication:** Sensitivity to the ingredients, liver problems, chronic kidney disese **Side-effect**: GI disorder, irritation, abdominal cramps	Glycerol 2.3, 1.035, 1.15 gm Suppository	BNF-78 page:63	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
134.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Glycerol 4 gm Suppository	Glycerol BP 4gm	Laxatives Therapeutic Code: 060	For the relief of occasional constipation	**Contra-indication:** Sensitivity to the ingredients, liver problems, chronic kidney disese **Side-effect**: GI disorder, irritation, abdominal cramps	Glycerol 2.3, 1.035, 1.15 gm Suppository	BNF-78 page:63	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
135.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Clobetasol 0.05gm + Fusidic Acid 2gm/100gm Cream	Clobetasol Propionate BP 0.05gm + Fusidic Acid BP 2gm/100gm	Skin and Mucous Membrane Preparations Therapeutic Code: 071	It is used for the effective management of skin related disorders like severe eczema or psoriasis with bacterial infections (including deep skin infections)	**Contra-indication:** Known hypersensitivity, occlusive wrappings **Side-effect**: Site rections like burning, irritaions, itching and redness	Fusidic Acid 2gm/100gm Cream, Clobetasol 50mg/100 gm Cream	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
136.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Fluticasone 0.005gm + Mupirocin 2gm/Tube Ointment	Fluticasone propionate BP 0.005gm + Mupirocin USP 2gm	Skin and Mucous Membrane Preparations Therapeutic Code: 071	Dermatitis with secondary bacterial infection, wonds, impetigo, iiching , sneezing,	**Contra-indication:** Known hypersensitivity **Side-effect**: Pruritus, dryness,numbness of fingures, burning sensation	Mupirocin 100mg/ 5gm Ointment	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
137.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Luliconazole 1gm + Terbinafine 1gm/100gm Cream	Luliconazole INN 1gm + Terbinafine Hydrochloride BP 1gm/100gm Cream	Skin and Mucous Membrane Preparations Therapeutic Code: 071	Different fungal infections including Tinea Corporis, Tinea Cruris, Tinea Pedis	**Contra-indication:** Known hypersensitivity **Side-effect**: Contact dermatitis, cellulitis	Luliconazole 10mg/gm Cream	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
138.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Beacon Pharmaceuticals Ltd, Valuka, Mymansingh.	Paracetamol BP 500 mg + Ibuprofen 250 mg Tablet	Paracetamol BP 500 mg + Ibuprofen BP 250 mg	Analgesics and Antipyretics Therapeutic Code: 006	Relief of headache from musculo skeletal origine, feverishness, muscular pain, dental pain, menstrual pain, rheumatoid and osteoarthritis	**Contra-indication:** Clotting disorder, high blood pressure, chronic heart failure, stroke, stomach or intestinal ulcer, liver problems, chronic kidney disease **Side-effect**: Nausea, heart burn, stomach pain, loss of apetite, diarrhea, dizziness, drowsiness, headache, nervousness	Paracetamol 500 mg Tablet Ibuprofen 200 mg Tablet	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
139.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Calcium 12.5gm + Magnesium 3.6gm + Zinc 0.28gm + Cholecalciferol 4000 IU)/100 ml Suspension	Calcium Carbonate BP 12.5gm + Magnesium Hydroxide USP 3.6gm + Zinc Gluconate USP 0.28gm + Cholecalciferol Concentrate (Oily form) EP 4000 IU)/100 ml	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It is indicated in children, adults, pregnancy and lactation for the treatment of calcium deficiency nutritional rickets, brittle bone disease	**Contra-indication:** Hypercalcemia, hyperparathyroidism, hypercalciurea, nephrolithasis, renal insufficiency **Side-effect:** GI irritation, constipation, hypercalcemia,	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
140.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Nuvista Pharma Ltd. Beacon Pharmaceuticals Ltd, Valuka, Mymansingh. Beximco Pharmaceuticals Ltd. Tongi, gazipur, dhaka	Roxadustat 50mg Tablet	Roxadustat INN 50mg	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	For the treatment of renal anemia in patients on dialysis	**Contra-indication:** None**.** **Side-effect:** Upper repiratory infection, hypertension, hyperkalemia	New	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
141.	Nuvista Pharma Ltd. Beacon Pharmaceuticals Ltd, Valuka, Mymansingh.	Roxadustat 20mg Tablet	Roxadustat INN 20mg	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	Indications: Renal anemia in patients on dialysis.	Contraindication: Angina pectoris, bradycardia, coronary artery stenosis, sudden hearing loss, gastrointestinal hemorrhage, vascular stent occlusion, urinary tract infection, joint dislocation, spinal column injury, arteriogram coronary, investigation,	NEW	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						lumbar spinal stenosis, gastric cancer, cerebral infarction, asthma, coronary, angioplasty, orthostatic hypotension, venous occlusion, subclavian vein stenosis. Side Effects: Thromboembolism, Hypertension.				
142.	Nuvista Pharma Ltd.	Relugolix 40mg Tablet	Relugolix INN 40mg	Hormone Therapeutic Code: 056	Indications: Relief of the following symptoms associated with uterine fibroids: menorrhagia, lower abdominal pain, lumbar pain, and anemia.	**Contraindication:** The most commonly reported adverse reactions include Hot flush, Abnormal uterine bleeding, Menorrhagia, Headache, Excessive amount of sweat and genital bleeding, Depressed mood, Pessimistic, Decline of thinking ability, Insomnia, Loss of appetite, General malaise, Easy fatigability, General malaise, Weakness, nausea Loss of appetite [liver dysfunction] Side Effects: Side effects of Relugolix include menstrual abnormalities, hot flashes, excessive sweating, headache, and decreased bone mineral density.	NEW	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
143.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Chlorhexidine gluconate 20% solution 1gm/100ml Solution	Chlorhexidine gluconate 20% solution BP 1gm/100ml	Other Classification Therapeutic Code: 075	Relief of external genital itching, burning sensation and irritation commonly experienced during menstruation. Prevention and treatment of infections of veginal wounds, external genital wash before and after sexual intercourse	**Contra-indication:** None. **Side-effect:** Burning /stinging sensation, local irritation, wheezing or difficulty in breathing, swealling of the face, hives, rash	Chlorhexidine gluconate 4 gm/100 ml Solution	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
144.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited	Lesinurad 200 mg + Allopurinol 300 mg Tablet	Lesinurad INN 200 mg + Allopurinol BP 300 mg Tablet	Uricosuric and Anti-Gout Agents Therapeutic Code: 076	It is indicated in adults for the treatment of hyperuricamea in gout patients who have not achieved target serum uric acid levels with an adequate dose of Allopurinol alone	**Contra-indication:** Hypersensitivity, dermatitis, pruritus, **Side-effect:** Influenza, GERD, headache, serum creatinine increased skin rash. **WARNINGS AND PRECAUTIONS:** • Renal events: Adverse reactions related to renal function, including	Allopurinol 100 mg, 300 mg Tablet	USFDA & EMA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						acute renal failure, have occurred after initiating lesinurad, one of the components of Lesinurad 200 mg + Allopurinol 300 mg Tablet. A higher incidence has occurred at the 400 mg dose of lesinurad than at the 200 mg dose. Monitor renal function at initiation and during therapy with Lesinurad 200 mg + Allopurinol 300 mg Tablet, particularly in patients with eCLcr below 60 mL/min, and evaluate for signs and symptoms of acute uric acid nephropathy. • Skin Rash and Hypersensitivity: Lesinurad 200 mg + Allopurinol 300 mg Tablet, should be discontinued at the first appearance of skin rash or other signs that may indicate an allergic reaction, as allopurinol has been associated with severe hypersensitivity (some resulting in death). • Hepatotoxicity: Hepatotoxicity has been reported in patients on allopurinol. Inform patients of warning signs and symptoms of hepatotoxicity. If symptoms develop, liver function evaluation should be performed. • Cardiovascular events: Major adverse cardiovascular events were observed with lesinurad; a causal relationship has not been established. • Bone Marrow Suppression: Bone marrow depression affecting one or more cell lines has been reported with allopurinol.				
145.	Navana Pharmaceuticals Limited	Lesinurad 200 mg + Allopurinol 200 mg Tablet	Lesinurad INN 200 mg + Allopurinol BP 200 mg Tablet	Uricosuric and Anti-Gout Agents Therapeutic Code: 076	It is indicated in adults for the treatment of hyperuricamea in gout patients who have not achieved target serum uric acid levels with an adequate dose of Allopurinol alone	**Contra-indication:** Hypersensitivity, dermatitis, pruritus, **Side-effect:** Influenza, GERD, headache, serum creatinine increased	New	USFDA & EMA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						skin rash. **<u>WARNINGS AND PRECAUTIONS:</u>** • Renal events: Adverse reactions related to renal function, including acute renal failure, have occurred after initiating lesinurad, one of the components of Lesinurad 200 mg + Allopurinol 300 mg Tablet. A higher incidence has occurred at the 400 mg dose of lesinurad than at the 200 mg dose. Monitor renal function at initiation and during therapy with Lesinurad 200 mg + Allopurinol 300 mg Tablet, particularly in patients with eCLcr below 60 mL/min, and evaluate for signs and symptoms of acute uric acid nephropathy. • Skin Rash and Hypersensitivity: Lesinurad 200 mg + Allopurinol 300 mg Tablet, should be discontinued at the first appearance of skin rash or other signs that may indicate an allergic reaction, as allopurinol has been associated with severe hypersensitivity (some resulting in death). • Hepatotoxicity: Hepatotoxicity has been reported in patients on allopurinol. Inform patients of warning signs and symptoms of hepatotoxicity. If symptoms develop, liver function evaluation should be performed. • Cardiovascular events: Major adverse cardiovascular events were observed with lesinurad; a causal relationship has not been established. • Bone Marrow Suppression: Bone marrow depression affecting one or more cell lines				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						has been reported with allopurinol.				
146.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Vitamin A Palmitate (Vitamin A) BP 17.648 mg (eq. to 20000 IU Vitamin A) + Cholecalciferol Cone. (Vitamin 03) BP 6.00 mg (eq. to 4000 IU Vitamin D3) + Thiamine Hydrochloride (Vitamin B1) BP 12mg + Riboflavin Sodium Phosphate (Vitamin B2) BP 13.98 mg (eqv. to Riboflavin 10.00 mg) + Pyridoxine Hydrochloride (Vitamin B6) BP 12mg + DL-A-Tocopherol Acetate (Vitamin E) BP 110.00 mg (eqv. to 100 IU Vitamin E) + Nicotinamide BP 132mg + Dexpanthenol (Pantothenic Acid) USP 44.84 mg (eqv. to 40mg Pantothenic acid) + Lysine hydrochloride USP 1920mg/100ml Syrup	Vitamin A Palmitate (Vitamin A) BP 17.648 mg (eq. to 20000 IU Vitamin A) + Cholecalciferol Cone. (Vitamin 03) BP 6.00 mg (eq. to 4000 IU Vitamin D3) + Thiamine Hydrochloride (Vitamin B1) BP 12mg + Riboflavin Sodium Phosphate (Vitamin B2) BP 13.98 mg (eqv. to Riboflavin 10.00 mg) + Pyridoxine Hydrochloride (Vitamin B6) BP 12mg + DL-A-Tocopherol Acetate (Vitamin E) BP 110.00 mg (eqv. to 100 IU Vitamin E) + Nicotinamide BP 132mg + Dexpanthenol (Pantothenic Acid) USP 44.84 mg (eqv. to 40mg Pantothenic acid) + Lysine hydrochloride USP 1920mg/100ml	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It is indicated for the 1. Normal growth and development of children 2. Fill nutritional gaps Ensure healthy metabolic process	**Side-effects:** The product is usually well tolerated and exerts no untowards effects if taken in the dosage recommended. **Contra-indication:** Hypersensitivity to any of the ingrediants	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
147.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Lysine hydrochloride USP 3.6gm + Thiamine hydrochloride (Vit B1) BP 0.12gm + Pyridoxine hydrochloride (Vit B6) BP 0.055 gm + Cyanocobalamin (Vit B12) BP 0.375 mg + Ferric pyrophosphate In-house	Lysine hydrochloride USP 3.6gm + Thiamine hydrochloride (Vit B1) BP 0.12gm + Pyridoxine hydrochloride (Vit B6) BP 0.055 gm + Cyanocobalamin (Vit B12) BP 0.375 mg +	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It is indicated for the 1. Normal growth and development of children 2. Fill nutritional gaps Ensure healthy metabolic process	**Side-effects:** The product is usually well tolerated and exerts no untowards effects if taken in the dosage recommended. **Contra-indication:** Hypersensitivity to any of the ingrediants	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
		0.667 gm (eqv. to Iron 100.00 mg)/100ml Syrup	Ferric pyrophosphate In-house 0.667 gm (eqv. to Iron 100.00 mg)/100ml							
148.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Dry Vitamin A Palmitate 5 Lac IU BP 2mg + Beta Carotene (as Beta Tab 20%) In-house 3mg + Dry Vitamin E 50% (Acetate) BP 27.660 mg + Ascorbic Acid (Coated) BP 150mg + Folic Acid BP 0.4mg + Thiamine Nitrate BP 4.75mg + Riboflavin BP 3.850 mg + Pyridoxine Hydrochloride BP 6.078 mg + Nicotinamide BP 14mg + Cyanocobalamine 1 % USP 2.16mg + Dry Vitamin D3 USP 20mcg + Biotin BP 45mcg + Calcium Pantothenate BP 23.909 mg + Dry Vitamin K1 5% SD In-house 400mcg + Calcium Carbonate (Heavy) BP 998.921mg + Potassium Iodide USP 0.196 mg + Dried Ferrous Sulphate (86%) BP 23.722 mg + Magnesium Oxide BP 106.131 mg + Cupric Sulphate USP 2.261 mg + Manganese Sulphate Monohydrate USP 15.382 mg + Chromium (III) Chloride Hexahydrate USP 128.111 mcg + Sodium Selenate In-house 131.607 mcg + Zinc Oxide USP 9.958 mg + Lutein USP 1mg + Lycopene USP 0.600mg Tablet	Dry Vitamin A Palmitate 5 Lac IU BP 2mg + Beta Carotene (as Beta Tab 20%) In-house 3mg + Dry Vitamin E 50% (Acetate) BP 27.660 mg + Ascorbic Acid (Coated) BP 150mg + Folic Acid BP 0.4mg + Thiamine Nitrate BP 4.75mg + Riboflavin BP 3.850 mg + Pyridoxine Hydrochloride BP 6.078 mg + Nicotinamide BP 14mg + Cyanocobalamine 1 % USP 2.16mg + Dry Vitamin D3 USP 20mcg + Biotin BP 45mcg + Calcium Pantothenate BP 23.909 mg + Dry Vitamin K1 5% SD In-house 400mcg + Calcium Carbonate (Heavy) BP 998.921mg + Potassium Iodide USP 0.196 mg + Dried Ferrous Sulphate (86%) BP 23.722 mg + Magnesium Oxide BP 106.131 mg + Cupric Sulphate USP 2.261 mg + Manganese Sulphate Monohydrate USP 15.382 mg +	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It is indicated for the 1. Helps support the immune system, maintain bone health, healthy skin and the body's ability to metabolize nutrients A complete formulation of vitamins and minerals to support good health	**Side-effects:** The product is usually well tolerated and exerts no untowards effects if taken in the dosage recommended. **Contra-indication:** Hypersensitivity to any of the ingrediants	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			Chromium (III) Chloride Hexahydrate USP 128.111 mcg + Sodium Selenate In-house 131.607 mcg + Zinc Oxide USP 9.958 mg + Lutein USP 1mg + Lycopene USP 0.600mg							
149.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Orphenadrine citrate 50 mg + Aspirin 770 mg + Caffeine 60 mg Tablet	Orphenadrine citrate BP 50 mg + Aspirin BP 770 mg + Caffeine BP 60 mg	Analgesics and Antipyretics Therapeutic Code: 006	It is used to treat muscle spasms/pain. It is usually used along with rest, physical therapy and other treatment	**Side-effects:** Dry mouth, blurred vision, dilatation of the pupil, increased intraocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, and rarely, urticaria and other dermatoses **Contra-indication:** Because of the mild anti-cholinergic effect of orphenadrine, Norgesic Forte Tablets should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy, or obstructions at the bladder neck. Norgesic Forte Tablets are also contraindicated in patients with myasthenia gravis and in patients known to be sensitive to aspirin or caffeine. The drug is contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.	Aspirin 75mg, 150mg, 300mg	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
150.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Paracetamol 250mg Orodispersible Tablet	Paracetamol BP 250mg	Analgesics and Antipyretics Therapeutic Code: 006	It is indicated in children from the age of four and adolescents for symptomatic treatment of mild to moderate pain and/or fever.	**Side-effects:** Nausea or Vomiting, Allergic skin reaction, Gastric / Mouth Ulcer, Anemia, Fatigue, Unusual bleeding or bruising **Contra-indication:** Patients with severe renal function impairment and hepatic disease.	Paracetamol 500 mg Orodispersible Tablet	BNF-78 page-446	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
151.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Navana Pharmaceuticals Limited Acme Laboratories Ltd., Dhamrai, Dhaka	Metoclopramide15.00mg/Spray Nasal Spray	Metoclopramide BP 15.00mg	Other Classification Therapeutic Code: 075	It is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis	**Contraindication:** History of TD or dystonic reaction to metoclopramide, when stimulation of gastrointestinal motility might be dangerous, Pheochromocytoma, catecholamine-releasing paragangliomas, Epilepsy, Hypersensitivity to metoclopramide **Side Effects:** dysgeusia, headache, and fatigue. **<u>WARNINGS AND PRECAUTIONS:</u>** Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage. Discontinue Metoclopramide in patients who develop signs or symptoms of TD. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the risk of developing TD with longer-term use.	Metoclopramide10 mg	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
152.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ascorbic Acid 300 mg + Colecalciferol (Dry Vitamin D3) 10 mcg + Zinc 10 mg Capsule	Ascorbic Acid (Coated) BP 300 mg + Colecalciferol (Dry Vitamin D3) BP 10.000 mcg + Zinc Sulfate Monohydrate USP 27.455 mg (eqv. to Zinc 10 mg)	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	It can provide meaningful support for the immune system	**Contraindications:** Hypersensitivity to any of the active substances or to any of the excipients listed **Side Effects:** Well tolerated and exerts no untoward effects if taken in the dosage recommended	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
153.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Glycopyrronium 50 mcg + Indacaterol 150 mcg + Mometasone Furoate 80mcg Dry powder inhaler (DPI) Capsule	Glycopyrronium Bromide (Micronized) EP 63mcg (eqv. to Glycopyrronium 50 mcg) + Indacaterol Acetate (Micronized) INN 173 mcg (eqv. to	COPD Therapeutic Code: 044	Indicated as a maintenance treatment of asthma, and to reduce asthma exacerbations, in adults not adequately controlled with a maintenance combination of a long-acting	**Contraindication:** Hypersensitivity to any of the active substances or excipients. **Side Effects:** Infections and infestations: Nasopharyngitis, Upper respiratory	Glycopyrronium 50 mcg + Indacaterol 110 mcg DPI Capsule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			Indacaterol 150 mcg) + Mometasone Furoate (Micronized) BP 80mcg		beta2-agonist and an inhaled corticosteroid.	tract infection, Candidiasis & urinary tract infection, Immune system disorders: Hypersensitivity, Nervous system disorders: Headache, Cardiac disorders: Tachycardia, Respiratory, thoracic and mediastinal disorders: Asthma, Oropharyngeal Pain, Cough & Dysphonia, Gastrointestinal disorders: Gastroenteritis & Dry Mouth, Skin and subcutaneous tissue disorders: Rash, Musculoskeletal and connective tissue disorders: Musculoskeletal Pain & Muscle Spasms, General disorders and administration site conditions: Pyrexia				
154.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Eskayef Pharmaceuticals Limited,Tongi, Gazipur.	Ascorbic Acid 1000mg + Zinc 10mg Effervescent Tablet	Ascorbic Acid (Fine Powder) BP 1000mg + Zinc Sulphate Monohydrate USP 27.455mg (eqv. to Zinc 10mg)	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	Treatment of vitamin C and Zinc deficiency.	**CONTRAINDICATIONS:** • Hypersensitivity to any of the active substances or to any of the excipients listed • Patients suffering from or having a history of Nephrolitiasis must not take this product. • Patients suffering from oxalate urolithiasis or oxaluria must not take this product. • Patients suffering from severe renal insufficiency or renal failure must not take the product. • This includes patients on dialysis. • Patients suffering from Hemochromatosis must not take this product. **SIDE EFFECTS:** • Gastrointestinal disorders • Immune System Disorders **WARNINGS AND PRECAUTIONS:** • Patients with rare hereditary problems of fructose intolerance should not take this medicine	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Patients suffering from renal insufficiency • Patients suffering from glucose-6-phosphatase deficiency Do not exceed the recommended doses				
155.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Carbimazole 10mg Tablet	Carbimazole BP 10mg Tablet	Thyroid and Antithyroid Therapeutic Code: 074	It is an antithyroid medicine that's used to decrease the amount of thyroid hormones produced by the thyroid gland.	**Side Effects:** • Feeling sick. • Upset stomach. • Change in the way things taste. • Headache. • Fever (high temperature). • Feeling generally unwell. • Pain in the joints. • Skin rashes. • Itching. • Hair loss. **Contraindication:** Hypersensitivity to active substances or excipients. Severe hepatic insufficiency, serious haematological contitions	New	MHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
156.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Opsonin Pharma Limited, Rupatali, Barishal.	Amisulpride BP 5mg/2ml (2.5 mg/ml) Ampoule Injection	Amisulpride BP 5mg/2ml (2.5 mg/ml) Ampoule Injection	Antiemetic Therapeutic Code: 018	It is a dopamine-2 (D2) antagonist indicated in adults for: • Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class. • Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.	**Contraindications:** Known hypersensitivity to amisulpride. **Side Effects:** Most common adverse reactions (≥ 2%) are: • Prevention of PONV: increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, and abdominal distension. • Treatment of PONV: infusion site pain. **Warnings And Precautions:** Occurs in a dose- and concentration-dependent manner. Avoid use in patients with congenital long QT syndrome and in patients taking droperidol. ECG monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders; electrolyte	Amisulpride 50 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						abnormalities (e.g., hypokalemia or hypomagnesemia); congestive heart failure; and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval				
157.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Amisulpride 100gm/100ml Oral Solution	Amisulpride BP 100gm/100ml	Antipsychotic Code:028	Acute psychotic episode in schizophrenia. Schizophrenia with predominantly negative symptoms.	Contra-indications: CNS depression, comatose states, phaeochromocytoma, prolactin-dependent tumours Side-effects: Common or very common: Anxiety, Uncommon: Bradycardia		BNF 79, Page -404	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
158.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd. Delta Pharma Ltd. Nuvista Pharma Ltd. Arges Life Science Limited. Beacon Pharmaceuticals Ltd, Valuka, Mymansingh.	Rimegepant 75mg Orally Dispersible Tablet	Rimegepant Sulfate INN 85.650 mg (eqv. to Rimegepant 75mg)	Drug used in migraine Therapeutic Code: 018	Acute treatment of migraine with or without aura in adults	**Contra-indication:** Patients with a history of hypersensitivity reaction to rimegepant, NURTEC ODT, or to any of its components. **Side-effect**: rash; difficult breathing; swelling of your face, lips, tongue, or throat. **<u>WARNINGS AND PRECAUTIONS:</u>** Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue Rimegepant and initiate appropriate therapy. Severe hypersensitivity reactions have included dyspnea and rash, and can occur days after administration.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
159.	Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited	Diethylpropion HCl 25mg Tablet	Diethylpropion HCl 25mg	Anticonvulsants Therapeutic Code: 013	Indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m2 or higher and who have not responded to	Contraindications: Pulmonary hypertension, advanced arteriosclerosis, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma, severe hypertension, Agitated states, Patients with a history of drug abuse, Use in combination with other	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					appropriate weight reducing regimen (diet and/or exercise) alone.	anorectic agents is contraindicated. During or within 14 days following the administration of monoamine oxidase inhibitors, hypertensive crises may result. Side Effects: Cardiovascular: Precordial pain, arrhythmia (including ventricular), ECG changes, tachycardia, elevation of blood pressure, palpitation and rare reports of pulmonary hypertensionCNS: Dyskinesia, blurred vision, overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, mydriasis, drowsiness, malaise, headache, and cerebrovascular accident, Gastrointestinal: Vomiting, diarrhea, abdominal discomfort, dryness of the mouth, unpleasanttaste, nausea, constipation, other gastrointestinal disturbancesAllergic: Urticaria, rash, ecchymosis, erythema Endocrine: Impotence, changes in libido, gynecomastia, menstrual upset Hematopoietic System: Bone marrow depression, agranulocytosis, leukopenia				
160.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Elemental Iron (III) 6.75mg/4.5ml Solution for IV Injection	Ferric Pyrophosphate Citrate eqv. to as elemental Iron (III) INN 6.75mg/4.5ml	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	Replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD)	**Contra-indication:** None **Side-effect**: headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, procedural hypotension, muscle spasms, pain in extremity, back pain, and dyspnea. **WARNINGS AND PRECAUTIONS:** Hypersensitivity Reactions: Observe for signs and symptoms of hypersensitivity during and after hemodialysis and until clinically stable.	Ferric Pyrophosphate Citrate eqv. to Iron (III) 27.2 mg/5ml Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
161.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Luspatercept-aamt 75mg lyophilized powder /Vial Injection	Luspatercept-aamt INN 75mg	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions	**Contra-indication:** None **Side-effect**: fatigue, headache, musculoskeletal pain, arthralgia, dizziness/vertigo, nausea, diarrhea, cough, abdominal pain, dyspnea, and hypersensitivity. **WARNINGS AND PRECAUTIONS:** • Thrombosis/Thromboembolism: Increased risk in patients with beta thalassemia. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly . • Hypertension: Monitor blood pressure (BP) during treatment. Initiate anti-hypertensive treatment if necessary. Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
162.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Luspatercept-aamt 25 mg lyophilized powder /Vial Injection	Luspatercept-aamt INN 25mg	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions	**Contra-indication:** None **Side-effect**: fatigue, headache, musculoskeletal pain, arthralgia, dizziness/vertigo, nausea, diarrhea, cough, abdominal pain, dyspnea, and hypersensitivity. **WARNINGS AND PRECAUTIONS:** • Thrombosis/Thromboembolism: Increased risk in patients with beta thalassemia. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly . • Hypertension: Monitor blood pressure (BP) during treatment. Initiate anti-hypertensive treatment if necessary.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.				
163.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Solithromycin 400mg Powder for Injection for IV Infusion	Solithromycin for Injection (sterile, buffered and lyophilized) INN 455mg (eqv. to 400mg Solithromycin INN)	Anti-infective Therapeutic Code: 023	Community acquired pneumonia (CAP) and other infections.	**Contra-indication:** None **Side-effect:** drug-induced liver injury, infusion-site reactions.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
164.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Nafamostat Mesilate 50mg / vial Injection	Nafamostat Mesilate INN 50mg/Vial	Anticoagulants and Fibrinolytic Drug Therapeutic Code: 012	It is used as an anticoagulant in patients with disseminative blood vessel coagulation, hemorrhagic lesions, and hemorrhagic tendencies. It prevents blood clot formation during extracorporeal circulation in patients undergoing continuous renal replacement therapy and extra corporeal membrane oxygenation.	**Adverse effect:** Reported incidence of agranulocytosis, hyperkalaemia, anaphylaxix **Side-effect**: Several allergic reactions caused by nafamostat mesilate have been reported in Japan. Most allergic reactions reported that there were mild symptoms, such as abdominal pain, nausea, vomiting, anorexia, myalgia, and arthralgia.	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
165.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Nafamostat Mesilate 50mg/Vial Powder for Infusion	Nafamostat Mesilate INN 50mg/Vial	Anticoagulant Therapeutic Code: 12	Used as an anticoagulant in patients with disseminative blood vessel coagulation, hemorrhagic lesions, and hemorrhagic tendencies. It prevents blood clot formation during extracorporeal circulation in patients undergoing continuous renal replacement therapy and extra corporeal membrane oxygenation	**Contraindication** Patients with a history of hypersensitivity **Side-effects:** Reported incidences of agranulocytosis, hyperkalemia, and anaphylaxis. The use of nafamostat has been reported to cause cardiac arrest in patients receiving dialysis due to a sudden change in the patient's condition such as dyspnea. A study suggests that the drug and its metabolites may inhibit the amiloride-sensitive sodium (Na) conductance at the collecting ducts, resulting in an inhibition of K secretion and hyperkalemia.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
166.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Nafamostat Mesilate 10 mg/Vial Powder for Infusion	Nafamostat Mesilate INN 10 mg/Vial	serine protease inhibitor Therapeutic Code: 012	Used as an anticoagulant in patients with disseminative blood vessel coagulation, hemorrhagic lesions, and hemorrhagic tendencies. It prevents blood clot formation during extracorporeal circulation in patients undergoing continuous renal replacement therapy and extra corporeal membrane oxygenation	**Contraindication** Patients with a history of hypersensitivity **Side-effects:** Reported incidences of agranulocytosis, hyperkalemia, and anaphylaxis. The use of nafamostat has been reported to cause cardiac arrest in patients receiving dialysis due to a sudden change in the patient's condition such as dyspnea. A study suggests that the drug and its metabolites may inhibit the amiloride-sensitive sodium (Na) conductance at the collecting ducts, resulting in an inhibition of K secretion and hyperkalemia.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
167.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka	Empagliflozin 5 mg + Linagliptin 2.5 mg + Metformin 1000 mg extended release Tablet	Empagliflozin INN 5 mg + Linagliptin INN 2.5 mg + Metformin Hydrochloride EP 1000 mg	Antidiabetes Therapeutic Code: 015	Glycemic control in adults with type 2 diabetes mellitus with established cardiovascular disease	**Contra-indication:** Severe renal impairment, Metabolic acidosis, Hypersensitivity to empagliflozin, linagliptin, metformin **Side-effect**: Upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis. **<u>WARNINGS AND PRECAUTIONS:</u>** • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate	Empagliflozin 10, 25 mg Tablet, Empagliflozin 5 mg + Metformin 500 mg, Linagliptin 2.5 mg + Metformin 1000, Linagliptin 5 mg + Metformin 1000, Linagliptin 2.5 mg + Metformin 850	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age ≥65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. If lactic acidosis is suspected, discontinue this drug and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.				
168.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Empagliflozin 12.5 mg + Linagliptin 2.5 mg + Metformin 1000 mg extended release Tablet	Empagliflozin INN 12.5 mg + Linagliptin INN 2.5 mg + Metformin Hydrochloride EP 1000 mg	Antidiabetes Therapeutic Code: 015	glycemic control in adults with type 2 diabetes mellitus with established cardiovascular disease	**Contra-indication:** Severe renal impairment, Metabolic acidosis, Hypersensitivity to empagliflozin, linagliptin, metformin **Side-effect**: Upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis. **<u>WARNINGS AND PRECAUTIONS:</u>** • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory	Empaglifl ozin 10, 25 mg Tablet, Empaglifl ozin 5 mg + Metformin 500 mg, Linagliptin 2.5 mg + Metformin 1000, Linagliptin 5 mg + Metformin 1000, Linagliptin 2.5 mg + Metformin 850	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age ≥65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. If lactic acidosis is suspected, discontinue this drug and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.				
169.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Ziska Pharmaceuticals Ltd.	Empagliflozin 25 mg + Linagliptin 5 mg + Metformin 1000 mg extended release Tablet	Empagliflozin INN 25 mg + Linagliptin INN 5 mg + Metformin Hydrochloride EP 1000 mg	Antidiabetes Therapeutic Code: 015	glycemic control in adults with type 2 diabetes mellitus with established cardiovascular disease	**Contra-indication:** Severe renal impairment, Metabolic acidosis, Hypersensitivity to empagliflozin, linagliptin, metformin **Side-effect**: Upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis. **<u>WARNINGS AND PRECAUTIONS:</u>** • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included	Empagliflozin 10, 25 mg Tablet, Empagliflozin 5 mg + Metformin 500 mg, Linagliptin 2.5 mg + Metformin 1000, Linagliptin 5 mg + Metformin 1000, Linagliptin 2.5 mg +	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age ≥65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. If lactic acidosis is suspected, discontinue this drug and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.	Metformin 850			
170.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Solithromycin 200mg Capsule	Solithromycin INN 200mg Capsule	Anti-infective Therapeutic Code: 023	Community acquired pneumonia (CAP) and other infections.	**Contra-indication:** None **Side-effect:** drug-induced liver injury, infusion-site reactions.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
171.	Navana Pharmaceuticals Limited Acme Laboratories Ltd., Dhamrai, Dhaka	Alogliptin INN 12.5 mg and Metformin Hydrochloride BP 1000 mg Tablet.	Alogliptin INN 12.5 mg and Metformin Hydrochloride BP 1000 mg.	Antidiabetes Therapeutic Code: 015	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Contraindications: • Renal impairment. • Metabolic acidosis, including diabetic ketoacidosis. • History of a serious hypersensitivity reaction to alogliptin or metformin, components of this drug, such as anaphylaxis, angioedema or severe cutaneous adverse reactions.	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side effects: Common adverse reactions reported in ≥4% of patients treated with coadministration of alogliptin with metformin were: upper respiratory tract infection, nasopharyngitis, diarrhea, hypertension, headache, back pain and urinary tract infection. WARNINGS AND PRECAUTIONS: • Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure. • Symptoms include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap and elevated blood lactate. • If acidosis is suspected, discontinue this drug and hospitalize the patient immediately.				
172.	Navana Pharmaceuticals Limited	Alogliptin INN 12.5 mg and Metformin Hydrochloride BP 500 mg Tablet.	Alogliptin INN 12.5 mg and Metformin Hydrochloride BP 500 mg.	Antidiabetes Therapeutic Code: 015	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Contraindications: • Renal impairment. • Metabolic acidosis, including diabetic ketoacidosis. • History of a serious hypersensitivity reaction to alogliptin or metformin, components of this drug, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Side effects: Common adverse reactions reported in ≥4% of patients treated with coadministration of alogliptin with metformin were: upper respiratory tract infection, nasopharyngitis, diarrhea,	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						hypertension, headache, back pain and urinary tract infection. WARNINGS AND PRECAUTIONS: • Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure. • Symptoms include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap and elevated blood lactate. • If acidosis is suspected, discontinue this drug and hospitalize the patient immediately.				
173.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Pancrelipase 70% EC pallets 540 mg Delayed release Capsule	Pancrelipase 70% EC pallets Ph. Grade 540 mg contains Lipase USP 36,000 Units+ Protease USP 1,14,000 Units + Amylase USP 1,80,000 Units	Enzymes Therapeutic Code: 051	Exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions	**Contra-indication:** None **Side-effect**: vomiting, dizziness, cough, hyperglycemia, hypoglycemia, abdominal pain, abnormal feces, flatulence, frequent bowel movements, and nasopharyngitis. **<u>WARNINGS AND PRECAUTIONS:</u>** • Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement in the treatment of cystic fibrosis patients. Exercise caution when doses of this drug exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day). • To avoid irritation of oral mucosa, do not chew this drug or retain in the mouth.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Exercise caution when prescribing this drug to patients with gout, renal impairment, or hyperuricemia. • There is theoretical risk of viral transmission with all pancreatic enzyme products including this drug. • Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.				
174.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Itopride 150 mg Sustained Release Tablet	Itopride Hydrochloride INN 150 mg	Antiemetic Therapeutic code: 018	Dyspepsia of a non-ulcer/dysmotility type gastric fullness, discomfort, and possible pain, gastroparesis (delayed gastric emptying), anorexia, heartburn, regurgitation, bloating, nausea and vomiting, other possible gastric, prolactin, or dopamine related conditions	**Contra-indication:** hypersensitivity to itopride or benzamides; lactation, GI hemorrhage, obstruction or perforation **Side-effect:** mild to moderate abdominal pain and diarrhoea.[7] Some other side effects that may occur include: rash, giddiness, exhaustion, back or chest pain, increased salivation, constipation, headache, sleeping disorders, dizziness, galactorrhea, and gynecomastia.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
175.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Pancrelipase 70% EC pallets 240 mg Delayed release Capsule	Pancrelipase 70% EC pallets Ph. Grade 240 mg contains Lipase USP 12,000 Units+ Protease USP 38,000 Units + Amylase USP 60,000 Units	Enzymes Therapeutic code: 051	exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions	**Contra-indication:** None **Side-effect**: vomiting, dizziness, cough, hyperglycemia, hypoglycemia, abdominal pain, abnormal feces, flatulence, frequent bowel movements, and nasopharyngitis. **WARNINGS AND PRECAUTIONS:** • Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement in the treatment of cystic fibrosis patients. Exercise caution when doses of this drug exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day).	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• To avoid irritation of oral mucosa, do not chew this drug or retain in the mouth. • Exercise caution when prescribing this drug to patients with gout, renal impairment, or hyperuricemia. • There is theoretical risk of viral transmission with all pancreatic enzyme products including this drug. • Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.				
176.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Diquafosol 30mg/ml Ophthalmic Solution	Diquafosol Sodium INN 30mg/ml	Eye Preparations Therapeutic code: 052	Dry eye, associated with keratoconjunctival epithelium disorders	**Contra-indication:** hypersensitivity to Diquafosol **Side-effect**: Eye discharge, conjunctival hyperaemia, eye pain, eye itching, foreign body sensation in eyes, visual discomfort, hyposphagma, abnormal sensation in eye (eyes dry feeling of, eye strange sensation of, sticky eye sensation), vision blurred, photophobia, lacrimation, Headache, increased eosinophils	New	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
177.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Oxymetazoline 1mg/ml Ophthalmic Solution	Oxymetazoline HCl BP 1mg/ml	Eye Preparations Therapeutic code: 052	It is indicated for the treatment of acquired blepharoptosis in adults.	**Contra-indication:** None **Side-effect**: Punctate keratitis, conjunctival hyperemia, dry eye, vision blurred, instillation site pain, eye irritation and headache. **<u>WARNINGS AND PRECAUTIONS:</u>** • Alpha-adrenergic agonists as a class may impact blood pressure. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens. • Use with caution in patients with cerebral or coronary insufficiency or Sjögren's syndrome and advice	Oxymetazoline 0.5%, 0.025% Nasal Drops, 1gm/100 gm Cream	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop. • Advise patients to seek immediate medical care if pain, redness, blurred vision and photophobia occur (signs and symptoms of acute angle closure).				
178.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Elemental Iron 510.00 mg as Ferumoxytol (Non - Stoichiometric Magnetite)/17 ml Solution for IV Infusion	Ferumoxytol (Non-Stoichiometric Magnetite) INN 510.00 mg Elemental Iron as Ferumoxytol (Non - Stoichiometric Magnetite)/17 ml	Drug used in Anemia and other blood disorder Therapeutic code: 045	Indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD)	**Contra-indication:** Evidence of iron overload. Known hypersensitivity to this drug or any of its components. Anemia not caused by iron deficiency. **Side-effect**: diarrhea, nausea, dizziness, hypotension, constipation, and peripheral edema. **<u>WARNINGS AND PRECAUTIONS:</u>** • Hypersensitivity Reactions: Observe for signs and symptoms of hypersensitivity for at least 30 minutes following the administration of this drug. • Hypotension: this drug may cause hypotension. Monitor for signs and symptoms of hypotension following the administration of this drug. • Iron Overload: Regularly monitor hematologic responses during this drug therapy. Do not administer this drug to patients with iron overload. • Magnetic Resonance Imaging: this drug can alter magnetic resonance imaging (MRI) studies.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
179.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cefiderocol 1gm)/Vial Lyophilized Powder for injection for Infusion	Cefiderocol Sulfate Tosylate (Sterile Lyophilized) INN 2720.00 mg (eqv. to of 1gm Cefiderocol)/Vial	Anti-infective Therapeutic Code: 023	Indicated in patients 18 years of age or older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms	**Contraindications:** It is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol and other beta-lactam antibacterial drugs or other components of cefiderocol. **Side-effects:** The most frequently occurring adverse reactions in greater than or equal to 2%	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Opsonin Pharma Limited, Rupatali, Barishal.					of patients treated with cefiderocol were diarrhea, infusion site reactions, constipation, rash, candidiasis, cough, elevations in liver tests, headache, hypokalemia, nausea, and vomiting. **Warning & Precaution:** • Increase in All-Cause Mortality in Patients with Carbapenem-Resistant Gram-Negative Bacterial Infections: An increase in all-cause mortality was observed in Cefiderocol-treated patients compared to those treated with best available therapy (BAT). Reserve Cefiderocol for use in patients who have limited or no alternative treatment options for the treatment of cUTI. Closely monitor the clinical response to therapy in patients with cUTI. • Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving betalactam antibacterial drugs. Hypersensitivity was observed with Cefiderocol. Cross-hypersensitivity may occur in patients with a history of penicillin allergy. If an allergic reaction occurs, discontinue Cefiderocol. •Clostridioides difficile-Associated Diarrhea (CDAD): CDAD has been reported with nearly all systemic antibacterial agents, including Cefiderocol. Evaluate if diarrhea occurs. • Seizures and Other Central Nervous System (CNS) Adverse Reactions: CNS adverse reactions such as seizures have been reported with Cefiderocol. If focal tremors, myoclonus, or seizures occur, evaluate patients to determine whether Cefiderocol should be discontinued.				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
180.	Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka	Cefiderocol Sulfate Tosylate1 g lyophilized powder for intravenous injection	Cefiderocol Sulfate Tosylate INN 1 g	Anti-infective Therapeutic Code: 023	It is indicated in patients 18 years of age or older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms. Approval of this indication is based on limited clinical safety and efficacy data for this. To reduce the development of drug-resistant bacteria and maintain the effectiveness of this and other antibacterial drugs, It should be used only to treat or prevent infections thatare proven or strongly suspected to be caused by bacteria.	**Contraindications:** It is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol and other beta-lactam antibacterial drugs or other components of cefiderocol. **Side-effects:** The most frequently occurring adverse reactions in greater than or equal to 2% of patients treated with cefiderocol were diarrhea, infusion site reactions, constipation, rash, candidiasis, cough, elevations in liver tests, headache, hypokalemia, nausea, and vomiting. **Warning & Precaution:** • Increase in All-Cause Mortality in Patients with Carbapenem-Resistant Gram-Negative Bacterial Infections: An increase in all-cause mortality was observed in Cefiderocol-treated patients compared to those treated with best available therapy (BAT). Reserve Cefiderocol for use in patients who have limited or no alternative treatment options for the treatment of cUTI. Closely monitor the clinical response to therapy in patients with cUTI. • Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving betalactam antibacterial drugs. Hypersensitivity was observed with Cefiderocol. Cross-hypersensitivity may occur in patients with a history of penicillin allergy. If an allergic reaction occurs, discontinue Cefiderocol. •Clostridioides difficile-Associated Diarrhea (CDAD): CDAD has been reported with nearly all systemic antibacterial agents, including Cefiderocol. Evaluate if diarrhea occurs.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Seizures and Other Central Nervous System (CNS) Adverse Reactions: CNS adverse reactions such as seizures have been reported with Cefiderocol. If focal tremors, myoclonus, or seizures occur, evaluate patients to determine whether Cefiderocol should be discontinued.				
181.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur. Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited	Cetirizine hydrochloride 10mg Orally Disintegrating Tablet	Cetirizine hydrochloride BP 10mg	Antihistamine Therapeutic code: 021	Temporarily relieves symptoms including Runny nose, Sneezing, Itchy, watery eyes & itching of the nose or throat due to hay fever or other upper respiratory allergies.	**Side-effect**: The most common side effects are headache and somnolence. The incidence of headache associated with cetirizine hydrochloride was not different from placebo. The incidence of somnolence associated with cetirizine hydrochloride was dose related and predominantly mild to moderate. **Contra-indication and Warnings:** Cetirizine hydrochloride is contraindicated in those patients with a known hypersensitivity to it or to its parent compound, hydroxyzine, in patients who are hypersensitive to any other ingredient in the formulation.	Cetirizine Dihydrochloride 10mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
182.	Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cefotetan 2g/Vial Injection	Cefotetan Disodium (Sterile) USP2.16gm (eqv. to 2 g Cefotetan)/Vial	Anti-infective Therapeutic code: 023	To reduce the development of drug -resistant bacteria and maintain the effectiveness of Cefotetan and other antibacterial drugs, Cefotetan should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Urinary Tract Infections, Lower Respiratory Tract Infections, Skin and Skin Structure Infections, Gynecologic Infections, Intra-abdominal	**Side-effect**: Gastrointestinal, Hematologic, Hepatic, Hypersensitivity Reaction **Contra-indication and Warnings:** Cefotetan is contraindicated in patients with a known allergy to the cephalosporin group of antibiotics and in those individuals, who have experienced a cephalosporin associated hemolytic anemia.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Infections, Bone and Joint Infections & Surgical Prophylaxis can be treated with Cefotetan.					
183.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cefotetan 1 gm Injection	Cefotetan for injection (sterile) USP 1.076 gm eq to Cefotetan 1 gm	Anti-infective Therapeutic code: 023	To reduce the development of drug -resistant bacteria and maintain the effectiveness of Cefotetan and other antibacterial drugs, Cefotetan should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Urinary Tract Infections, Lower Respiratory Tract Infections, Skin and Skin Structure Infections, Gynecologic Infections, Intra-abdominal Infections, Bone and Joint Infections & Surgical Prophylaxis can be treated with Cefotetan.	**Side-effect**: Gastrointestinal, Hematologic, Hepatic, Hypersensitivity Reaction **Contra-indication and Warnings:** Cefotetan is contraindicated in patients with a known allergy to the cephalosporin group of antibiotics and in those individuals, who have experienced a cephalosporin associated hemolytic anemia.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
184.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Temocillin 1 gm)/Vial Powder for Solution for Injection/Infusion	Temocillin Disodium Sterile Powder for Injection In-House 1.11gm (eqv. to Temocillin 1 gm)/Vial	Anti-infective Therapeutic code: 023	It is indicated for the treatment of septicaemia, urinary tract infection and lower respiratory tract infection where susceptible gram-negative bacilli are suspected or confirmed. In mixed infections where gram-positive or anaerobic bacteria are also liable to be implicated, co-administration with other appropriate antibacterial agents should be considered.	**Side-effect**: Undesirable effects are typical of the injectable penicillins: they may include diarrhoea, pain at the site of I.M. injection, occasionally rash, either urticarial or erythematous. Certain reactions such as fever, arthralgia or myalgia, sometimes develop more than 48 hours after the start of the treatment. **Contraindications:** It is contraindicated in patients with a history of allergic reactions to any of the penicillins or any other type of beta-lactam drug.	New	BNF-78 page-555	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
185.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 50 mg + Cloxacillin 25 mg/ Vial Solution for Injection	Ampicillin Sodium and Cloxacillin Sodium Sterile Powder for Injection In-house 80.909 mg (equivalent to 50 mg ampicillin + 25 mg Cloxacillin)/ Vial	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 1. Surgery: post-operative wound infections, post-operative pulmonary infections. 2. Respiratory infections: bronchopneumonia, acute exacerbations of chronic bronchitis. Obstetrics: puerperal fever. 3. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg, 500 mg capsule, 125mg/5 ml powder for suspension	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
186.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 10.00gm + Cloxacillin 5 gm/100 ml Powder for Neonatal Oral Drops	Ampicillin Trihydrate BP 1.548 gm (eqv. to 10.00gm Ampicillin) + Cloxacillin Sodium BP 5.450 gm (equivalent to 5.00 gm Cloxacillin)/100 ml	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 4. Surgery: post-operative wound infections, post-operative pulmonary infections. 5. Respiratory infections: bronchopneumonia, acute exacerbations of chronic bronchitis. Obstetrics: puerperal fever.	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg, 500 mg capsule, 125mg/5 ml powder	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.		for suspension			
187.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 125 mg + Cloxacillin 125 mg Capsule	Ampicillin Trihydrate BP 144.35 mg (equivalent to 125 mg Ampicillin) + Cloxacillin Sodium BP 136.250 mg (equivalent to 125 mg Cloxacillin)	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 6. Surgery: post-operative wound infections, post-operative pulmonary infections. 7. Respiratory infections: bronchopneumonia, acute exacerbations of chronic bronchitis. Obstetrics: puerperal fever. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg, 500 mg capsule, 125mg/5 ml powder for suspension	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
188.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 125 mg + Cloxacillin 125 mg/ Vial Powder for Injection	Ampicillin Sodium and Cloxacillin Sodium Sterile Powder for Injection In-house 269.695 mg (equivalent to 125 mg ampicillin + 125 mg Cloxacillin)/ Vial	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 8. Surgery: post-operative wound infections, post-operative pulmonary infections. 9. Respiratory infections: bronchopneumonia, acute exacerbations of chronic	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg, 500 mg capsule,	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					bronchitis. Obstetrics: puerperal fever. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.		125mg/5 ml powder for suspension			
189.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 2.50 gm + Cloxacillin 2.50 gm/100 ml Powder for Suspension	Ampicillin Trihydrate BP 2.887 gm (equivalent to 2.50 gm Ampicillin) + Cloxacillin Sodium BP 2.725 gm (equivalent to 2.50 gm Cloxacillin) /100 ml	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 10. Surgery: post-operative wound infections, post-operative pulmonary infections. 11. Respiratory infections: bronchopneumonia, acute exacerbations of chronic bronchitis. Obstetrics: puerperal fever. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg, 500 mg capsule, 125mg/5 ml powder for suspension	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
190.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 250 mg + Cloxacillin 250 mg Capsule	Ampicillin Trihydrate BP 288.70 mg (equivalent to 250 mg Ampicillin) + Cloxacillin Sodium BP 272.50 mg (equivalent to 250 mg Cloxacillin)	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 12. Surgery: post-operative wound infections, post-operative pulmonary infections. 13. Respiratory infections: bronchopneumonia, acute	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg,	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					exacerbations of chronic bronchitis. Obstetrics: puerperal fever. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.		500 mg capsule, 125mg/5 ml powder for suspension			
191.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna	Ampicillin 5.00 gm) + Cloxacillin 5.00 gm/100 ml Powder for Suspension	Ampicillin Trihydrate BP 5.774 gm (equivalent to 5.00 gm Ampicillin) + Cloxacillin Sodium BP 5.450 gm (equivalent to 5.00 gm Cloxacillin)/100 ml	Anti-infective Therapeutic code: 023	It is indicated for the treatment of the following infections including mixed Grampositive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections: 14. Surgery: post-operative wound infections, post-operative pulmonary infections. 15. Respiratory infections: bronchopneumonia, acute exacerbations of chronic bronchitis. Obstetrics: puerperal fever. 16. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.	**Side-effect**: Nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically. AMPICLOX is a combination of ampicillin and cloxacillin. **Contraindications:** It should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients.	Ampicillin 250, 500 capsule, 125mg/1.25ml, 125mg/5 ml powder for suspension, 250 mg, 500 mg IM/IV injection, Cloxacillin 250mg, 500 mg capsule, 125mg/5 ml powder for suspension	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
192.	Square Pharmaceuticals Ltd., (Chemical Division), BSCIC, Pabna. Opsonin Pharma Limited, Rupatali, Barishal.	Omeprazole 10 mg + Amoxicillin 250mg + Rifabutin 12.5mg Capsule	Omeprazole EC Pellet 8.5% Ph. Grade 120.000 mg (Enteric coated pellets eqv. to 10.000 mg Omeprazole BP) + Amoxicillin Trihydrate BP 286.900 mg (eqv. to Amoxicillin 250mg + Rifabutin USP 12.500 mg	Proton pump inhibitor Therapeutic code: 067	It is indicated for the treatment of Helicobacter pylori infection in adults. To reduce the development of drug-resistant bacteria and maintain the effectiveness of TALICIA and other antibacterial drugs, TALICIA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Side effects:** Diarrhea, headache, nausea, abdominal pain, abnormally colored urine, rash, heartburn/indigestion, mouth and hroat pain **Contraindications:** Known hypersensitivity to omeprazole, amoxicillin or any other betalactam antibacterial drugs, rifabutin or any other rifamycin, or any component of this drug.	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Rilpivirine-containing products. • Delavirdine • Voriconazole **WARNINGS AND PRECAUTIONS:** • Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of this drug. If hypersensitivity reactions occur, discontinue this drug and institute immediate therapy (e.g., anaphylaxis management). • Clostridioides difficile-Associated Diarrhea (CDAD): Evaluate if diarrhea occurs. • Reduction in the Efficacy of Hormonal Contraceptives: Additional nonhormonal highly effective methods of contraception should be used while taking this drug. • Acute Interstitial Nephritis (AIN): Observed in patients taking (Proton Pump Inhibitors (PPIs) and penicillins. Discontinue this drug if AIN develops. Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue this drug and evaluate.				
193.	Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka One Pharma Ltd., Bogura Opsonin Pharma Limited, Rupatali, Barishal.	Ubrogepant 50 mg Tablet	Ubrogepant INN 50 mg	Drug used in migraine Therapeutic Code: 046	It is indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: It is not indicated for the preventive treatment of migraine.	**Contraindications:** Concomitant use with strong CYP3A4 inhibitors. **Side effects:** The most common adverse reactions (at least 2% and greater than placebo) were nausea and somnolence.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
194.	Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka One Pharma Ltd., Bogura Opsonin Pharma Limited, Rupatali, Barishal.	Ubrogepant 100 mg Tablet	Ubrogepant INN 100 mg	Drug used in migraine Therapeutic Code: 046	It is indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: It is not indicated for the preventive treatment of migraine.	**Contraindications:** • Concomitant use with strong CYP3A4 inhibitors. **Side effects:** The most common adverse reactions (at least 2% and greater than placebo) were nausea and somnolence.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
195.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited	Omeprazole Magnesium 10 mg+ Amoxicillin 250 mg +Rifabutin 12.5 mg Capsule	Omeprazole Magnesium USP 10 mg+ Amoxicillin USP 250 mg + Rifabutin USP 12.5 mg	Proton pump inhibitor Therapeutic Code: 067	It is indicatedfor the treatment of *Helicobacter pylori* infection in adults. To reduce the development of drug-resistant bacteria and maintain the effectiveness of this and other antibacterial drugs, it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** Known hypersensitivity to omeprazole, amoxicillin or any other betalactam antibacterial drugs, rifabutin or any other rifamycin, or to any of its components. • Rilpivirine-containing products. • Delavirdine. • Voriconazole. **Side effects:** Most common adverse reactions (≥1%) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis. **Warning & Precaution:** • Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of this medicine. If hypersensitivity reactions occur, discontinue this medicine and institute immediate therapy (e.g., anaphylaxis management). • Clostridioides difficile-Associated Diarrhea (CDAD): Evaluate if diarrhea occurs. • Reduction in the Efficacy of Hormonal Contraceptives: Additional nonhormonal highly effective methods of contraception should be used while taking this medicine.	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Acute Interstitial Nephritis (AIN): Observed in patients taking (Proton Pump Inhibitors (PPIs) and penicillins. Discontinue this medicinen if AIN develops. • Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue this medicine and evaluate.				
196.	Ziska Pharmaceuticals Ltd.	Cetirizine Hydrochloride 10 mg/ml Injection	Cetirizine Hydrochloride USP 10 mg/ml	Antihistamine Therapeutic Code: 021	It is indicated for the treatment of acute urticaria in adults and children 6 months of age and older. Limitations of Use: Not recommended in pediatric patients less than 6 years of age with impaired renal or hepatic function.	**Contraindications:** Known hypersensitivity to cetirizine hydrochloride or any of its ingredients, levocetirizine, or hydroxyzine. **Side effects:** The most common adverse reactions (incidence less than 1%) with cetirizine hydrochloride are dysgeusia, headache, paresthesia, presyncope, dyspepsia, feeling hot, and hyperhidrosis. Most common adverse reactions (incidence equal to or greater than 2%) with use of oral cetirizine hydrochloride are somnolence, fatigue, dry mouth, pharyngitis, and dizziness. **Warning & Precaution:** • Somnolence/Sedation: Exercise caution when driving a car or operating potentially dangerous machinery.	Cetirizine Dihydrochloride 10 mg Tablet, 10 mg Orodispersible Tablet, 2.5 mg/ml Pediatric Drop, 5 mg/5 ml Syrup, 240 mg/100 ml Eye Drops	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
197.	Ziska Pharmaceuticals Ltd. **Acme Laboratories Ltd., Dhamrai, Dhaka** Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Arges Life Science Limited.	Lemborexant 5 mg Tablet	Lemborexant INN 5 mg	Opid Analgesics Therapeutic Code: 075	It is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications:** It is contraindicated in patients with narcolepsy. **Side-effects:** The most common adverse reaction (reported in ≥5% of patients treated with lemborexant and at least twice the rate of placebo) was somnolence. **Warning & Precaution:** • CNS Depressant Effects and Daytime Impairment: Impairs alertness and motor coordination including morning impairment. Risk increases with dose	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						and use with other central nervous system (CNS) depressants. For patients taking Lemborexant 10 mg, caution against next-day driving and other activities requiring complete mental alertness. • Sleep Paralysis, Hypnogogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms: May occur with use of Lemborexant. • Complex Sleep Behaviors: Behaviors including sleep-walking, sleep-driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if a complex sleep behavior occurs. • Compromised Respiratory Function: Effect on respiratory function should be considered. • Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur. Prescribe the lowest number of tablets feasible to avoid intentional overdosage. • Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days of treatment.				
198.	Ziska Pharmaceuticals Ltd. **Acme Laboratories Ltd., Dhamrai, Dhaka** Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Arges Life Science Limited.	Lemborexant 10 mg Tablet	Lemborexant INN 10 mg	Opid Analgesics Therapeutic Code: 075	It is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications:** It is contraindicated in patients with narcolepsy. **Side-effects:** The most common adverse reaction (reported in ≥5% of patients treated with lemborexant and at least twice the rate of placebo) was somnolence. **Warning & Precaution:** • CNS Depressant Effects and Daytime Impairment: Impairs alertness and motor coordination including morning impairment. Risk increases with dose and use with other central nervous system (CNS) depressants. For patients taking Lemborexant 10 mg,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						caution against next-day driving and other activities requiring complete mental alertness. • Sleep Paralysis, Hypnogogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms: May occur with use of Lemborexant. • Complex Sleep Behaviors: Behaviors including sleep-walking, sleep-driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if a complex sleep behavior occurs. • Compromised Respiratory Function: Effect on respiratory function should be considered. • Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur. Prescribe the lowest number of tablets feasible to avoid intentional overdosage. • Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days of treatment.				
199.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Phentermine 7.5 mg + Topiramate 46 mg extended-release Capsule	Phentermine USP 7.5mg + Topiramate USP 46mg	Other Classification Therapeutic Code: 075	It is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. Limitations of Use: The effect of it on cardiovascular morbidity and mortality has not been established. • The safety and effectiveness of it in combination with otherproducts intended for weight loss, including prescription and over the-counter drugs, and herbal	**Contraindications:** •Pregnancy • Glaucoma • Hyperthyroidism • During or within 14 days of taking monoamine oxidase inhibitors • Known hypersensitivity or idiosyncrasy to sympathomimetic amines. **Side effects:** Most common adverse reactions (incidence greater than or equal to 5%) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth. **Warning & Precaution:** • Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. This medicine is	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					preparations, have not been established.	available through a limited program under a Risk Evaluation and Mitigation Strategy (REMS). • Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease. • Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue this medicine if symptoms develop. • Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue this medicine. • Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms. • Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment. • Metabolic Acidosis: Measure electrolytes before/during treatment. • Elevated Creatinine: Measure creatinine before/during treatment. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment.				
200.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Phentermine 3.75 mg + Topiramate 23 mg extended-release Capsule	Phentermine USP 3.75 mg + Topiramate USP 23mg	Other Classification Therapeutic Code: 075	It is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. Limitations of Use: The effect of it on cardiovascular morbidity	**Contraindications:** •Pregnancy • Glaucoma • Hyperthyroidism • During or within 14 days of taking monoamine oxidase inhibitors • Known hypersensitivity or idiosyncrasy to sympathomimetic amines. **Side effects:** Most common adverse reactions (incidence greater than or equal to 5%) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.	New	US FDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					and mortality has not been established. • The safety and effectiveness of it in combination with other products intended forweight loss, including prescription and over the-counter drugs, and herbal preparations, have not been established.	**Warning & Precaution:** • Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. This medicine is available through a limited program under a Risk Evaluation and Mitigation Strategy (REMS). • Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease. • Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue this medicine if symptoms develop. • Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue this medicine. • Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms. • Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment. • Metabolic Acidosis: Measure electrolytes before/during treatment. • Elevated Creatinine: Measure creatinine before/during treatment. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment.				
201.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited. Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Phentermine 11.25 mg +Topiramate 69 mg extended-release Capsule	Phentermine USP 11.25 mg + Topiramate USP 69 mg	Other Classification Therapeutic Code: 075	It is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese) or • 27 kg/m2 or	**Contraindications:** •Pregnancy • Glaucoma • Hyperthyroidism • During or within 14 days of taking monoamine oxidase inhibitors • Known hypersensitivity or idiosyncrasy to sympathomimetic amines.	New	US FDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. Limitations of Use: The effect of it on cardiovascular morbidity and mortality has not been established. • The safety and effectiveness of it in combination with other products intended forweight loss, including prescription and over the-counter drugs, and herbal preparations, have not been established.	**Side effects:** Most common adverse reactions (incidence greater than or equal to 5%) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth. **Warning & Precaution:** • Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. This medicine is available through a limited program under a Risk Evaluation and Mitigation Strategy (REMS). • Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease. • Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue this medicine if symptoms develop. • Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue this medicine. • Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms. • Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment. • Metabolic Acidosis: Measure electrolytes before/during treatment. • Elevated Creatinine: Measure creatinine before/during treatment. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment.				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
202.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Eskayef Pharmaceuticals Limited,Tongi, Gazipur.	Phentermine 15 mg + Topiramate 92 mg extended-release Capsule	Phentermine USP 15 mg + Topiramate USP 92 mg	Other Classification Therapeutic Code: 075	It is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. Limitations of Use: The effect of it on cardiovascular morbidity and mortality has not been established. • The safety and effectiveness of it in combination with otherproducts intended for weight loss, including prescription and over the-counter drugs, and herbal preparations, have not been established.	**Contraindications:** •Pregnancy • Glaucoma • Hyperthyroidism • During or within 14 days of taking monoamine oxidase inhibitors • Known hypersensitivity or idiosyncrasy to sympathomimetic amines. **Side effects:** Most common adverse reactions (incidence greater than or equal to 5%) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth. **Warning & Precaution:** • Fetal Toxicity: Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. This medicine is available through a limited program under a Risk Evaluation and Mitigation Strategy (REMS). • Increase in Heart Rate: Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease. • Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue this medicine if symptoms develop. • Acute Myopia and Secondary Angle Closure Glaucoma: Discontinue this medicine. • Mood and Sleep Disorders: Consider dose reduction or withdrawal for clinically significant or persistent symptoms. • Cognitive Impairment: May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment. • Metabolic Acidosis: Measure electrolytes before/during treatment.	New	US FDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Elevated Creatinine: Measure creatinine before/during treatment. • Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment.				
203.	Ziska Pharmaceuticals Ltd.	Methylprednisolone Aceponate 0.1% Cream	Methylprednisolone Aceponate INN 0.1%	Steroid Therapeutic Code: 072	It suppresses inflammatory and allergic skin reactions as well as reactions associated with increased cellular regeneration, leading to regression of the objective symptoms (erythema, oedema, thickening of the skin, coarsening of the skin surface) and the subjective complaints (itching, burning, pain). It is approved for use in Atopic dermatitis (endogenous eczema, neurodermatitis), contact eczema, degenerative, dyshidrotic, vulgar eczema, eczema in children.	**Contraindications:** Tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. varicella, herpes zoster), rosacea, perioral dermatitis and postvaccination skin reactions in the area to be treated. Hypersensitivity to the active substance or to any of the excipients. **Side effects:** • In 8-week comparative study comparing Methylprednisolone Aceponate and betamethasone 17-valerate (BMV), it showed that BMV twice daily produces a higher incidence of and more significant ($p < 0.0034$) telangiectasia and skin thinning than Methylprednisolone Aceponatecream once daily. • In a comparative study, after 7 weeks of occlusive exposure of Methylprednisolone Aceponate, clobetasol propionate (CPB) and BMV, the atrophgenic potential of CBP is highly greater than Methylprednisolone Aceponateand BMV. Though there is no significant difference between Methylprednisolone Aceponate and BMV, the atrophenic potential of Methylprednisolone Aceponate is low. • Local symptoms such as atrophy of the skin, telangiectasia, striae, acneform changes of the skin and systemic effects of the corticoid due to absorption may occur when topical preparations containing corticoids are applied to large areas of the body (about 10% and more) or for prolonged periods of time (more than 4 weeks). However, during the clinical investigation, none of these	New	রেফারেন্স নাই TGA	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						side effects occurred on Methylprednisolone Aceponate treatment up to 12 weeks (adults) and 4 weeks (children). • It is suggested that Methylprednisolone Aceponate has a lower incidence of skin atrophy and can be used for a long time of treatment. The lower incidence of adverse effects may due to quick inactivation during circulation. **Warning & Precaution:** Patients who are allergic to prednisone and who have medical history, especiallyof: bleeding problems, blood clots, osteoporosis, diabetes, eye diseases, heart problems, high blood pressure, current/ past infections, kidney disease, liver disease, mental/mood conditions, stomach/intestinal problems, seizures.This drug may make you dizzy. Alcoholor marijuana (cannabis) can make you dizzier. Methylprednisolone can make you more likely to get infections or may worsen any current infections. This medicine may cause stomach bleeding. Daily use of alcohol while using this medicine may increase your risk for stomach bleeding. Limit alcoholic beverages.				
204.	Ziska Pharmaceuticals Ltd. Square Pharmaceuticals Ltd, Salgaria, Pabna. Navana Pharmaceuticals Limited Beacon Pharmaceuticals Ltd, Valuka, Mymansingh. Opsonin Pharma Limited, Rupatali, Barishal.	Acetaminophen 250 mg + Ibuprofen 125 mg Tablet	Acetaminophen BP 250 mg + Ibuprofen BP 125 mg	Analgesic & Antipyretic Therapeutic Code: 006	Pain reliever. Temporarily relieves minor aches and pains due to: headache, toothache, backache, menstrual cramps, muscular aches, minor pain of arthritis.	**Contraindications:** Do not use •with any other drug containing acetaminophen (prescription or nonprescription). If patients are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.•if patients have ever had an allergic reaction to acetaminophen or any other pain reliever •right before or after heart surgery. **Side effects:** Stop use and ask a doctor if • Patient experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit	New	US FDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						blood ■ have bloody or black stools ■ have stomach pain that does not get better • Patients have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling • pain gets worse or lasts more than 10 days • redness or swelling is present in the painful area • any new symptoms appear. **Warning & Precaution:** **Acetaminophen liver damage warning:** This product contains acetaminophen. Severe liver damage may occur if patients take: • with other drugs containing acetaminophen • more than 6 caplets in 24 hours, which is the maximum daily amount for this product • 3 or more alcoholic drinks every day while using this product **Acetaminophen allergy alert:** May cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If skin reaction occurs, stop use and seek medical help right away. **NSAID allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters. If an allergic reaction occurs, stop use and seek medical help right away. **NSAID stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if patients:				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if patients use more than directed or for longer than directed.				
205.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Nuvista Pharma Ltd.	Ospemifene 60 mg Tablet	Ospemifene INN 60 mg	Contraceptives Therapeutic Code: 039	It is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.	**Contraindications:** Undiagnosed abnormal genital bleeding • Known or suspected estrogen-dependent neoplasiaActive DVT, pulmonary embolism (PE), or a history of these conditions • Active arterial thromboembolic disease (for example, stroke and myocardial infarction [MI]), or a history of theseconditions • Known or suspected pregnancy. **Side effects:** Adverse reactions (≥1 percent) include: hot flush, vaginal discharge, muscle spasms, genital discharge, hyperhidrosis. **Warning & Precaution:** Venous Thromboembolism: Risk of DVT and pulmonary embolism • Known, suspected, or history of breast cancer • Severe Hepatic Impairment.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
206.	Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Eskayef Pharmaceuticals Limited,Tongi, Gazipur.	Elagolix 300 mg+ estradiol 1 mg + norethindrone acetate 0.5 mg capsule	Elagolix INN 300 mg+ estradiol USP 1 mg + norethindrone acetate USP 0.5 mg	Hormone Therapeutic Code: 056	It is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitation of Use: • Use of it should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.	**Contraindications:** High risk of arterial, venous thrombotic, or thromboembolic disorder. • Pregnancy. • Known osteoporosis. • Current or history of breast cancer or other hormonally-sensitive malignancies. • Known liver impairment or disease. • Undiagnosed abnormal uterine bleeding. • Known hypersensitivity to ingredients of ORIAHNN. • Organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations. **Side effects:** Most common adverse reaction (>5%) in clinical trials were hot flushes, headache, fatigue, metrorrhagia. **Warning & Precaution:** • Thromboembolic Disorders and Vascular Events: Discontinue this medicine if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs. Stop this medicine if there is sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately. • Bone Loss: Duration-dependent decreases in bone mineral density (BMD) that may not be completely reversible. Baseline and periodic BMD assessments are recommended. Assess risk-benefit for women with additional risk factors for bone loss. • Suicidal Ideation and Mood Disorders: Advise patients to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes. • Hepatic Impairment and Transaminase Elevations: Counsel	New	US FDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						patients on signs and symptoms of liver injury. • Elevated Blood Pressure: Do not use in women with uncontrolled hypertension. For women with well-controlled hypertension, continue to monitor blood pressure and stop this medicine if blood pressure rises significantly. • Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy: Advise women to use non-hormonal contraception during treatment and for one week after discontinuing this medicine. This medicine may delay the ability to recognize the occurrence of a pregnancy because it alters menstrual bleeding. Perform pregnancy testing if pregnancy is suspected and discontinue this medicine if pregnancy is confirmed. • Risk of Allergic Reactions Due to the Inactive Ingredient (FD&C Yellow No 5): This product contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons.				
207.	Ziska Pharmaceuticals Ltd.	Elagolix 300 mg Capsule	Elagolix INN 300 mg	Hormone Therapeutic Code: 056	It is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitation of Use: • Use of it should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.	**Contraindications:** High risk of arterial, venous thrombotic, or thromboembolic disorder. • Pregnancy. • Known osteoporosis. • Current or history of breast cancer or other hormonally-sensitive malignancies. • Known liver impairment or disease. • Undiagnosed abnormal uterine bleeding. • Known hypersensitivity to ingredients of ORIAHNN. • Organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations. **Side effects:**	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Most common adverse reaction (>5%) in clinical trials were hot flushes, headache, fatigue, metrorrhagia. **Warning & Precaution:** • Thromboembolic Disorders and Vascular Events: Discontinue this medicine if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs. Stop this medicine if there is sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately. • Bone Loss: Duration-dependent decreases in bone mineral density (BMD) that may not be completely reversible. Baseline and periodic BMD assessments are recommended. Assess risk-benefit for women with additional risk factors for bone loss. • Suicidal Ideation and Mood Disorders: Advise patients to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes. • Hepatic Impairment and Transaminase Elevations: Counsel patients on signs and symptoms of liver injury. • Elevated Blood Pressure: Do not use in women with uncontrolled hypertension. For women with well-controlled hypertension, continue to monitor blood pressure and stop this medicine if blood pressure rises significantly. • Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy: Advise women to use non-hormonal contraception during treatment and for one week after discontinuing this medicine. This medicine may delay the ability to				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						recognize the occurrence of a pregnancy because it alters menstrual bleeding. Perform pregnancy testing if pregnancy is suspected and discontinue this medicine if pregnancy is confirmed. • Risk of Allergic Reactions Due to the Inactive Ingredient (FD&C Yellow No 5): This product contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons.				
208.	Ziska Pharmaceuticals Ltd.	Heparinoid 0.3% Cream	Heparinoid INN 0.3%	Local Anti-coagulant Therapeutic Code: 012	When applied to the skin, relieves pain and inflammation in addition to promoting healing in superficial thrombophlebitis (inflammation of the veins) and bruising (including haematoma).	**Contraindications:** Do not use • if you are allergic to heparinoid or any of the other ingredients of heparinoid cream. • if you have broken skin or large areas of skin. • on or near sensitive areas such as the mouth, eyes or ano-genital regions. • should not be used on children under the age of 5 years old. **Side effects:**Rarely heparinoid cream can cause a rash in sensitive individuals. **Warning & Precaution**: For external use only. If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.	New	UKMHRA, TGA & BNF-78 (page-1254)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
209.	Ziska Pharmaceuticals Ltd.	Heparinoid 0.3% Gel	Heparinoid INN 0.3%	Local Anti-coagulant Therapeutic Code: 012	When applied to the skin, relieves pain and inflammation in addition to promoting healing in superficial thrombophlebitis (inflammation of the veins) and bruising (including haematoma).	**Contraindications:**Do not use • if you are allergic to heparinoid or any of the other ingredients of heparinoid gel. • if you have broken skin or large areas of skin. • on or near sensitive areas such as the mouth, eyes or ano-genital regions. • should not be used on children under the age of 5 years old.	New	UKMHRA, TGA & BNF-78 (page-1254)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side effects: Rarely heparinoid gel can cause a rash in sensitive individuals. **Warning & Precaution**: For external use only. If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.				
210.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited	Mucopolysaccharide Polysulphate (MPS) 0.2% + Salicylic Acid 2% Gel	Mucopolysaccharide Polysulphate (MPS) INN 0.2% + Salicylic Acid USP 2%	Analgesic and Antipyretic Therapeutic Code: 006	When applied to the skin, provides relief from muscular pain and stiffness, sprains and strains, and pain due to rheumatic and non-serious arthritic conditions.	**Contraindications:** Do not use: • if you are allergic (hypersensitive) to mucopolysaccharide polysulfate, salicylic acid (or any other aspirin-like medicine) or other related painkillers known as non-steroidal anti-inflammatory drugs (NSAIDS). This is particularly important if you suffer from asthma • if you are allergic to any of the other ingredients • if you have broken skin, infected skin or eczema • on large areas of skin • on or near sensitive areas such as the mouth, eyes or ano-genital regions. • It should not be used on children under the age of 12 years old. **Side effects:** Rarely, it can cause the following in sensitive individuals: • redness • burning sensation • a rash. **Warning & Precaution:** For external use only. The stated dose should not be exceeded. If the condition persists or worsens, consult a doctor or pharmacist. Although systemic absorption of topical salicylate is much less than for oral dosage forms, the side	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						effects of salicylates are theoretically possible • Consult a doctor or pharmacist before use if pregnant, breast-feeding, asthmatic have pre-existing renal damage or on any prescribed medicines • Some people may experience discomfort, particularly those with sensitive skin or if used in hot weather or after a bath. Wash hands immediately after use • Discontinue use if excessive irritation or other unwanted effects occur Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.				
211.	Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur. Beximco Pharmaceuticals Ltd. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Pharmasia Limited	Bempedoic acid 180 mg Tablet	Bempedoic acid INN 180 mg	Antihypertensive **Therapeutic code:** 022	It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Limitations of Use: The effect of Bempedoic acid on cardiovascular morbidity and mortality has not been determined.	**Contraindications:**None. **Side effects:** Most common (incidence ≥ 2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. **Warning & Precaution:** Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. **USE IN SPECIFIC POPULATIONS:** Pregnancy: Based on mechanism of action, may cause fetal harm.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur. Opsonin Pharma Limited, Rupatali, Barishal.					Lactation: Breastfeeding is not recommended with Bempedoic acid.				
212.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Beximco Pharmaceuticals Ltd. Drug International Ltd (Unit-3) 31/1,Satrong, Tongi I/A, Gazipur. Acme Laboratories Ltd., Dhamrai, Dhaka Opsonin Pharma Limited, Rupatali, Barishal.	Bempedoic acid 180 mg + Ezetimibe 10 mg Tablet	Bempedoic acid INN 180 mg + Ezetimibe USP 10 mg	Antihypertensive **Therapeutic code:** 022	It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Limitations of Use: The effect of Bempedoic acid & Ezetimibe on cardiovascular morbidity and mortality has not been determined.	**Contraindications:** Known hypersensitivity to ezetimibe tablets. **Side effects:** Most common (incidence ≥2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis, fatigue, and influenza. **Warning & Precaution:** • Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with uratelowering drugs as appropriate. • Tendon Rupture: Tendon rupture has occurred. Discontinue this medication at the first sign of tendon rupture. Avoid this medication in patients who have a history of tendon disorders or tendon rupture. **<u>USE IN SPECIFIC POPULATIONS:</u>** Pregnancy: Based on mechanism of action, may cause fetal harm. Lactation: Breastfeeding is not recommended with Bempedoic acid and Ezetimibe.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
213.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Ziska Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Opsonin Pharma Limited, Rupatali, Barishal.	Lactic acid BP 1.8% + citric acid USP 1% + potassium bitartrate USP 0.4% Vaginal Gel	Lactic acid BP 1.8% + citric acid USP 1% + potassium bitartrate USP 0.4%	Contraceptive Therapeutic Code: 039	It is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.	**Contraindications:** None. **Side effects:** Most common adverse reactions (≥2%) were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain. **Warning & Precaution:** • Cystitis and Pyelonephritis: Avoid use in women with a history of recurrent UTI or urinary tract abnormalitiesx.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
214.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Empagliflozin 5 mg + Linagliptin 2.5 mg + Metformin HCl 1000 mg Extended Release Tablet	Empagliflozin INN 5 mg + Linagliptin INN 2.5 mg + Metformin HCl BP 1000 mg Extended Release Tablet	Anti-diabetics Therapeutic Code: 015	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use • Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis • Has not been studied in patients with a history of pancreatitis.	**Contraindication:** I) Severe renal impairment (eGFR less than 30 mL/min/1.73 m²), end-stage renal disease, or dialysis. II) Metabolic acidosis, including diabetic ketoacidosis. III) Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients. **Side-effect:** The most common adverse reactions associated with this drug (5% or greater incidence) were upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis. **WARNINGS AND PRECAUTIONS:** **LACTIC ACIDOSIS :** • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included	New	US FDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age ≥65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue it and institute general supportive measures in a hospital setting.				
215.	Ziska Pharmaceuticals Ltd.	Dequalinium Chloride 0.25 mg+ Lidocaine Hydrochloride 1 mg Lozenge	Dequalinium Chloride BP 0.25 mg+ Lidocaine Hydrochloride BP 1 mg	Analgesic & Antipyretics Therapeutic Code: 006	Adjuvant treatment for oroharyngeal disorder. In cardiological practice: treatment and prevention of ventricular arrhythmias (extrasystoles, tachycardia, atrial flutter, atrial fibrillation), including in acute myocardial infarction, implantation of artificial pacemaker in the glycoside intoxication, narcosis. Anaesthesia: terminal, infiltration, conduction, spinal (epidural) anesthesia in surgery, obstetrics and gynecology, urology, ophthalmology, dentistry, otolaryngology, blockade of peripheral nerves and ganglion.	**Contraindications:** Severe bleeding, shock, hypotension, infection of the proposed injection site, marked bradycardia, cardiogenic shock, severe forms of chronic heart failure, SSS in elderly patients, AV-block II and III degree (except in cases when the probe was introduced to stimulate the ventricles), severe liver function abnormalities. For subarachnoid anesthesia - complete heart block, bleeding, hypotension, shock, infection of the venue lumbar puncture, septicemia. Increased sensitivity to Dequalinium chloride and Lidocaine HCl and other amide type local anesthetics. **Side effects:** **CNS and peripheral nervous system: dizziness, headache, weakness, motor restlessness, nystagmus,loss of consciousness, drowsiness, visual and auditory**	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						disturbances, tremor, trismus, seizures (risk oftheir development against the backdrop of increasing hypercapnia and acidosis), a syndrome of"cauda equina" (paralysis of the legs, paresthesia), paralysis of respiratory muscles, respiratory arrest,a block of motor and sensitive, respiratory paralysis (usually develops in the subarachnoid anesthesia),numb tongue (when used in dentistry).Cardiovascular system: increased or decreased blood pressure, tachycardia if used with avasoconstrictor, peripheral vasodilatation, collapse, chest pain.Digestive system: nausea, vomiting, involuntary defecation.Allergic reactions: skin rash, hives (on skin and mucous membranes), itching, angioedema,anaphylactic shock.Local reactions: during spinal anesthesia a pain in theback, with an epidural anesthesia a random hit in the subarachnoid space, when applied topically in urology urethritis.Other: incontinent,methemoglobinemia, persistent anesthesia, decreased libido and / or potency,respiratory depression, until the stop, hypothermia; duringanesthesia in dentistry: numbness and paresthesia of the lips and tongue, the lengthening of anesthesia. **Warning & Precaution:** Use with caution in liver disease and kidney failure, hypovolemia, severe heart failure, in violation of the contractility of genetic susceptibility to malignant hyperthermia. In children, debilitated patients, elderly patients are required in dosage adjustment in				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						accordance with the age and physical status. When injected into vascularized tissue it is recommended an aspiration test.				
216.	Ziska Pharmaceuticals Ltd. Navana Pharmaceuticals Limited	Zinc 2.5 mg + Vitamin C 100 mg + Vitamin D3 5µg Lozenge	Zinc BP 2.5mg + Vitamin C BP 100mg + Vitamin D3 USP 5 µg	Vitamin & Mineral Therapeutic Code: 078	Immune system booster.	**Contraindications:** **Zinc:**It is contraindicated in patients known to have hypersensitivity to the drug or any of its components. **Vitamin-C:** No known contraindications. Use cautiously in patients with renal insufficiency. **Vitamin-D3:** Should not be given with hypercalcemia or evidence of vitamin-D toxicity. Also avoid in patients with hypersensitivity to propylene glycol & in premature infants. **Warning & Precaution:** **Zinc:**Parenteral use of zinc is contraindicated in patients with renal failure or biliary obstruction (and requires caution in all patients); monitor zinc plasma levels frequently. Don't exceed prescribed dosages. In patients with renal dysfunction or GI malfunction, trace metal supplements may need to be reduced, adjusted, or omitted. Hypersensitivity may result. Routine use of zinc supplementation during pregnancy isn't recommended. Administering copper in the absence of zinc or administering zinc in the absence of copper may result in decreased serum levels of either element. When only one trace element is needed, it should be added separately and serum levels monitored closely. To avoid overdose, administer multiple trace elements only when clearly needed. In patients with extreme vomiting or diarrhea, large amounts of trace element replacement may be needed. Excessive intake in healthy persons may be deleterious.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Vitamin-C: Hypersensitivity to ascorbic acid or any other ingredient found in the supplement. High doses of vitamin C increase the risk of a rare condition known as hyperoxaluria. **Vitamin-D3:** Hypersensitivity to Vitamin-D3. Use with cautious in case of hypervitaminosis D, hypercalcemia, malabsorption, heart disease, kidney disease, an electrolyte imbalance. **Side effects:** **Zinc:**The most common adverse reactions of oral zinc are nausea, bad taste, diarrhea, vomiting, mouth irritation, and, rarely, mouth sores. **Vitamin-C:** Redness and warm feeling of the skin, or flushing, Headache, Nausea, vomiting, or diarrhea, Upset stomach during or after eating, Feeling faint. **Vitamin-D3:** Side effects of taking too much vitamin D include weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea, vomiting, and others.				
217.	Ziska Pharmaceuticals Ltd. Opsonin Pharma Limited, Rupatali, Barishal.	Cangrelor 50 mg Lyophilized powder	Cangrelor INN 50 mg	Antiplatelet Therapeutic Code: 026	It is indicated as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a $P2Y_{12}$ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.	**Contraindications:** • Significant active bleeding. • Hypersensitivity to Cangrelor or any component of the product. **Side effects:** The most common adverse reaction is bleeding. **Warning & Precaution:** Bleeding: Like other drugs that inhibit platelet P2Y12 function, Cangrelor can increase the risk of bleeding.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
218.	Beximco Pharmaceuticals Ltd. Ziska Pharmaceuticals Ltd.	Bilastine 2.5 mg /ml Oral Solution	Bilastine INN 2.5 mg /ml	Antihistamine Therapeutic Code: 021	It is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic	**Contraindications:** Do not use Bilastine: - if your child is allergic to bilastine or any of the other ingredients of this medicine	Bilastine 20 mg Tablet	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Navana Pharmaceuticals Limited Square Pharmaceuticals Ltd, Salgaria, Pabna.				rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria). It is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.	**Side effects:** Common: may affect up to 1 in 10 people • rhinitis (nasal irritation) • allergic conjunctivitis (eye irritation) • headache • stomach pain (abdominal /upper abdominal pain) Uncommon: may affect up to 1 in 100 people • eye irritation. dizziness • loss of consciousness •diarrhoea• nausea (the feeling of being sick) • lip swelling • eczema • urticaria (hives) • fatigue. **Warnig& Precaution:** Talk to doctor or pharmacist before usingBilastine if patient have moderate or severe renal impairment and in addition patient is taking other medicines.				
219.	Ziska Pharmaceuticals Ltd.	Naftidrofuryl oxalate 200 mg capsule	Naftidrofuryl oxalate BP 200 mg	Peripheral vasodilator Therapeutic Code: 046	Peripheral vascular disorders - intermittent claudication, night cramps, rest pain, incipient gangrene, trophic ulcers, Raynaud's Syndrome, diabetic arteriopathy and acrocyanosis.	**Contraindications:**Hypersensitivity to the drug: patient with a history of hyperoxaluria or recurrent calcium-containing stones. **Side effects:** Occasionally nausea, epigastric pain & rashes have been noted. **Warning & Precaution:**The administration of Naftidrofuryl may modify the composition of the urine, promoting the formation of calcium oxalate kidney stones (the oxalate content is 19 mg per 100 mg of active ingredient).A sufficient amount of liquid should be taken during treatment to maintain an adequate level of diuresis.The administration of Naftidrofuryl without liquid before going to bed may cause local oesophagitis. Therefore, it is essential to always take the capsule with a sufficient amount of water.Cases of liver damage have been reported. In the event of symptoms suggesting liver damage, Naftidrofuryl must be discontinued.	Naftidrofuryl oxalate BP 100 mg	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
220.	Popular Pharmaceuticals Limited 164, Tongi I/A, Tongi, Gazipur	Colecalciferol 50000 IU Tablet	Colecalciferol BP 50000 IU Tablet	Vitamins and Combinations **Therapeutic code: 078**	Vitamin D_3 deficiency can occur in people whose exposure to sunlight is limited and in those whose diet is deficient in vitamin D_3. Vitamin D_3 is essential for the effective calcium and phosphate absorption required for healthy bones and teeth, preventing rickets, osteomalacia and osteoporosis. High doses are also very effective in institutionalized or hospitalized patients. Vitamin D_3 is important during pregnancy and breast-feeding as it is an essential nutrient for a growing infant. But Vitamin D_3 in such high doses may cause toxicity and therefore should be taken only if prescribed by a physician.	**Contraindication:** Vitamin D_3 is contraindicated in all diseases associated with hypercalcaemia. It is also contraindicated in patients with known hypersensitivity to Vitamin D_3 (or medicines of the same class) and any of the excipients. It is contraindicated if there is evidence of Vitamin D_3 toxicity. **Side-effects:** Symptoms rarely include anorexia, lassitude, nausea & vomiting, diarrhea, constipation, weight loss, polyuria, sweating, headache, thirst, vertigo, and raised concentrations of calcium and phosphate in plasma and urine.	1. Colecalciferol 1000 IU Tablet 2. Colecalciferol 2000 IU Tablet 3. Colecalciferol 20000 IU Capsule 4. Colecalciferol 40000 IU Capsule	**BNF-78 (page- 1084)** **UKMHRA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
221.	Popular Pharmaceuticals Limited 164, Tongi I/A, Tongi, Gazipur	Bilastine 12.5 Mg Per 5 ML Syrup	Bilastine INN 12.5 Mg Per 5 ML Syrup	Antihistamine **Therapeutic code: 021**	Allergic Rhinitis: Bilastine is indicated for the symptomatic relief of nasal and non-nasal symptoms of allergic rhinitis. Allergic Rhinoconjunctivitis: Bilastine is indicated for the relief of the symptoms associated with allergic rhinoconjunctivitis.Urticaria: Bilastine is indicated for the relief of the symptoms associated with urticaria (e.g. pruritus and hives).	**Contraindication:** Bilastine is contraindicated in patients with: Hypersensitivity to Bilastine or to any ingredient in the formulation or component of the Syrup. **Side-effects:** The most common side effects of Bilastine include: headache, dizziness, and fatigue.	5. Bilastine INN 20 mg Tablet	**UKMHRA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
222.	Popular Pharmaceuticals Limited 164, Tongi I/A, Tongi, Gazipur	Frovatriptan Succinate 3.910 mg equivalent to Frovatriptan 2.5 mg Film Coated Tablet	Frovatriptan Succinate 3.910 mg equivalent to Frovatriptan 2.5 mg	Drug used in migraine **Therapeutic code: 047**	Frovatriptan is a serotonin (5-HT1B/1D) receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use • Use only after a clear diagnosis of migraine has been established.	**Contraindication:** History of coronary artery disease or coronary artery vasospasm. • Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders. • History of stroke, transient ischemic attack, or hemiplegic or basilar migraine.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					• Not indicated for the prophylactic therapy of migraine. • Not indicated for the treatment of cluster headache.	• Peripheral vascular disease. • Ischemic bowel disease. • Uncontrolled hypertension. • Recent (within 24 hours) use of treatment with another 5-HT1 agonist, or an ergotamine-containing medication. • Hypersensitivity to Frovatriptan (angioedema and anaphylaxis seen). **Side-effects:** Most common adverse reactions were dizziness, headache, paresthesia, dry mouth, dyspepsia, fatigue, hot or cold sensation, chest pain, skeletal pain, and flushing.				
223.	Beximco Pharmaceuticals Ltd.	Benidipine Hydrochloride INN 2.00mg Tablet	Benidipine Hydrochloride INN 2.00mg	Antihypertensive **Therapeutic code: 022**	It is a potent and long-lasting drug indicated for the treatment of cardiovascular diseases such as hypertension, renoparenchymal hypertension and angina pectoris.	**Contrindication:** • Hypersensitivity to the dihydropyridine Ca2+ channel blockers. • Pregnancy and lactation **Side effects:** • Headache • Dizziness • Constipation • Skin rash • Decreased blood pressure • Nausea • Lightheadedness • Palpitations Edema	New	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
224.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Famotidine 10 mg + Calcium carbonate 800 mg + Magnesium hydroxide 165 mg Chewable Tablet	Famotidine BP 10 mg + Calcium Carbonate BP 800 mg + Magnesium Hydroxide BP 165mg	H2 Receptor Blocking **Therapeutic code: 055**	It relieves heartburn associated with acid indigestion and sour stomach.	**Contrindication:** Hypersensitivity to any of the active components, other acid reducers, or to any of the ingredients	Famotidine BP 20 mg and 40 mg tablet.	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						-Patients that have trouble/pain swallowing food, vomiting with blood, or bloody/black stools -Use with other acid reducers Safety and efficacy have not been established in patients younger than 12 years. **Side Effects**: Even though it may be rare, some people may have faced side effects when taking this drug. For example- • Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. • Dizziness or passing out. • A fast heartbeat. • A heartbeat that does not feel normal. Muscle weakness.				
225.	Beximco Pharmaceuticals Ltd.	Dextromethorphan polistirex 0.800gm/100 ml Extended release suspension	Dextromethorphan polistirex 0.800gm/100 ml (equivalent to Dextromethorphan hydrobromide BP 30 mg/ml)	Common Cold Preparations **Therapeutic code: 038**	It is temporarily relieving cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants	**Contraindications**: Hypersensitivity to any of the ingredients. Taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication. If you are not sure if your prescription medication contains one of these medicines, ask a doctor or pharmacist before taking this product. **Side effects:** Along with its needed effects, dextromethorphan may cause some unwanted effects. Although not all	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						of these side effects may occur, if they do occur they may need medical attention. Check with your doctor as soon as possible if any of the following side effects occur while taking dextromethorphan: common side effects are: • Confusion • constipation • dizziness (mild) • drowsiness (mild) • headache • nausea or vomiting stomach pain				
226.	Beximco Pharmaceuticals Ltd. Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Levamlodipine 1.600mg (eq. to Levamlodipine 1.25 mg) tablet.	Levamlodipine INN 1.600mg (eq. to Levamlodipine 1.25 mg)	Antihypertensive **Therapeutic code:** 022	**Levamlodipine, also known as S-amlodipine, is a pharmacologically active enantiomer of amlodipine.**. Levamlodipine is indicated for the treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including Levamlodipine. Levamlodipine may be used alone or in combination with other antihypertensive agents.	**Contraindications:** Levamlodipine is contraindicated in patients with known sensitivity to amlodipine. **Side effects:** Side effects of Conjupri include: • fluid retention (edema), • fatigue, • nausea, • abdominal pain, • flushing, • palpitations, and • drowsiness **WARNINGS AND PRECAUTIONS:** • Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely. • Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of amlodipine, particularly in patients with severe obstructive coronary artery disease. Titrate slowly in patients with severe hepatic impairment.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
227.	Beximco Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Levamlodipine 2.50 mg Tablet	Levamlodipine Maleate INN 3.21 mg eqv. to Levamlodipine 2.50 mg	Antihypertensive **Therapeutic code:** 022	**Levamlodipine, also known as S-amlodipine, is a pharmacologically active enantiomer of amlodipine.**. Levamlodipine is indicated for the treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including Levamlodipine. Levamlodipine may be used alone or in combination with other antihypertensive agents.	**Contraindications:** Levamlodipine is contraindicated in patients with known sensitivity to amlodipine. **Side effects:** Side effects of Conjupri include: • fluid retention (edema), • fatigue, • nausea, • abdominal pain, • flushing, • palpitations, and • drowsiness **WARNINGS AND PRECAUTIONS:** • Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely. • Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of amlodipine, particularly in patients with severe obstructive coronary artery disease. Titrate slowly in patients with severe hepatic impairment.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
228.	Beximco Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Levamlodipine 5 mg Tablet	Levamlodipine Maleate INN 6.42 mg eqv. to Levamlodipine 5 mg	Antihypertensive **Therapeutic code:** 022	**Levamlodipine, also known as S-amlodipine, is a pharmacologically active enantiomer of amlodipine.**. Levamlodipine is indicated for the treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic	**Contraindications:** Levamlodipine is contraindicated in patients with known sensitivity to amlodipine. **Side effects:** Side effects of Conjupri include: • fluid retention (edema), • fatigue, • nausea, • abdominal pain, • flushing, • palpitations, and • drowsiness **WARNINGS AND PRECAUTIONS:**	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					classes including Levamlodipine. Levamlodipine may be used alone or in combination with other antihypertensive agents.	• Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely. • Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of amlodipine, particularly in patients with severe obstructive coronary artery disease. Titrate slowly in patients with severe hepatic impairment.				
229.	Beximco Pharmaceuticals Ltd.	Nebivolol Hydrochloride equivalent to Nebivolol 5 mg and Valsartan 80 mg tablet	Nebivolol Hydrochloride INN equivalent to Nebivolol 5 mg and Valsartan USP 80 mg	Antihypertensive Therapeutic Code:022	It is indicated for the treatment of hypertension	**Contraindications:** Nebivolol and Valsartan single pill combination is contraindicated in the following conditions: • Severe bradycardia • Heart block greater than first degree • Patients with cardiogenic shock • Decompensated cardiac failure • Sick sinus syndrome (unless a permanent pacemaker is in place) • Patients with severe hepatic impairment (Child-Pugh >B) • Hypersensitivity to any component of this product **Side effects:** Common side effects include dizziness, drowsiness, tired feeling, flushing (warmth, redness, or tingly feeling), back pain, nausea, diarrhea, stomach pain. Swelling hands/ankles/feet or flushing may also occur. WARNINGS AND PRECAUTIONS Acute exacerbation of coronary artery disease upon cessation of therapy: Do not abruptly discontinue.	Nebivolol 2.5 mg and 5 mg, Valsartan 80 mg and 160 mg 6.	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Diabetes: Monitor glucose as β-blockers may mask symptoms of hypoglycemia. • Monitor renal function and potassium in susceptible patients.				
230.	Beximco Pharmaceuticals Ltd.	Dupilumab 200 mg /1.14ml Injection	Dupilumab INN 200 mg/1.14 ml	Skin & Mucous Membran Preperations Therapeutic Code:071	Atopic Dermatitis Dupilumabt is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. Asthma Dupilumab is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.	**Contraindications:** Known hypersensitivity to Dupilumab **Side effects:** Atopic Dermatitis: Most common adverse reactions (incidence ≥1%) are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, and dry eye. Asthma: Most common adverse reactions (incidence ≥1%) are injection site reactions, oropharyngeal pain, and eosinophilia. WARNINGS AND PRECAUTIONS • Hypersensitivity: Hypersensitivity reactions (urticaria, rash, erythema nodosum, anaphylaxis, and serum sickness) have occurred after administration of this drug. Discontinue this drug in the event of a hypersensitivity reaction. • Conjunctivitis and Keratitis: Patients should report new onset or worsening eye symptoms to their healthcare provider. • Eosinophilic Conditions: Be alert to vasculitic rash, worsening pulmonary symptoms, and/or neuropathy, especially upon reduction of oral corticosteroids. • Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of therapy with this drug. Decrease steroids gradually, if appropriate. • Parasitic (Helminth) Infections: Treat patients with pre-existing helminth	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						infections before initiating therapy with this drug. If patients become infected while receiving treatment with this drug and do not respond to anti-helminth treatment, discontinue treatment with this drug until the infection resolves.				
231.	Beximco Pharmaceuticals Ltd.	Glycopyrrolate (Glycopyrronium bromide) eq. to 50 mcg Glycopyrronium , Indacaterol (as acetate) 150 mcg & Mometasone furoate 160 mcg Dry powder for inhalation (DPI) capsule	Glycopyrrolate (Glycopyrronium bromide) eq. to 50 mcg Glycopyrronium , Indacaterol (as acetate) 150 mcg & Mometasone furoate 160 mcg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	It is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients **Side effects:** The most common adverse reactions over 52 weeks were asthma (exacerbation) (41.8%), nasopharyngitis (10.9%), upper respiratory tract infection (5.6%) and headache (4.2%).	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
232.	Beximco Pharmaceuticals Ltd.	Metoclopramide Hydrochloride 25.329 gm (eq. to Metoclopramide 21.429gm) / 100ml Nasal Spray	Metoclopramide Hydrochloride BP 25.329 gm (eq. to Metoclopramide 21.429gm) / 100ml	Proton Pump Inhabitor Therapeutic Code:067	It is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis	**Contraindications:** History of TD or dystonic reaction to Metoclopramide • When stimulation of gastrointestinal motility might be dangerous) • Pheochromocytoma, catecholamine-releasing paragangliomas) • Epilepsy • Hypersensitivity to metoclopramide **Side effects:** Most common adverse reactions (≥5%) are: dysgeusia, headache, and fatigue. **WARNINGS AND PRECAUTIONS** • Tardive dyskinesia (TD), other extrapyramidal symptoms (EPS), and neuroleptic malignant syndrome (NMS): Avoid concomitant use of other drugs known to cause TD/EPS/NMS and avoid use in patients with Parkinson's disease. If symptoms occur, discontinue this drug and seek immediate medical attention. • Depression and suicidal ideation/suicide: Avoid use **ADVERSE REACTIONS** Most common adverse reactions (≥5%) are: dysgeusia, headache, and fatigue.	Metoclopramide 10 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
233.	Beximco Pharmaceuticals Ltd. Acme Laboratories Ltd., Dhamrai, Dhaka	Oliceridine Fumarate 2.60 mg (eq. to 2mg Oliceridine) / 2ml Injection	Oliceridine Fumarate INN 2.60 mg (eq. to 2mg Oliceridine) / 2ml	Opioid Analgesic Therapeutic class:065	Indicated for management of moderate-to-severe acute pain that is severe enough to require an IV opioid and for which alternative treatments are inadequate	**Contraindications:** Significant respiratory depression. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment. Known or suspected GI obstruction, including paralytic ileus. Known hypersensitivity (eg, anaphylaxis) **Side effects:** The most common Side effects are: Nausea (56-75%) Vomiting (22-43%) Dizziness (9-35%) Hypoxia (5-20% Somnolence (5-19%) Pruritus (11-17%) Constipation (11-17%) Sedation (9-14%) Back pain (11-13%) **WARNINGS AND PRECAUTIONS** Potential for QT Prolongation with Daily Doses Exceeding 27 mg: May increase risk for QT interval prolongation. Do not exceed a cumulative daily dose of 27 mg. Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. Adrenal Insufficiency: If diagnosed, treat with physiologic replacement corticosteroids and wean the patient off the opioid. Severe Hypotension: Monitor patients during initiation or titration. Avoid use of this drug in patients with circulatory shock. Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Consciousness: Monitor for signs of sedation and respiratory depression. Avoid the use of this drug in patients with impaired consciousness or coma. **ADVERSE REACTIONS** The most common (incidence ≥10%) adverse reactions in controlled clinical trials (Studies 1 and 2) were nausea, vomiting, dizziness, headache, constipation, pruritus, and hypoxia.				
234.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oliceridine 1 mg/ml Injection	Oliceridine Fumarate INN 1.30 mg eqv. to Oliceridine 1 mg/ml	Opioid Analgesic Therapeutic class:065	Indicated for management of moderate-to-severe acute pain that is severe enough to require an IV opioid and for which alternative treatments are inadequate	**Contra-indication:** Significant respiratory depression, Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment, Known or suspected gastrointestinal obstruction, including paralytic ileus, Known hypersensitivity to Oliceridine. **Side-effects:** Nausea, vomiting, dizziness, headache, constipation, itching, and low blood oxygen. **Warnings & Precautions:** • Addiction, Abuse, and Misuse • Life-threatening Respiratory Depression Neonatal Opioid Withdrawal Syndrome • Interactions with Benzodiazepines or Other CNS Depressants • Adrenal Insufficiency • Severe Hypotension • Gastrointestinal Adverse Reactions Seizures	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
235.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oliceridine 30 mg/30 ml Injection	Oliceridine Fumarate INN 39 mg eqv. to Oliceridine 30 mg/30 ml	Opioid Analgesic Therapeutic class:065	Indicated for management of moderate-to-severe acute pain that is severe enough to require an IV opioid and for which alternative treatments are inadequate	**Contra-indication:** Significant respiratory depression, Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment, Known or suspected gastrointestinal obstruction, including paralytic ileus, Known hypersensitivity to Oliceridine. **Side-effects:** Nausea, vomiting, dizziness,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						headache, constipation, itching, and low blood oxygen. **Warnings & Precautions:** • Addiction, Abuse, and Misuse • Life-threatening Respiratory Depression Neonatal Opioid Withdrawal Syndrome • Interactions with Benzodiazepines or Other CNS Depressants • Adrenal Insufficiency • Severe Hypotension • Gastrointestinal Adverse Reactions Seizures				
236.	Beximco Pharmaceuticals Ltd.	Amlodipine Besilate 13.890mg equivalent to Amlodipine 10 mg and Olmesartan Medoxomil 40 mg tablet	Amlodipine Besilate BP 13.890mg equivalent to Amlodipine 10 mg and Olmesartan Medoxomil BP 40 mg.	Antihypertensive Therapeutic code:022	Indicated for dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents.	**Contraindications:** It is contraindicated with aliskiren in patients with diabetes and hypersensitivity to the active substance or to any of the excipients. **Side effects:** The most common side effects include edema, dizziness, flushing, palpitation. Other side effects may include vomiting, diarrhoea, rhabdomyolysis, alopecia, pruritus, urticaria etc. **Warnings and Precautions**: Hypotension in volume- or salt-depleted patients with treatment initiation may be anticipated. Start treatment under close supervision. Increased angina or myocardial infarction may occur upon dosage initiation or increase. Impaired renal function: changes in renal function may be anticipated in susceptible individual. Sprue-like enteropathy has been reported. Consider discontinuation of this medication in cases where no other etiology is found.	Amlodipine Besilate 6.640mg equivalent to Amlodipine 5 mg and Olmesartan Medoxomil 40 mg tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Hepatic Impairment: Caution should be exercised when administering the drug to patients with severe hepatic impairment.				
237.	Beximco Pharmaceuticals Ltd.	Efavirenz 400 mg tablet	Efavirenz USP 400 mg	Antiviral Therapeutic Code: 032	Efavirenz is indicated in antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected adults, adolescents and children 3 months of age and older	**Contraindications:** Hypersensitivity to Bilastine or to any of the excipients. Patients with severe hepatic impairment (Child Pugh Code C **Side effects:** the most frequently reported adverse reactions of at least moderate severity reported in at least 5% of patients were rash (11.6%), dizziness (8.5%), nausea (8.0%), headache (5.7%) and fatigue (5.5%). The most notable adverse reactions associated with efavirenz are rash and nervous system symptoms. Nervous system symptoms usually begin soon after therapy onset and generally resolve after the first 2 - 4 weeks. Receiving placebo (68.5% versus 67.5%). **WARNINGS AND PRECAUTIONS** • Do not use as a single agent or add on as a sole agent to a failing regimen. Consider potential for cross-resistance when choosing other agents. • Not recommended contains efavirenz, emtricitabine, and tenofovir disoproxil fumarate, unless needed for dose adjustment when coadministered with rifampin. • Serious psychiatric symptoms: Immediate medical evaluation is recommended for serious psychiatric symptoms such as severe depression or suicidal ideation. • Nervous system symptoms (NSS): NSS are frequent and usually begin 1-2 days after initiating therapy and resolve in 2-4 weeks. Dosing at bedtime may improve tolerability. NSS are not predictive of onset of psychiatric symptoms.	Efavirenz 600 mg tablet.	WHO Guideline CMSD তে দরপত্রে অংশ গ্রহণের জন্য	শুধুমাত্র সরকারি দরপত্রে অংশ গ্রহণের নিমিত্তে অনুমোদনের সুপারিশ করা হয়।	শুধুমাত্র সরকারি দরপত্রে অংশ গ্রহণের নিমিত্তে অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Embryo-Fetal Toxicity: Avoid administration in the first trimester of pregnancy as fetal harm may occur. • Hepatotoxicity: Monitor liver function tests before and during treatment in patients with underlying hepatic disease, including hepatitis B or C coinfection, marked transaminase elevations, or who are taking medications associated with liver toxicity. Among reported cases of hepatic failure, a few occurred in patients with no pre-existing hepatic disease. • Rash: Rash usually begins within 1-2 weeks after initiating therapy and resolves within 4 weeks. Discontinue if severe rash develops. • Convulsions: Use caution in patients with a history of seizures. • Lipids: Total cholesterol and triglyceride elevations. Monitor before therapy and periodically thereafter. • Immune reconstitution syndrome: May necessitate further evaluation and treatment. • Redistribution/accumulation of body fat: Observed in patients receiving antiretroviral therapy. ADVERSE REACTIONS: Most common adverse reactions (>5%, moderate-severe) are impaired concentration, abnormal dreams, rash, dizziness, nausea, headache, fatigue, insomnia, and vomiting.				
238.	Beximco Pharmaceuticals Ltd.	Amlodipine Besilate 13.890mg equivalent to Amlodipine 10 mg and Olmesartan Medoxomil 20 mg tablet	Amlodipine Besilate BP 13.890mg equivalent to Amlodipine 10 mg and Olmesartan Medoxomil BP 20 mg.	Antihypertensive Therapeutic code:022	Indicated for dihydropyridine calcium channel blocker and angiotensin II receptor blocker combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents.	**Contraindications:** It is contraindicated with aliskiren in patients with diabetes and hypersensitivity to the active substance or to any of the excipients. **Side effects:** The most common side effects include edema, dizziness, flushing, palpitation. Other side effects may include vomiting, diarrhoea,	Amlodipine Besilate 6.640mg equivalent to Amlodipine 5 mg and Olmesartan	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						rhabdomyolysis, alopecia, pruritus, urticaria etc. **Warnings and Precautions**: Hypotension in volume- or salt-depleted patients with treatment initiation may be anticipated. Start treatment under close supervision. Increased angina or myocardial infarction may occur upon dosage initiation or increase. Impaired renal function: changes in renal function may be anticipated in susceptible individual. Sprue-like enteropathy has been reported. Consider discontinuation of this medication in cases where no other etiology is found. Hepatic Impairment: Caution should be exercised when administering the drug to patients with severe hepatic impairment.	Medoxomil 20 mg tablet			
239.	Beximco Pharmaceuticals Ltd.	Efavirenz 400 mg + Lamivudine 300mg + Tenofovir disoproxil fumarate 300 mg tablet	Efavirenz USP 400 mg, Lamivudine USP 300mg and Tenofovir disoproxil fumarate INN 300 mg	Antiviral Therapeutic Code:032	Treatment of HIV-1 infection in adult and pediatric patients weighing ≥40 kg	**Contraindications:** contraindicated in patients with a previous hypersensitivity reaction (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to any of the components contained in the formulation **Side effects:** Most common adverse reactions (> 5%) are rash and dizziness **WARNINGS AND PRECAUTIONS** • Lactic Acidosis/Severe Hepatomegaly with Steatosis: Discontinue treatment in patients who develop symptoms or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity. • New Onset or Worsening Renal Impairment: Can include acute renal failure and Fanconi syndrome. Assess estimated creatinine clearance before	Efavirenz 600 mg tablet., Tenofovir disoproxil fumarate 300 mg tablet, Lamivudine 150 mg tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						initiating treatment with tenofovir disoproxil fumarate, a component of this drug. In patients at risk for renal dysfunction, assess estimated creatinine clearance, serum phosphorus, and urine glucose and urine protein before initiating treatment with tenofovir and periodically during treatment. Avoid administering this drug with concurrent or recent use of nephrotoxic drugs. • Serious Psychiatric Symptoms: Immediate medical evaluation is recommended for serious psychiatric symptoms such as severe depression or suicidal ideation. • Nervous System Symptoms (NSS): NSS are frequent, usually begin 1 to 2 days after initiating therapy and resolve in 2 to 4 weeks. Dosing at bedtime may improve tolerability. NSS are not predictive of onset of psychiatric symptoms. • Rash: Rash usually begins within 1 to 2 weeks after initiating therapy and resolves within 4 weeks. Discontinue if severe rash develops. • Hepatotoxicity: Monitor liver function tests before and during treatment in patients with underlying hepatic disease, including hepatitis B or C coinfection, marked transaminase elevations, or who are taking medications associated with liver toxicity. Among reported cases of hepatic failure, a few occurred in patients with no pre-existing hepatic disease. • Hepatic decompensation, some fatal, has occurred in HIV-1/HCV coinfected patients receiving combination antiretroviral therapy and interferon and ribavirin-based regimens. Monitor for treatment-associated toxicities. Discontinue this drug, as medically				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						appropriate, and consider dose reduction or discontinuation of interferon alfa, ribavirin, or both. • Pancreatitis: Use with caution in pediatric patients with a history of pancreatitis or other significant risk factors for pancreatitis. Discontinue this drug as clinically appropriate. • Convulsions: Use caution in patients with a history of seizures. • Lipids: Total cholesterol and triglyceride elevations. Monitor before therapy and periodically thereafter. • Decreases in Bone Mineral Density (BMD): Observed in HIV-infected patients. Consider assessment of BMD in patients with a history of pathologic fracture or other risk factors for osteoporosis or bone loss. • Immune Reconstitution Syndrome: Observed in HIV-infected patients. May necessitate further evaluation and treatment. • Redistribution/Accumulation of Body Fat: Observed in HIV-infected patients receiving antiretroviral combination therapy. **ADVERSE REACTIONS:** Most common adverse reactions (> 5% with this drug) are rash and dizziness.				
240.	Navana Pharmaceuticals Limited	Pranlukast hydrate INN 10% Dry syrup	Pranlukast hydrate INN 10% Dry syrup	COPD Therapeutic code: 044	Treatment in adult and paediatric patients with persistent asthma of all severities	Contraindications: None Side Effects: Diarrhea, dizziness, and bilateral leg edema	New	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
241.	Navana Pharmaceuticals Limited	Pranlukast hydrate 112.5 mg Capsule	Pranlukast hydrate 112.5 mg	COPD Therapeutic code: 044	Treatment in adult patients with persistent asthma of all severities	Contraindications: None Side Effects: Diarrhea, dizziness, and bilateral leg edema	New	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
242.	Navana Pharmaceuticals Limited	Colecalciferol (Vitamin D3)	Colecalciferol (Vitamin D3) [1 MIU/g] BP 0.20 mg eqv. to Vitamin D3 200 IU/0.5 ml Syrup	Vitamins Therapeutic Code: 078	Vitamin D deficiency	Contraindications: Hypercalcemia Side Effects: Laryngeal oedema, drymouth, muscle pain, pancreatitis, abdominal pain	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
243.	Navana Pharmaceuticals Limited	Acetylcystein INN 600mg effervescent Tablet	Acetylcystein INN 600mg	Antitussives, Expectorants and Mucolytic Therapeutic Code: 031	Indicated for use as a mucolytic in respiratory disorders such as in bronchitis, emphysema, mucoviscidoses and bronchiectasis	**Contraindications:** Hypersensitivity to acetylcysteine or to any of the excipients. The tablets should not be used by children under 2 years of age. **Side Effects:** Headache, Tinnitus, Stomatitis, abdominal pain, nausea, vomiting, diarrhoea, Pyrexia, Low blood pressure **Warnings and precautions:** Bronchospasms may occur with the use of Acetylcysteine. If bronchospasm occurs, the medicinal product should be discontinued immediately. Caution is advised in patients with a history of peptic ulcer, especially when used concomitantly with other medicinal products known to irritate the mucous membrane of the gastrointestinal tract. Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have very rarely been reported in temporal connection with the use of acetylcysteine. In most cases, at least one other suspect medicinal product, which was more likely the cause of the mucocutaneous syndrome could be identified. If cutaneous or mucosal alterations newly occur, immediate medical advice should be sought and the treatment with Acetylcysteine should be discontinued immediately. Bronchial secretions may become more fluid and increase in volume, in particular at the start of the treatment with acetylcysteine. When a patient is unable to cough up the secretions effectively, postural drainage and bronchoaspiration should be performed	New	BNF-76 (Page-290)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
244.	Navana Pharmaceuticals Limited Acme Laboratories Ltd., Dhamrai, Dhaka Nuvista Pharma Ltd.	Clascoterone 150 mg/15 g (1%) Cream	Clascoterone Cream 1%	Skin and Mucous Membrane Preparations Therapeutic Code: 071	is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older	**Contraindications:** None **Side Effects:** Most common adverse reactions occuing in 7 to 12% of patients are erythema/reddening. pruritis and scaling/dryness. Additionally edema, stinging and burning occured in >3 % of patients and were reported in a similar percentage of subjects treated with vehicle. **Warnings and precautions:** Local irritation : Pruritus,burning,skin redness or peeling may be experienced with clascoterone cream.If these effects occure, discontinue or reduce the frequency of application of Clascoterone cream. Hypothalamic – pituitary-adrenal (HPA) axis suppression may occur during or after treatment with Clascoterone. Attempt to withdraw use if HPA axis suppression develops. Pediatric patients may be more susceptible to systemic toxicity. Hyperkalemia: elevated pottassium levels were observed in some subjects during the clinical trials.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
245.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Memantine HCl 7 mg+ Donepezil HCl 10 mg ER Capsule	Memantine HCl (15 % w/w) ER pellets INN 46.6666 mg eq to mamantine Hcl 7 mg+ Donepezil HCl (20 % w/w)ER pellets INN 20 mg eq to Donepezil HCL 10 mg	Cholinergic Therapeutic Code: 037	MEMANTINE HCL & Donepezil HCl is indicated for the treatment of moderate to severe Alzheimer's type dementia	**Contraindication** Contraindicated in patients with known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation. **Side-effects:** • The most common adverse reactions occurring at a frequency of at least 5% and greater than placebo with memantine hydrochloride extendedrelease 28 mg/day were headache, diarrhea, and dizziness	Existing Memantine Hydrochloride 14mg Extended-Release + Donepezil Hydrochloride	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• The most common adverse reactions occurring at a frequency of at least 5% in patients receiving donepezil and at twice or more the placebo rate, include diarrhea, anorexia, vomiting, nausea, and ecchymosis. **<u>WARNINGS AND PRECAUTIONS:</u>** This drug is likely to exaggerate succinylcholine-type muscle relaxation during anesthesia . • This drug may have vagotonic effects on the sinoatrial and atrioventricular nodes manifesting as bradycardia or heart block • Monitor patients for symptoms of active or occult gastrointestinal bleeding, especially those at increased risk for developing ulcers • This drug can cause diarrhea, nausea, and vomiting • This drug may cause bladder outflow obstructions • Conditions that raise urine pH may decrease the urinary elimination of memantine, resulting in increased plasma levels of memantine.	10mg Capsule (DCC 250) Memantine Hydrochloride 28mg Extended-Release + Donepezil Hydrochloride 10mg Capsule (DCC 250)			
246.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Citicoline 100mg/ml Oral Solution	Citicoline sodium INN 104.505mg eqv. to Citicoline 100mg/ml	Cerebral Vasodilator Therepeutic Code: 036	Citicoline is indicated in adults for: • Ischemic stroke, acute phase and its neurological sequelae (as a part of complex therapy) • Rehabilitation period of ischemic and hemorrhagic stroke • Traumatic Brain injury and its neurological sequelae, acute phase (as a part of complex therapy) and rehabilitation period Cognitive and behavioral impairment secondary to	**Contraindications:** • Hypersensitivity to any component • Expressed vagotonia • Rare inherited diseases associated with fructose intolerance • Because of the absence of sufficient clinical data Ceraxon OS is not recommended for use in children under 18 years **Side-effect**: Most people who take citicoline don't experience problematic side effects. But some people can have side effects such as trouble sleeping (insomnia), headache,	Citicoline 500mg Tablet, Citicoline 500 mg/4 ml Injection	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					chronic vascular and degenerative cerebral disorders.	constipation, diarrhea, nausea, stomach pain, blurred vision, chest pains, and others.				
247.	Renata Limited **Mirpur, Dhaka**	Vitamin A (Retinyl Acetate) USP 0.80mg + Vitamin D3 (Colecalciferol) USP 0.005mg (Equivalent to 200 IU of Vitamin D3) + Vitamin C (Ascorbic Acid Coated) USP 70mg + Vitamin B1(as Thiamine Mononitrate) USP 1.4mg + Vitamin B2 (as Riboflavin 5 phosphate Sodium) USP 1.4mg + Vitamin B6 (as Pyridoxine Hydrochloride) USP 1.9mg + Vitamin E Acetate USP 10.98mg (Equivalent to 10mg Vitamin E as Vitamin E Acetate) + Niacinamide USP 18mg + Vitamin B12 (Cyanocobalamin) USP 0.0026 mg + Folic Acid USP 0.4mg + Ferrous Fumarate USP 91.28mg (Equivalent to 30mg Iron as Ferrous Fumarate) +Copper gluconat USP 14.28mg (Equivalent to 2mg Copper as Copper Gluconate) + Zinc Gluconate USP 104.55mg (Equivalent to 15mg Zinc as Zinc Gluconate) + Potassium Iodide USP 0.196mg (Equivalent to 0.150mg Iodine as Potassium Iodide) + Sodium Selenite Anhydrous USP 0.142mg (Equivalent to 0.065mg Selenium as Sodium Selenite)	Vitamin A (Retinyl Acetate) USP 0.80mg + Vitamin D3 (Colecalciferol) USP 0.005mg (Equivalent to 200 IU of Vitamin D3) + Vitamin C (Ascorbic Acid Coated) USP 70mg + Vitamin B1(as Thiamine Mononitrate) USP 1.4mg + Vitamin B2 (as Riboflavin 5 phosphate Sodium) USP 1.4mg + Vitamin B6 (as Pyridoxine Hydrochloride) USP 1.9mg + Vitamin E Acetate USP 10.98mg (Equivalent to 10mg Vitamin E as Vitamin E Acetate) + Niacinamide USP 18mg + Vitamin B12 (Cyanocobalamin) USP 0.0026 mg + Folic Acid USP 0.4mg + Ferrous Fumarate USP 91.28mg (Equivalent to 30mg Iron as Ferrous Fumarate) +Copper gluconat USP 14.28mg (Equivalent to 2mg Copper as Copper Gluconate) + Zinc Gluconate USP 104.55mg (Equivalent to 15mg Zinc as Zinc Gluconate) + Potassium Iodide USP 0.196mg (Equivalent	Vitamins and Combinations Theraputic Code: 078	Indication • Prevention & treatment of anemia and micronutrients deficiencies among pregnant and lactating women • To supplement the treatment of moderate acute malnutrition	Should not be used with drugs like: anisindione, bortezomib, capecitabine, cholestyramine, colesevelam, colestipol, dicumarol, fluorouracil, orlistat, sevelamer, warfarin		রেফারেন্স নাই পদটি United Nation International Multiple Micronutrient Antenatal Preparation (**UNIMMAP**) এর Formula-3 অনুযায়ী Pregnant and Lactating মহিলাদের দেওয়া হয়। পদটি অনুমোদনের নিমিত্তে জনস্বাস্থ্য পুষ্টি প্রতিষ্ঠান হতে সুপারিশ করা হয়েছে। পদটি বাংলাদেশ সরকারের পুষ্টি সেবা কার্যক্রমের অন্তর্ভূক্ত।	পদটি বাংলাদেশ সরকারের পুষ্টি সেবা কার্যক্রমের অন্তর্ভূক্ত বিধায় পুষ্টি সেবা কার্যক্রমে ব্যবহারের নিমিত্তে অনুমোদনের সুপারিশ করা হয়।	পদটি বাংলাদেশ সরকারের পুষ্টি সেবা কার্যক্রমের অন্তর্ভূক্ত বিধায় পুষ্টি সেবা কার্যক্রমে ব্যবহারের নিমিত্তে অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			to 0.150mg Iodine as Potassium Iodide) + Sodium Selenite Anhydrous USP 0.142mg (Equivalent to 0.065mg Selenium as Sodium Selenite)							
248.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Opsonin Pharma Limited, Rupatali, Barishal.	Ozanimod 0.46 mg Tablet	Ozanimod INN 0.46 mg	Immune-suppressant Therapeutic Code: 58	Ozanimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	**Contraindication** •In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure •Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker •Severe untreated sleep apnea •Concomitant use of a monoamine oxidase inhibitor **Side-effects:** Most common adverse reactions (incidence ≥4%): Upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension. **Warnings And Precautions:** •Infections: Ozanimod may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 3 months after discontinuation. Do not start Ozanimod in patients with active infections •Bradyarrhythmia and Atrioventricular Conduction Delays: Ozanimod may result in transient decrease in heart rate; titration is required for treatment	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						initiation. Check an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting Ozanimod. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate •Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating Ozanimod •Fetal Risk: Women of childbearing potential should use effective contraception during treatment and for 3 months after stopping Ozanimod •Increased Blood Pressure (BP): Monitor BP during treatment •Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated •Macular Edema: A prompt ophthalmic evaluation is recommended if there is any change in vision while taking Ozanimod Diabetes mellitus and uveitis increase the risk of macular edema; patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation				
249.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Opsonin Pharma Limited, Rupatali, Barishal.	Ozanimod 0.92 mg Tablet	Ozanimod INN 0.92 mg	Immune-suppressant Therapeutic Code: 58	Ozanimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	**Contraindication** •In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure •Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker •Severe untreated sleep apnea •Concomitant use of a monoamine oxidase inhibitor	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side-effects: Most common adverse reactions (incidence ≥4%): Upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension. **Warnings And Precautions:** •Infections: Ozanimod may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 3 months after discontinuation. Do not start Ozanimod in patients with active infections •Bradyarrhythmia and Atrioventricular Conduction Delays: Ozanimod may result in transient decrease in heart rate; titration is required for treatment initiation. Check an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting Ozanimod. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate •Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating Ozanimod •Fetal Risk: Women of childbearing potential should use effective contraception during treatment and for 3 months after stopping Ozanimod •Increased Blood Pressure (BP): Monitor BP during treatment •Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated •Macular Edema: A prompt ophthalmic evaluation is recommended if there is				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						any change in vision while taking Ozanimod Diabetes mellitus and uveitis increase the risk of macular edema; patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation				
250.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Memantine HCl 7 mg ER Capsule	Memantine Hcl (15 % w/w)ER pellets INN 46.6666 mg eq. to Memantine Hcl 7 mg	Cholinergic Therapeutic Code: 37	Memantine Hcl, an NMDA receptor antagonist indicated for the treatment of moderate to severe dementia of the Alzheimer's type.	**Contraindication** Memantine Hcl is contraindicated in patients with known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation. **Side-effects:** The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo with administration of Memantine Hcl ER 28 mg/day were headache, diarrhea and dizziness. Other less common and sometimes serious adverse events have been reported. **Warnings And Precautions:** Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine.	Existing Memantine Hydrochloride 10 mg Tablet (DCC 238) Memantine Hydrochloride 05 mg Tablet (DCC 238)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
251.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Memantine HCl 14 mg ER Capsule	Memantine Hcl (15 % w/w)ER pellets INN 93.3333 mg eq.to Memantine Hcl 14 mg	Cholinergic Therapeutic Code: 37	Memantine Hcl, an NMDA receptor antagonist indicated for the treatment of moderate to severe dementia of the Alzheimer's type.	**Contraindication** Memantine Hcl is contraindicated in patients with known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation. **Side-effects:** The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo with administration of Memantine Hcl ER 28 mg/day were headache, diarrhea and dizziness. Other less common and	Existing Memantine Hydrochloride 10 mg Tablet (DCC 238) Memantine Hydrochloride 05	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						sometimes serious adverse events have been reported. **Warnings And Precautions:** Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine.	mg Tablet (DCC 238)			
252.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Folate (as Quatrefolic) 1 mg Tablet	Quatrefolic INN 1.8500 mg eq.to folic acid 1 mg	Vitamins and Combinations Therapeutic Code: 78	Folic acid is the man-made form of folate. Folate is a B-vitamin naturally found in some foods. It is needed to form healthy cells, especially red blood cells. Folic acid supplements may come in different forms (such as L-methylfolate, levomefolate, methyltetrahydrofolate). They are used to treat or prevent low folate levels. Low folate levels can lead to certain types of anemia.	**Contraindication** None **Side-effects:** A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), dizziness, trouble breathing.	Existing	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
253.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Riboflavin (Vitamin B2) 25 mg + Pyridoxine 50 mg + Folate 2000 mcg +Methylcobalamine (Vitamin B12) 1 mg + Trimethyl Glycine (Betaine) 500 mg Tablet	Quatrefolic INN 3.4000 mg eq to + Riboflavin BP/Ph Eur 25.00 mg + Methycobalamin BP/Ph Eur. 1.00 mg + Pyridoxine Hcl BP/Ph.Eur. 60.0000 mg eq to Pyridoxine 50 mg + Trimethyl Glycine (Betaine) BP/Ph.Eur. 500.0000 mg	Vitamins and Combinations Therapeutic Code: 78	Folate Folate is a water soluble member of the B complex vitamins that is critical for maintaining optimal methylation. Folate is abundantly found in foods such as fruits and dark leafy vegetables but, can be easily destroyed by cooking or processing. The bioactive form of folate is 5-methyltetrahydrofolate (5-MTHF). 5-MTHF is required as a methyl group donor for several processes, including the production of mood regulating neurotransmitters, the synthesis of melatonin, and DNA production and repair. Vitamin B12	**Contraindication** None **Side-effects:** Riboflavin is LIKELY SAFE for most people when taken by mouth. In some people, riboflavin can cause the urine to turn a yellow-orange color. It may also cause diarrhea. Vitamin B6 Pyridoxine usually has no side effects when used in recommended doses. Pyridoxine can cause side effects when taken in large doses for a long time. Tell your doctor right away if any of these unlikely but serious side effects occur: headache, nausea, drowsiness, numbness/tingling of arms/legs. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any	Existing	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Vitamin B12 works with folate in many body processes, including the synthesis of DNA, red blood cells and supporting health of the myelin sheath, the insulating exterior that surrounds nerve cells. B12 is found primarily in animal foods. Vegetarians and the elderly run the highest risk of B12 deficiency. Methylcobalamin is the preferred form of B12, as it is the biologically active form of B12 and supports the up-regulation of methylation pathways. Vitamin B6 Vitamin B6 is a crucial B vitamin that is involved in the production of proteins in the body, neurotransmitters that help regulate mood, red blood cell formation and the proper functioning of the immune system. B6 is required for more than 60 different enzymatic reactions that occur in the body. Vitamin B6 works along with 5-MTHF and B12 in the recycling of homocysteine. B6 also supports a healthy cardiovascular system by promoting healthy platelet aggregation and aids in maintaining normal blood pressure. Vitamin B2 Optimizing B2 status helps support healthy blood pressure, particularly in patients with genetic mutations (MTHFR 677 > T polymorphism). Betaine (Trimethylglycine)	symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. Vitamin B12 Hematological: Polycythemia vera Gastrointestinal: Mild transient diarrhea Dermatological: Itching; transitory exanthema Miscellaneous: Feeling of swelling of entire body				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					As a methyl donor, trimethylglycine supports liver function, including detoxification pathways. Trimethylglycine has been shown to be beneficial in protecting against fat accumulation in the liver, due to its lipotropic properties (donating a methyl group to aid in the transport of fat out of the liver). Trimethylglycine also works alongside B2, B6, B12 and folate in maintaining normal homocysteine levels.					
254.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Atovaquone 750 mg/5ml oral suspension	Atovaquone USP 15 gm per 100 ml	Antimalarial Antikalazor Therapeutic Code: 24	ATOVAQUONE oral suspension is a quinone antimicrobial drug indicated for: Prevention of Pneumocystis jirovecii pneumonia (PCP) in adults and adolescents aged 13 years and older who cannot tolerate trimethoprimsulfamethoxazole (TMP-SMX). Treatment of mild-to-moderate PCP in adults and adolescents aged 13 years and older who cannot tolerate T MP-SMX.	**Contraindication** Known serious allergic/hypersensitivity reaction (e.g., angioedema, bronchospasm, throat tightness, urticarial) to atovaquone or any of the components of ATOVAQUONE. **Side-effects:** 1. PCP Prevention: The most frequent adverse reactions (≥25% that required discontinuation) were diarrhea, rash, headache, nausea, and fever. 2. PCP Treatment: The most frequent adverse reactions (≥14% that required discontinuation) were rash (including maculopapular), nausea, diarrhea, headache, vomiting, and fever. **Warnings And Precautions:** •Failure to administer Atovaquone oral suspension with food may result in lower plasma atovaquone concentrations and may limit response to therapy. Patients with	Existing Atovaquone 62.5 mg + Proguanil HCl 25 mg Tablet (DCC 233)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						gastrointestinal disorders may have limited absorption resulting in suboptimal atovaquone concentrations. • Hepatotoxicity: Elevated liver chemistry tests and cases of hepatitis and fatal liver failure have been reported				
255.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Naratriptan 1 mg Tablet	Naratriptan Hcl USP 1.1100 mg eq.to Naratriptan 1 mg	Drug used in migraine Therapeutic Code:47	NARATRIPTAN is a serotonin (5-HT 1B/ I D) receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults.	**Contraindication** •History of coronary artery disease or coronary artery vasospasm •Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders •History of stroke, transient ischemic attack, or hemiplegic or basilar migraine • Peripheral vascular disease •Ischemic bowel disease •Uncontrolled hypertension •Recent (within 24 hours) use of another 5-HT 1 agonist (e.g., another triptan) or an ergotamine-containing medication •Hypersensitivity to Naratriptan (angioedema and anaphylaxis seen) •Severe renal or hepatic impairment **Side-effects:** Most common adverse reactions (≥2% and >placebo) were paresthesias, nausea, dizziness, drowsiness, malaise/fatigue, and throat/neck symptoms. **Warnings And Precautions:** •Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors. •Arrhythmias: Discontinue Naratriptan if occurs •Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia;	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						evaluate for CAD in patients at high risk. •Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue Naratriptan if occurs. •Gastrointestinal ischemic reactions and peripheral vasospastic reactions: Discontinue Naratriptan if occurs. •Medication overuse headache: Detoxification may be necessary. •Serotonin syndrome: Discontinue Naratriptan if occurs.				
256.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Naratriptan 2.5 mg Tablet	Naratriptan Hcl USP 2.7800 mg eq.to Naratriptan 2.5 mg	Drug used in migraine Therapeutic Code:47	NARATRIPTAN is a serotonin (5-HT 1B/ I D) receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults.	**Contraindication** •History of coronary artery disease or coronary artery vasospasm •Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders •History of stroke, transient ischemic attack, or hemiplegic or basilar migraine • Peripheral vascular disease •Ischemic bowel disease •Uncontrolled hypertension •Recent (within 24 hours) use of another 5-HT 1 agonist (e.g., another triptan) or an ergotamine-containing medication •Hypersensitivity to Naratriptan (angioedema and anaphylaxis seen) •Severe renal or hepatic impairment **Side-effects:** Most common adverse reactions (≥2% and >placebo) were paresthesias, nausea, dizziness, drowsiness, malaise/fatigue, and throat/neck symptoms. **Warnings And Precautions:** •Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors. •Arrhythmias: Discontinue Naratriptan if occurs	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for CAD in patients at high risk. •Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue Naratriptan if occurs. •Gastrointestinal ischemic reactions and peripheral vasospastic reactions: Discontinue Naratriptan if occurs. •Medication overuse headache: Detoxification may be necessary. •Serotonin syndrome: Discontinue Naratriptan if occurs.				
257.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Brilliant Blue G 0.25 mg per ml Ophthalmic Solution for Pre-filled Syringe	Brilliant Blue G INN 0.25 mg per ml	Eye Preparations Therapeutic Code: 52	Brilliant Blue G Ophthalmic Solution 0.025% is a disclosing agent indicated to selectively stain the internal limiting membrane (ILM).	**Contraindication** None **Side-effects:** Reactions that have been reported in procedures that included the use of TissueBlue 0.025% have often been associated with the surgical procedure. The complications include retinal (retinal break, tear, hemorrhage, and detachment and cataracts.) **Warnings And Precautions:** Excessive staining: Excess Brilliant Blue G 0.025% should be removed from the eye immediately after staining. Use of the syringe: Make sure the plunger moves smoothly before injecting the solution.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
258.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Abatacept 125 mg/ml Injection	Abatacept ready to fill sterile bulk INN 1 mg per ml eq to Abatacept 125 mg	Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic Code: 64	Abatacept is a selective T cell costimulation modulator indicated for: **Adult Rheumatoid Arthritis (RA)** moderately to severely active RA in adults. Abatacept may be used as	**Contraindication** None **Side-effects:** Most common adverse events (10%) are headache, upper respiratory tract infection, nasopharyngitis, and nausea. **Warnings And Precautions:**	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					monotherapy or concomitantly with DMARDs other than TNF antagonists **Juvenile Idiopathic Arthritis** moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older. Abatacept may be used as monotherapy or concomitantly with methotrexate. **Important Limitations of Use** should not be given concomitantly with TNF antagonists	Concomitant use with a TNF antagonist can increase the risk of infections and serious infections Hypersensitivity, anaphylaxis, and anaphylactoid reactions Patients with a history of recurrent infections or underlying conditions predisposing to infections may experience more infections Discontinue if a serious infection develops Screen for latent TB infection prior to initiating therapy. Patients testing positive should be treated prior to initiating Abatacept Live vaccines should not be given concurrently or within 3 months of discontinuation Patients with juvenile idiopathic arthritis should be brought up to date with all immunizations prior to Abatacept therapy Based on its mechanism of action, Abatacept may blunt the effectiveness of some immunizations COPD patients may develop more frequent respiratory adverse events				
259.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh. Opsonin Pharma Limited, Rupatali, Barishal.	Voxelotor 500 mg Tablet	Voxelotor INN 500 mg	DRUG used in Anemia and other Blood disorder Therapeutic Code: 45	Hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older	**Contraindication** Prior drug hypersensitivity to voxelotor or excipients **Side-effects:** Most common adverse reactions (incidence >10%) are headache, diarrhea, abdominal pain, nausea, fatigue, rash, and pyrexia **Warnings And Precautions:** Hypersensitivity Reactions: Observe for signs and symptoms and manage promptly. Laboratory Test Interference: Perform quantification of hemoglobin species when patient is not receiving Voxelotor	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
260.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Tofacitinib 10 mg tablet	Tofacitinb citrate INN 16.000 mg eq.to Tofacitib 10 mg	Immune-suppressant Therapeutic Code: 58	**Rheumatoid Arthritis** Tofacitinib is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Tofacitinib is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).	**Contraindication** None **Side-effects:** Most common adverse reactions are: Rheumatoid and Psoriatic Arthritis: Reported during the first 3 months in rheumatoid arthritis controlled clinical trials and occurring in ≥2% of patients treated with Tofacitinib monotherapy or in combination with DMARDs: upper respiratory tract infection, nasopharyngitis, diarrhea, and headache. Ulcerative Colitis: Reported in ≥5% of patients treated with either 5 mg or 10 mg twice daily of Tofacitinib and ≥1% greater than reported in patients receiving placebo in either the induction or maintenance clinical trials: nasopharyngitis, elevated cholesterol levels, headache, upper respiratory tract infection, increased blood creatine phosphokinase, rash, diarrhea, and herpes zoster. **Warnings And Precautions:** Serious Infections: Avoid use of Tofacitinib during an active serious infection, including localized infections. Gastrointestinal Perforations: Use with caution in patients that may be at increased risk Laboratory Monitoring: Recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids. Immunizations: Live vaccines: Avoid use with Tofacitinib	Existing Tofacitinib 5 mg Tablet (DCC 244) Tofacitinib 11 mg Xr Tablet (DCC 245)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
261.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Diazepam 250 mg/5 ml nasal Spray	Diazepam BP/Ph.Eur. 250 mg per 5 ml	Hypnotics,Sedatives& Anxiolitic Therapeutic Code: 57	DIAZEPAM is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual	**Contraindication** • Hypersensitivity to diazepam. • Acute narrow-angle glaucoma. **Side-effects:**	Diazepam 5 mg Tablet (DCC 140)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					seizure pattern in patients with epilepsy 6 years of age and older	The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort. **Warnings And Precautions:** •CNS Depression: May cause an increased CNS-depressant effect when used with alcohol or other CNS depressants. •Suicidal Behavior and Ideation: Antiepileptic drugs increase the risk of suicidal ideation and behavior.	Diazepam 10 mg/2 ml Injection(DCC 160) Diazepam 10 mg Suppository (DCC23)			
262.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Pegylated rHu Erythropoietin 100 mcg/0.3 ml Prefilled Syringe Injection.	Pegylated rHu Erythropoietin INN 0.10 mg/0.3 ml	DRUG used in Anemia and other Blood disorder Therapeutic Code:45	Pegylated Erythropoeitin is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: • adult patients on dialysis and adult patients not on dialysis. • pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.	**Contraindication** 1. Uncontrolled hypertension 2. Pure red cell aplasia (PRCA) that begins after treatment with Pegylated Erythropoeitin or other erythropoietin protein drugs 3. History of serious allergic reactions to Pegylated Erythropoeitin , including anaphylaxis **Side-effects:** The most common adverse reactions (≥ 10%) are hypertension, diarrhea. **Warnings And Precautions:** • Hypertension: Control hypertension prior to initiating and during treatment with Pegylated rHu Erythropoietin . • Seizures: Seizures have occurred in CKD patients participating in Pegylated rHu Erythropoietin clinical studies. Increase monitoring of these patients for changes in seizure frequency or premonitory symptoms . • PRCA: If severe anemia and low reticulocyte count develop during Pegylated rHu Erythropoietin treatment, withhold Pegylated rHu Erythropoietin and evaluate for PRCA • Serious Allergic Reactions: Discontinue Pegylated rHu Erythropoietin and manage reactions • Severe Cutaneous Reactions:	Existing Erythropoietin 2000 IU/.5 ml Injection (DCC 207) Erythropoietin 4000 IU/.4 ml Injection (DCC 207)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Discontinue Pegylated rHu Erythropoietin				
263.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Levodopa 42 mg DPI Capsule	Levodopa BP 42 mg	Antiparkinsonism Therapeutic Code: 25	LEVODOPA is indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.	**Contraindication** LEVODOPA is contraindicated in patients currently taking a nonselective monoamine oxidase (MAO) inhibitor or who have recently (within 2 weeks) taken a nonselective MAO inhibitor **Side-effects:** The most common adverse reactions (incidence ≥ 5% and higher than placebo) were cough, nausea, upper respiratory tract infection, and sputum discolored **Warnings And Precautions:** • May cause falling asleep during activities of daily living • Avoid sudden discontinuation or rapid dose reduction to reduce the risk of withdrawal-emergent hyperpyrexia and confusion • Hallucinations/ exacerbation of psychosis may occur. Patients with a major psychotic disorder should not be treated with Levodopa • Impulse Control Disorders: consider dose reduction or stopping Levodopa • May cause or exacerbate dyskinesia: adjustment of levodopa therapy may be considered, including stopping Levodopa • Not recommended in patients with asthma, COPD, or other chronic underlying lung disease	Existing Carbidopa 25 mg + Levodopa 250 mg Tablet (DCC 110)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
264.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. Opsonin Pharma Limited, Rupatali, Barishal.	Ozanimod 0.23 mg capsule	Ozanimod INN 0.23 mg	Immune-suppressant Therapeutic Code: 58	Ozanimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	**Contraindication** •In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure •Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker •Severe untreated sleep apnea •Concomitant use of a monoamine oxidase inhibitor **Side-effects:** Most common adverse reactions (incidence ≥4%): Upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension. **Warnings And Precautions:** •Infections: Ozanimod may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 3 months after discontinuation. Do not start Ozanimod in patients with active infections •Bradyarrhythmia and Atrioventricular Conduction Delays: Ozanimod may result in transient decrease in heart rate; titration is required for treatment initiation. Check an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting Ozanimod. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating Ozanimod •Fetal Risk: Women of childbearing potential should use effective contraception during treatment and for 3 months after stopping Ozanimod •Increased Blood Pressure (BP): Monitor BP during treatment •Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated •Macular Edema: A prompt ophthalmic evaluation is recommended if there is any change in vision while taking Ozanimod Diabetes mellitus and uveitis increase the risk of macular edema; patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation				
265.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Eptinezumab-jjmr 100mg/ml Injection	Eptinezumab-jjmr 100mg/ml ready to fill sterile bulk INN 1 ml eq.to 100 mg Eptinezumab-jjmr	Drug used in migraine Therapeutic Code: 47	EPTINEZUMAB-JJMR is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults	**Contraindication** EPTINEZUMAB-JJMR is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients **Side-effects:** The most common adverse reactions (≥2% and 2% or greater than placebo) were nasopharyngitis and hypersensitivity **Warnings And Precautions:** Hypersensitivity Reactions: Reactions have included angioedema, urticaria, facial flushing, and rash. If a hypersensitivity reaction occurs, consider discontinuing Eptinezumab-jjmr and initiate appropriate therapy	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
266.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Olanzapine 5 mg Orodispersible Tablet	Olanzapine BP/Ph.Eur . 5 mg	Antipsychotic Therapeutic Code: 28	Treatment of schizophrenia. Adults: Efficacy was established in three clinical trials in patients with schizophrenia: two 6-week trials and one maintenance trial	**Contraindication** • None with Olanzapine monotherapy. •When using Olanzapine and fluoxetine in combination, **Side-effects:** Most common adverse reactions (≥5% and at least twice that for placebo) associated with: Oral Olanzapine Monotherapy: Schizophrenia (Adults) – postural hypotension, constipation, weight gain, dizziness, personality disorder, akathisia Schizophrenia (Adolescents) – sedation, weight increased, headache, increased appetite, dizziness, abdominal pain, pain in extremity, fatigue, dry mouth Manic or Mixed Episodes, Bipolar I Disorder (Adults) – asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor Manic or Mixed Episodes, Bipolar I Disorder (Adolescents) – sedation, weight increased, increased appetite, headache, fatigue, dizziness, dry mouth, abdominal pain, pain in extremity Combination of Olanzapine and Lithium or Valproate: 4. Manic or Mixed Episodes, Bipolar I Disorder (Adults) – dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia **Warnings And Precautions:** •Elderly Patients with Dementia-Related Psychosis: Increased risk of death and increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack).	Existing Olanzapine 5 mg Tablet (DCC 215) Olanzapine 10 mg Tablet (DCC 215)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Suicide: The possibility of a suicide attempt is inherent in schizophrenia and in bipolar I disorder, and close supervision of high-risk patients should accompany drug therapy; when using in combination with fluoxetine •Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. •Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. •Hyperglycemia and Diabetes Mellitus: In some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients taking olanzapine. Patients taking olanzapine should be monitored for symptoms of hyperglycemia and undergo fasting blood glucose testing at the beginning of, and periodically during, treatment. •Dyslipidemia: Undesirable alterations in lipids have been observed. Appropriate clinical monitoring is recommended, including fasting blood lipid testing at the beginning of, and periodically during, treatment. •Weight Gain: Potential consequences of weight gain should be considered. Patients should receive regular monitoring of weight. •Tardive Dyskinesia: Discontinue if clinically appropriate. •Orthostatic Hypotension: Orthostatic hypotension associated with dizziness, tachycardia, bradycardia and, in some patients, syncope, may occur especially during initial dose titration. Use caution in patients with cardiovascular disease, cerebrovascular disease, and those				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						conditions that could affect hemodynamic responses. •Leukopenia, Neutropenia, and Agranulocytosis: Has been reported with antipsychotics, including Olanzapine. Patients with a history of a clinically significant low white blood cell count (WBC) or drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of Olanzapine should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. •Seizures: Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold. •Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Use caution when operating machinery. •Hyperprolactinemia: May elevate prolactin levels.				
267.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Olanzapine 10 mg Orodispersible Tablet	Olanzapine BP/Ph.Eur . 10 mg	Antipsychotic Therapeutic Code: 28	Treatment of schizophrenia. Adults: Efficacy was established in three clinical trials in patients with schizophrenia: two 6-week trials and one maintenance trial	**Contraindication** • None with Olanzapine monotherapy. •When using Olanzapine and fluoxetine in combination, **Side-effects:** Most common adverse reactions (≥5% and at least twice that for placebo) associated with: Oral Olanzapine Monotherapy: Schizophrenia (Adults) – postural hypotension, constipation, weight gain, dizziness, personality disorder, akathisia Schizophrenia (Adolescents) – sedation, weight increased, headache, increased appetite, dizziness, abdominal pain, pain in extremity, fatigue, dry mouth	Existing Olanzapine 5 mg Tablet (DCC 215) Olanzapine 10 mg Tablet (DCC 215)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Manic or Mixed Episodes, Bipolar I Disorder (Adults) – asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor Manic or Mixed Episodes, Bipolar I Disorder (Adolescents) – sedation, weight increased, increased appetite, headache, fatigue, dizziness, dry mouth, abdominal pain, pain in extremity Combination of Olanzapine and Lithium or Valproate: 5. Manic or Mixed Episodes, Bipolar I Disorder (Adults) – dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia **Warnings And Precautions:** •Elderly Patients with Dementia-Related Psychosis: Increased risk of death and increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack). •Suicide: The possibility of a suicide attempt is inherent in schizophrenia and in bipolar I disorder, and close supervision of high-risk patients should accompany drug therapy; when using in combination with fluoxetine •Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. •Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. •Hyperglycemia and Diabetes Mellitus: In some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						patients taking olanzapine. Patients taking olanzapine should be monitored for symptoms of hyperglycemia and undergo fasting blood glucose testing at the beginning of, and periodically during, treatment. •Dyslipidemia: Undesirable alterations in lipids have been observed. Appropriate clinical monitoring is recommended, including fasting blood lipid testing at the beginning of, and periodically during, treatment. •Weight Gain: Potential consequences of weight gain should be considered. Patients should receive regular monitoring of weight. •Tardive Dyskinesia: Discontinue if clinically appropriate. •Orthostatic Hypotension: Orthostatic hypotension associated with dizziness, tachycardia, bradycardia and, in some patients, syncope, may occur especially during initial dose titration. Use caution in patients with cardiovascular disease, cerebrovascular disease, and those conditions that could affect hemodynamic responses. •Leukopenia, Neutropenia, and Agranulocytosis: Has been reported with antipsychotics, including Olanzapine. Patients with a history of a clinically significant low white blood cell count (WBC) or drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of Olanzapine should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. •Seizures: Use cautiously in patients with a history of seizures or with				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						conditions that potentially lower the seizure threshold. •Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Use caution when operating machinery. •Hyperprolactinemia: May elevate prolactin levels.				
268.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Nuvista Pharma Ltd.	Dexamethasone 6mg/ml Injection	Dexamethasone sodium Phosphate BP/Ph Eur.7.818 2 mg/ml eq.to Dexameth asone 6 mg/ml	Steroidal Anti inflammatory Therapeutic Code:72	Dexamethasoe tablet is indicated in acute conditions in which oral glucocorticoid therapy is not feasible such as: Shock: of haemorrhagic, traumatic, surgical or septic origin; cerebral oedema associated with cerebral neoplasm; inflammatory diseases of joints and soft tissue such as rheumatoid arthritis. Short term management of acute self-limited allergic conditions such as angioneurotic oedema or acute exacerbations of chronic allergic disorders such as bronchial asthma or serum sickness. High doses of dexamethasone are intended for the adjunctive treatment of shock where massive doses of corticosteroids are needed. There is a lack of evidence that use of corticosteroids in septic shock affects mortality in the long term. Use must be accompanied by the appropriate concomitant systemic antibiotic treatment and supportive measures which the patient's condition may require.	**Contraindication** Unless considered to be life-saving systemic administration of corticosteroids are generally contraindicated in patients with systemic infections, (unless specific anti-infective therapy is employed). Hypersensitivity to any components of the injection. Administration of dexamethasone is contraindicated in patients with a known hypersensitivity to sulphites **Side-effects:** A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts). Psychotic reactions (including mania, delusions, hallucinations and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults the frequency of severe reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown. The incidence of predictable undesirable effects, including hypothalamic-pituitary-adrenal suppression correlates with the	Existing Dexamet hasone Sodium Phospha te 2 mg/ml Injection (DCC 238)	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						relative potency of the drug, dosage, timing of administration and the duration of treatment (see Other Special Warnings and Precautions). High doses of dexamethasone sodium phosphate are intended for short term therapy and therefore adverse reactions are uncommon. However, peptic ulceration and bronchospasm may occur. Except for hypersensitivity, the following adverse effects have been associated with prolonged systemic corticosteroid therapy. Endocrine disorders:: Suppression of the hypothalamic-pituitary adrenal axis; Cushing-like syndrome				
269.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Dexamethasone 2mg T ablet	Dexamethasone BP/Ph.Eur 2 mg	Steroidal Anti inflammatory Therapeutic Code:72	Dexamethasoe tablet is indicated in acute conditions in which oral glucocorticoid therapy is not feasible such as: Shock: of haemorrhagic, traumatic, surgical or septic origin; cerebral oedema associated with cerebral neoplasm; inflammatory diseases of joints and soft tissue such as rheumatoid arthritis. Short term management of acute self-limited allergic conditions such as angioneurotic oedema or acute exacerbations of chronic allergic disorders such as bronchial asthma or serum sickness. High doses of dexamethasone are intended for the adjunctive treatment of shock where massive doses of corticosteroids are needed. There is a lack of evidence that use of corticosteroids in septic	**Contraindication** Unless considered to be life-saving systemic administration of corticosteroids are generally contraindicated in patients with systemic infections, (unless specific anti-infective therapy is employed). Hypersensitivity to any components of the injection. Administration of dexamethasone is contraindicated in patients with a known hypersensitivity to sulphites **Side-effects:** A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts). Psychotic reactions (including mania, delusions, hallucinations and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults the frequency of severe	Existing Dexamethasone 4 mg Tablet (DCC 246)	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					shock affects mortality in the long term. Use must be accompanied by the appropriate concomitant systemic antibiotic treatment and supportive measures which the patient's condition may require.	reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown. The incidence of predictable undesirable effects, including hypothalamic-pituitary-adrenal suppression correlates with the relative potency of the drug, dosage, timing of administration and the duration of treatment (see Other Special Warnings and Precautions). High doses of dexamethasone sodium phosphate are intended for short term therapy and therefore adverse reactions are uncommon. However, peptic ulceration and bronchospasm may occur. Except for hypersensitivity, the following adverse effects have been associated with prolonged systemic corticosteroid therapy. Endocrine disorders:: Suppression of the hypothalamic-pituitary adrenal axis; Cushing-like syndrome.				
270.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Niclosamide 500mg Tablet	Niclosamide BP 500mg	Anthelmintics including schistosomiasis and filaricides Therapeutic Code: 08	Niclosamide is used in the treatment of: Helminthiasis	**Contraindication** No data available **Side-effects:** **I**nfrequent, mild, and transitory adverse events include nausea, vomiting, diarrhea, and abdominal discomfort.	Existing Levamisole 50 mg + Metoclopramide 2.5 mg + Niclosamide 450 mg Tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
271.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Camostat Mesilate 100mg Tablet	Camostat Mesilate INN 100 mg	Anticancer Therapeutic Code: 10	It is an inhibitor of the enzyme transmembrane protease, serine 2 (TMPRSS2). Inhibition of TMPRSS2 partially blocked infection by SARS-CoV and Human coronavirus NL63 in HeLa cell cultures. Another in vitro study showed that camostat significantly reduces the infection of Calu-3 lung cells by SARS-CoV-2, the virus responsible for COVID-19	**Contraindication** Patients with a history of hypersensitivity to any of the ingredient of this product **Side-effects:** The major adverse reactions were hepatic function abnormalities such as increased AST (GOT) · ALT (GPT) in 12 incidences (0.3%), diarrhea in 8 incidences (0.2%), nausea in 5 incidences (0.1%), etc	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
272.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Topiramate 25 mg ER capsule	Topiramate USP 25 mg (eq. to Topiramate ER Pellets 20% w/w In-house 125 mg)	Drug used in Epilepsy Therapeutic Code: 46	Monotherapyepilepsy: initialmonotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures Adjunctive therapy epilepsy: adjunctive therapy in patients 6 years of age and older with partial onset, primary generalized tonic -clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LCS) Migraine: Prophylaxis of migraine headache in adults and adolescents 12 years of age and older	**Contraindication** With recent alcohol use, ie, within 6 hours prior to and 6 hours after Topiramate use **Side-effects:** Epilepsy:Most common (≥ 10% more frequent than placebo or low-dose topiramate in monotherapy and adjunctive therapy) adverse reactions in adult and pediatric patients were paresthesia, anorexia, weight loss, speech disorders/related speech problems, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, abnormal vision, and fever . Migraine: Most common (≥5% more frequent than placebo) adverse reactions in adult and pediatric patients were: paresthesia, anorexia, weight loss, difficulty with memory, taste perversion, upper respiratory tract infections, abdominal pain, diarrhea, hypoesthesia, and nausea **Warnings And Precautions:** •Acute myopia and secondary angle closure glaucoma: can lead to permanent visual loss; discontinue Topiramate as soon as possible	Topiramate 25mg/50 mg Tablet (DCC 221)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Visual field defects: consider discontinuation of Topiramate •Oligohydrosis and hyperthermia: monitor decreased sweating and increased body temperature, especially in pediatric patients •Metabolic acidosis: baseline and periodic measurement of serum bicarbonate is recommended;consider dose reduction or discontinuation of Topiramate if clinically appropriate •Suicidal behavior and ideation: antiepileptic drugs increase the risk of suicidal behavior or ideation •Cognitive/neuropsychiatric: use caution when operating machinery including cars; depression and mood problems may occur •Fetal toxicity: use during pregnancy can cause cleft lip and/or palate and being small for gestational age •Withdrawal of AEDs: withdraw Topiramate gradually •Hyperammonemia/encephalopathy: measure ammonia if encephalopathic symptoms occur •Kidney stones: avoid use with other carbonic anhydrase inhibitors, other drugs causing metabolic acidosis, or in patients on a ketogenic diet •Hypothermia has been reported with and without hyperammonemia during topiramate treatment with concomitant valproic acid use				
273.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Topiramate 50 mg ER capsule	Topiramate USP 50 mg (eq. to Topiramate ER Pellets 20% w/w In-house 250 mg)	Drug used in Epilepsy Therapeutic Code: 46	Monotherapyepilepsy: initialmonotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures Adjunctive therapy epilepsy: adjunctive therapy in patients 6 years of age and older with partial onset, primary generalized tonic -clonic seizures, or seizures associated	**Contraindication** With recent alcohol use, ie, within 6 hours prior to and 6 hours after Topiramate use **Side-effects:** Epilepsy:Most common (≥ 10% more frequent than placebo or low-dose topiramate in monotherapy and adjunctive therapy) adverse reactions in adult and pediatric patients were	Existing Topiramate 25mg & 50mg Tablet (DCC 221)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					with Lennox-Gastaut syndrome (LCS) Migraine: Prophylaxis of migraine headache in adults and adolescents 12 years of age and older	paresthesia, anorexia, weight loss, speech disorders/related speech problems, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, abnormal vision, and fever . Migraine: Most common (≥5% more frequent than placebo) adverse reactions in adult and pediatric patients were: paresthesia, anorexia, weight loss, difficulty with memory, taste perversion, upper respiratory tract infections, abdominal pain, diarrhea, hypoesthesia, and nausea **Warnings And Precautions:** •Acute myopia and secondary angle closure glaucoma: can lead to permanent visual loss; discontinue Topiramate as soon as possible •Visual field defects: consider discontinuation of Topiramate •Oligohydrosis and hyperthermia: monitor decreased sweating and increased body temperature, especially in pediatric patients •Metabolic acidosis: baseline and periodic measurement of serum bicarbonate is recommended;consider dose reduction or discontinuation of Topiramate if clinically appropriate •Suicidal behavior and ideation: antiepileptic drugs increase the risk of suicidal behavior or ideation •Cognitive/neuropsychiatric: use caution when operating machinery including cars; depression and mood problems may occur •Fetal toxicity: use during pregnancy can cause cleft lip and/or palate and being small for gestational age •Withdrawal of AEDs: withdraw Topiramate gradually				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Hyperammonemia/encephalopathy: measure ammonia if encephalopathic symptoms occur •Kidney stones: avoid use with other carbonic anhydrase inhibitors, other drugs causing metabolic acidosis, or in patients on a ketogenic diet •Hypothermia has been reported with and without hyperammonemia during topiramate treatment with concomitant valproic acid use				
274.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Topiramate 100 mg ER capsule	Topiramate USP 100 mg eq.to Topiramate ER Pellets 20% w/w In-house 500 mg)	Drug used in Epilepsy Therapeutic Code: 46	Monotherapyepilepsy: initialmonotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures Adjunctive therapy epilepsy: adjunctive therapy in patients 6 years of age and older with partial onset, primary generalized tonic -clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LCS) Migraine: Prophylaxis of migraine headache in adults and adolescents 12 years of age and older	**Contraindication** With recent alcohol use, ie, within 6 hours prior to and 6 hours after Topiramate use **Side-effects:** Epilepsy:Most common (≥ 10% more frequent than placebo or low-dose topiramate in monotherapy and adjunctive therapy) adverse reactions in adult and pediatric patients were paresthesia, anorexia, weight loss, speech disorders/related speech problems, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, abnormal vision, and fever . Migraine: Most common (≥5% more frequent than placebo) adverse reactions in adult and pediatric patients were: paresthesia, anorexia, weight loss, difficulty with memory, taste perversion, upper respiratory tract infections, abdominal pain, diarrhea, hypoesthesia, and nausea **Warnings And Precautions:** •Acute myopia and secondary angle closure glaucoma: can lead to permanent visual loss; discontinue Topiramate as soon as possible •Visual field defects: consider discontinuation of Topiramate	Existing Topiramate 25mg/50 mg Tablet (DCC 221)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						•Oligohydrosis and hyperthermia: monitor decreased sweating and increased body temperature, especially in pediatric patients •Metabolic acidosis: baseline and periodic measurement of serum bicarbonate is recommended;consider dose reduction or discontinuation of Topiramate if clinically appropriate •Suicidal behavior and ideation: antiepileptic drugs increase the risk of suicidal behavior or ideation •Cognitive/neuropsychiatric: use caution when operating machinery including cars; depression and mood problems may occur •Fetal toxicity: use during pregnancy can cause cleft lip and/or palate and being small for gestational age •Withdrawal of AEDs: withdraw Topiramate gradually •Hyperammonemia/encephalopathy: measure ammonia if encephalopathic symptoms occur •Kidney stones: avoid use with other carbonic anhydrase inhibitors, other drugs causing metabolic acidosis, or in patients on a ketogenic diet •Hypothermia has been reported with and without hyperammonemia during topiramate treatment with concomitant valproic acid use				
275.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Sacituzurnab Govitecan-hziy 180 mg as Lyophilized Powder for Injection	Sacituzumab Govitecan-hziy 18mg/ml ready to fill sterile solution 10.000 ml/vial INN/In-house (eq. to Sacituzumab Govitecan-hziy 180 mg)	Anticancer Therapeutic Code: 10	Sacituzumab & Govitecan is a Trop-2-directed antibody and topoiscmerase inhibitor conjugate indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease, (1) This indication is approved under accelerated approval	**Contraindication** Severe hypersensitivity reaction to Sacituzurnab Govitecan-hziy **Side-effects:** Most common adverse reactions (incidence >25%) in patients with mTNBC are nausea, neutropenia, diarrhea, fatigue, anemia, vomiting. alopecia, constipation, rash, decreased appetite, and abdominal pain.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials	**Warnings And Precautions:** •Hypersensitivity: Hypersensitivity reactions including severe anaphylactic reactions have been observed. Monitor patients for infusion-related reactions. Permanently discontinue Sacituzurnab Govitecan-hziy if severe or life-threatening reactions occur. •Nausea/Vomiting: Use antiemetic preventive treatment and withhold Sacituzurnab Govitecan-hziy for patients with Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment. •Patients with Reduced UGT1A1 Activity: Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia following initiation of Sacituzurnab Govitecan-hziy treatment. •Embryo-Fetal Toxicity: Sacituzurnab Govitecan-hziy can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.				
276.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Indacaterol 150 mcg +Glycopyrronium 50 mcg+ Mometasone Furoate 80 mcg DPI	Indacaterol Acetate INN 0.1730 mg eq to Indacaterol 0.1500 mg + Glycopyrronium Bromide BP/PhËur 0.0630 mg eq. to Glycopyrronium 0.0500 mg + Mometasone Furcate BPIPh.Eur. 0.0800 mg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 44	Indacaterol/glycopyrronium bromide is a combination drug for inhalation consisting of the following two active ingredients: Indacaterol maleate - an ultra-long-acting beta-adrenoceptor agonist (ultra-l-ABA); Glycopyrronium bromide (glyccpyrrolate)—a muscarinic anticholinergic. Indacaterol maleate/glycopyrronium bromide is used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic	**Contraindication** It is contraindicated in patients who have demonstrated hypersensitivity to indacaterol, glycopyrrolate, or to any of the ingredients **Side-effects:** Paradoxical bronchospasm Immediate hypersensitivity reactions Cardiovascular effects	Existing Glycopyrronium 50 mcg + Indacaterol 110 mcg Inhalation Capsule (DCC 243) Mometasone Furoate 0.110 mg	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					obstructive pulmonary disease (COPD)		Capsule, Dry Powder Inhaler (DCC 240)			
277.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Indacaterol 150 mcg +Glycopyrronium 50 mcg+ Mometasone Furoate 160 mcg DPI	Indacaterol Acetate INN 0.1730 mg eq.to Indacaterol 0.1500 mg+ Glycopyrronium Bromide BP /Ph.Eur. 0.0630 mg eq.to Glycopyrronium 0.0500 mg+Mometasone Furoate BP /Ph.Eur. 0.1600 mg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 44	Indacaterol/glycopyrronium bromide is a combination drug for inhalation consisting of the following two active ingredients: Indacaterol maleate—an ultra-long-acting beta-adrenoceptor agonist (ultra-l-ABA); Glycopyrronium bromide (glyccpyrrolate)—a muscarinic anticholinergic. Indacaterol maleate/glycopyrronium bromide is used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)	**Contraindication** It is contraindicated in patients who have demonstrated hypersensitivity to indacaterol, glycopyrrolate, or to any of the ingredients **Side-effects:** Paradoxical bronchospasm Immediate hypersensitivity reactions Cardiovascular effects	Existing Glycopyrronium 50 mcg + Indacaterol 110 mcg Inhalation Capsule (DCC 243) Mometasone Furoate 0.110 mg Capsule, Dry Powder Inhaler (DCC 240)	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
278.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Fenfluramine 2.2 mg per ml oral solution	Fenfluramine Hydrochloride INN 0.250gm/100ml eq. to Fenfluramine 0.220 gm	Anticonvulsants Therapeutic Code: 13	FENFLURAMINE is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older	**Contraindication** Hypersensitivity to fenfluramine or any of the excipients in FENFLURAMINE Within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome **Side-effects:** The most common adverse reactions (incidence at least 10% and greater than placebo) were decreased appetite; somnolence, sedation, lethargy; diarrhea; constipation; abnormal echocardiogram; fatigue, malaise, asthenia; ataxia, balance disorder, gait disturbance; blood pressure increased; drooling, salivary hypersecretion;	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						pyrexia; upper respiratory tract infection; vomiting; decreased weight; fall; status epilepticus. **Warnings And Precautions:** •Decreased Appetite and Decreased Weight: Advise patients that Fenfluramine can cause decreased appetite and decreased weight. •Somnolence, Sedation, and Lethargy: Monitor for somnolence and sedation. Advise patients not to drive or operate machinery until they have gained sufficient experience on Fenfluramine •Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and thoughts. •Withdrawal of Antiepileptic Drugs: Fenfluramine should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus. •Serotonin Syndrome: Advise patients that serotonin syndrome is a potentially life-threatening condition and may occur with Fenfluramine, particularly with concomitant administration of Fenfluramine with other serotonergic drugs. •Increase in Blood Pressure: Monitor blood pressure during treatment. •Glaucoma: Discontinue therapy in patients with acute decrease invisual acuity or ocular pain.				
279.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Oxymetazoline Hydrochloride 0.1% Ophthalmic Solution	Oxymetazoline Hydrochloride USP 1.00 mg per ml	Eye Preparations Therapeutic Code: 52	Oxymetazoline HCl is indicated for the treatment of acquired blepharoptosis in adults.	**Contraindication** No data available **Side-effects:** Most common adverse reactions (incidence 1-5%) are punctate keratitis, conjunctival hyperemia, dry eye, vision blurred, instillation site pain, eye irritation and headache. **Warnings And Precautions:** • Alpha-adrenergic agonists as a class may impact blood pressure. Advise	Oxymetazoline Hydrochloride 0.05% Nasal Spray (DCC 250)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens. Use with caution in patients with cerebral or coronary insufficiency or Sjögren's syndrome and advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop. Advise patients to seek immediate medical care if pain, redness, blurred vision and photophobia occur (signs and symptoms of acute angle closure).	Oxymetazoline Hydrochloride 1.0gm/100gm Cream (DCC 248)			
280.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Luspatercept-aamt 75 mg injection	Luspatercept-Aamt 50mg/ml ready to fill sterile Solution 1.5 ml/vial (eq. to Luspatercept-Aamt 75 mg)	DRUG used in Anemia and other Blood disorder Therapeutic Code:45	LUSPATERCEPT-AAMT is an erythroid maturation agent indicated for the treatment of: • Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions • Anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) • Limitations of Use: LUSPATERCEPT-AAMT is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia	**Contraindication** None **Side-effects:** The most common (>10%) adverse reactions were fatigue, headache, musculoskeletal pain, arthralgia, dizziness/vertigo, nausea, diarrhea, cough, abdominal pain, dyspnea, and hypersensitivity **Warnings And Precautions:** Thrombosis/Thromboembolism: Increased risk in patients with beta thalassemia. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly. Hypertension: Monitor blood pressure (BP) during treatment. Initiate anti-hypertensive treatment if necessary . Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
281.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Luspatercept-aamt 25 mg vial for injection	Luspatercept-Aamt 50mg/ml ready to fill sterile Solution 0.5 ml/vial (eq. to Luspatercept-Aamt 25 mg)	DRUG used in Anemia and other Blood disorder Therapeutic Code: 45	LUSPATERCEPT-AAMT is an erythroid maturation agent indicated for the treatment of: • Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions • Anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) • Limitations of Use: LUSPATERCEPT-AAMT is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.	**Contraindication** None **Side-effects:** The most common (>10%) adverse reactions were fatigue, headache, musculoskeletal pain, arthralgia, dizziness/vertigo, nausea, diarrhea, cough, abdominal pain, dyspnea, and hypersensitivity **Warnings And Precautions:** Thrombosis/Thromboembolism: Increased risk in patients with beta thalassemia. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly. Hypertension: Monitor blood pressure (BP) during treatment. Initiate anti-hypertensive treatment if necessary . Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
282.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Treprostinil 75 mcg DPI Capsule	Treprostinil INN 0.0750 mg	Coronary Vasodilators and Antianginal drug Therapeutic Code: 40	Treprostinil is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance.	**Contraindication** No data available **Side-effects:** Most common adverse reactions (2 10%) are cough, headache, nausea dizziness, flushing, throat irritation, pharyngolaryngeal pain and diarrhea.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
283.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Treprostinil 150 mcg DPI Capsule	Treprostinil INN 0.1500 mg	Coronary Vasodilators and Antianginal drug Therapeutic Code: 40	Treprostinil is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance.	**Contraindication** No data available **Side-effects:** Most common adverse reactions (2 10%) are cough, headache, nausea dizziness, flushing, throat irritation, pharyngolaryngeal pain and diarrhea.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
284.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Budesonide 0.25 mg per 2 ml nebulizer suspension	Budenoside BP 12.5000 mg per 100 ml	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 44	BUDENOSIDE is indicated for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age. BUDENOSIDEis NOT indicated for the relief of acute bronchospasm.	**Contraindication** BUDENOSIDE is contraindicated as the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. Hypersensitivity to budesonide or any of the ingredients of this preparation **Side-effects:** Respiratory System Disorder Respiratory Infection Rhinitis Coughing Gastrointestinal System Disorders Gastroenteritis Vomiting	Budesonide 250 mcg/ml aqueous suspension for inhalation (DCC 237)	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
285.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Eberconazole 1% Cream	Eberconazole Nitrate INN 1.1910 gm/100gm eq to Eberconazole 1 gm/ 100gm	Antifungl Agent Therapeutic Code: 20	Used in the treatment of superficial skin infections caused by fungi.	**Contraindication:** Pregnancy Breastfeeding **Side-effects:** Major & minor side effects for Eberconazole 1 % Cream Burning sensation at the application site Erythema Itching Rash	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
286.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Fluocinonide 0.05 gm/100 gm Gel	Fluocinonide USP .05 gm per 100 gm	Skin and Mucous Membrane Preparations Therapeutic Code: 71	Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses	**Contraindication:** With a history of hypersensitivity to any of the components of the preparation **Side-effects:** Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Warnings And Precautions: • Modify use should HPA axis suppression develop Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption • Local adverse reactions with topical steroids may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation and allergic contact dermatitis and may be more likely to occur with occlusive use or more potent corticosteroids Children may be more susceptible to systemic toxicity when treated with topical corticosteroids				
287.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Fluocinonide 0.05 gm/100 gm Ointment	Fluocinonide USP .05 gm per 100 gm	Skin and Mucous Membrane Preparations Therapeutic Code: 71	Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses	**Contraindication:** With a history of hypersensitivity to any of the components of the preparation **Side-effects:** burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin **Warnings And Precautions:** • Modify use should HPA axis suppression develop Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption • Local adverse reactions with topical steroids may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation and allergic contact dermatitis and may be more likely to occur with occlusive use or more potent corticosteroids • Children may be more susceptible to systemic toxicity when treated with topical corticosteroids	New	US FDA BNF 79 (Page 1283)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
288.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Fluocinonide 0.05 gm/ 100 ml Topical Solution	Fluocinonide USP .05 gm per 100 ml	Skin and Mucous Membrane Preparations Therapeutic Code: 71	Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses	**Contraindication:** With a history of hypersensitivity to any of the components of the preparation **Side-effects:** Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin **Warnings And Precautions:** • Modify use should HPA axis suppression develop Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption • Local adverse reactions with topical steroids may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation and allergic contact dermatitis and may be more likely to occur with occlusive use or more potent corticosteroids • Children may be more susceptible to systemic toxicity when treated with topical corticosteroids	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
289.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Picaridine 20 gm/100 ml Lotion	Picaridine INN 20 gm per 100 ml	OtherClassification Therapeutic Code: 75	Picaridine is registered for use on the human body and clothing to repel biting flies, ticks, chiggers, fleas, and mosquitoes. Product formulations include pump sprays, aerosols, and impregnated wipes. Uses for individual Picaridine products vary widely.	**Contraindication:** Contraindicated in patients sensitive to the molecule. **Side-effects:** An effective insect and tick repellent, Picaridine is applied directly onto the skin. Picaridine side effects are rarely known and it considered safe to use	New	রেফারেন্স নাই	DCC-২৫১ তম সভার সিদ্ধান্ত মোতাবেক Insect Repellent জাতীয় পদ চ এঃঅঈ কর্তৃক অনুমোদন নিতে হবে, ঔষধ প্রশাসন অধিদপ্তর হতে নয়।	আবেদন নামঞ্জুর করা হয়। DCC-২৫১ তম সভার সিদ্ধান্ত মোতাবেক Insect Repellent জাতীয় পদ চ এঃঅঈ কর্তৃক অনুমোদন নিতে হবে, ঔষধ প্রশাসন অধিদপ্তর হতে নয়।
290.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Ethyl Butylacetylaminopropionate 19.70 gm/100 ml Multi dose spray solution	Ethyl Butylacetylaminopropionate INN 19.7000 gm per 100 ml	OtherClassification Therapeutic Code: 75	Repels mosquitoes that may transmit west nile virus Pepels mosquitoes, deer ticks ,back flies, sand flies, gnats, no-seeums & biting midges	**Contraindication:** Contraindicated in patients sensitive to the molecule. **Side-effects:** Mild skin irritation Eye Irritation	New	রেফারেন্স নাই	DCC-২৫১ তম সভার সিদ্ধান্ত মোতাবেক Insect Repellent জাতীয় পদ চ এঃঅঈ কর্তৃক অনুমোদন নিতে হবে, ঔষধ প্রশাসন অধিদপ্তর হতে নয়।	আবেদন নামঞ্জুর করা হয়। DCC-২৫১ তম সভার সিদ্ধান্ত মোতাবেক Insect Repellent জাতীয় পদ চ এঃঅঈ কর্তৃক অনুমোদন নিতে হবে, ঔষধ প্রশাসন অধিদপ্তর হতে নয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
291.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Undecylenic Acid 50 mg & Zinc Undercylenate 200 mg per gram Cream	Undecylenic Acid INN 50 mg and Zinc Undercylenate BP/Ph.Eur 200 mg	Antifungl Agent Code: 20	For the treatment and prevention of athlete's foot.	**Contraindication** Hypersensitivity to any of the ingredients **Side-effects:** Hypersensitivity reactions may occur occasionally. Irritation of the skin may rarely occur.	New	BNF 79 (Page 1272)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
292.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Undecylenic Acid 20 mg & Zinc Undercylenate 200 mg per gram powder	Undecylenic Acid INN 20 mg and Zinc Undercylenate BP/Ph.Eur 200 mg	Antifungl Agent Therapeutic Code: 20	For the treatment and prevention of athlete's foot.	**Contraindication** Hypersensitivity to any of the ingredients **Side-effects:** Hypersensitivity reactions may occur occasionally. Irritation of the skin may rarely occur.	New	BNF 79 (Page 1272)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
293.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Clascoterone 1gm/100gm (1%) Cream	Clascoterone INN1gm/100gm	Skin and Mucous Membrane Preparations Therapeutic Code: 71	Clascoterone cream 1 % is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.	**Contraindication:** None **Side-effects:** Most common Side-effects occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, sting ing, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle. **Warnings And Precautions:** Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with CLASCOTERONE cream. If these effects occur, discontinue or reduce the frequency of application of CLASCOTERONE cream. Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with CLASCOTERONE. In the PK trial, HPA axis suppression was observed in 1120 (5%) of adult subjects and 2/22	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						(9%) of adolescent subjects at Day 14. All subjects returned to normal HPA axis function at follow-up 4 weeks after stopping treatment. Conditions which augment systemic absorption include use over large surface areas, prolonged use, and the use of occlu sive dressings. Attempt to withdraw use if HPA axis suppression develops. Pediatric patients may be more susceptible to systemic toxicity. Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials. Shifts from normal to elevated potassium levels were observed in 5% of CLASCOTERONE-treated subjects and 4% of vehicle-treated subjects.				
294.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Lactic Acid 1.8 gm + Citric Acid 1gm and Potassium Bitartrate 0.4gm per 100gm Gel	Lactic Acid BP/Ph. Fur. 1.8 gm + Citric Acid BP/Ph. Fur. 1gm and Potassium Bitartrate USP 0.4gm per 100gm	Contraceptives (including devices) Therapeutic Code: 39	Lactic acid, citric acid, and potassium bitartrate is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.	**Contraindication** Hypersensitivity to any ingredient of this gel. **Side-effects:** Most common adverse reactions (≥2%) were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain. **Warnings And Precautions:** Cystitis and Pyelonephritis: Avoid use in women with a history of recurrent UTI or urinary tract abnormalities	Existing	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
295.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Guselkumab 100 mg/ml Injection	Guselkumab 100 mg/ml ready to fill sterile bulk INN 1ml eq to 100 mg Guselkumab	Skin and Mucous Membrane Preparations Therapeutic Code: 71	Interleukin-23 blocker indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	**Contraindication** None **Side-effects:** Most common (≥1%) adverse reactions associated with Guselkumab include upper respiratory infections, headache, injection site reactions, arthralgia, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections **Warnings And Precautions:** •Infections: Guselkumab may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Guselkumab until the infection resolves. •Tuberculosis (TB): Evaluate for TB prior to initiating treatment with Guselkumab.	New	US FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
296.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Magnesium Hydroxide 6gm, Liquid Paraffin 21.6gm and Sodium Picosulfate 0.067gm per 100ml Emulsion	Magnesium Hydroxide USP 6gm, Liquid Paraffin BP 21.6gm and Sodium Picosulfate BP 0.067gm per 100ml .	Laxative Therapeutic Code: 060	Used for a short time to treat occasional constipation. It is a laxative that is thought to work by drawing water in to the intestines, an effect that helps to cause movement of the intestine. Also used as a stool softener. It s contact stimulant laxative used as a treatment for contact stimulant laxative used as a treatment for constipation or to prepare the large bowel before colonoscopy or surgery.	**CONTRAINDICATIONS:** • Hypersensitivity to any ingredient of composition. • Contraindicated in children. **SIDE EFFECTS:** • Hypermagnesemia • Abdominal pain • Diarrhea	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
297.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Trimetazidine Dihydrochloride 80mg Prolonged Capsule	Trimetazidine Dihydrochloride Ph. Eur. 80mg	Coronary Vasodilators and Antianginal drug Therapeutic Code: 040	Trimetazidine is indicate in adults as add on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line anti-anginal therapies.	**CONTRAINDICATIONS:** • Hypersensitivity to the active substance or to any of the excipients. • Parkinson disease, parkinsonian symptoms, tremors, restless leg	**New** Trimetazidine Dihydrochloride 20mg Tablet,	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					WARNINGS AND PRECAUTIONS: Trimetazidine is not a curative treatment for angina attacks, nor an initial treatment for unstable angina pectoris. It is also not a treatment for myocardial infarction.	syndrome and other related movement disorders • Several renal impairment (creatinine clearance <30 ml/min) **SIDE EFFECTS:** • Dizziness, headache • Abdominal pain, diarrhoea, dyspepsia, nausea and vomiting • Rash, urticaria • Asthenia	approved DCC-226 Trimetazidine Dihydrochloride 35mg Tablet, approved DCC-229 Trimetazidine Dihydrochloride 60mg controlled release capsule, not approved 231			
298.	**Navana Pharmaceuticals Limited**	Nebumetone 500 mg Tablet	Nebumetone 500 mg	Steroidal Anti inflammatory Therapeutic Code: 072	Indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis.	**Contraindications:** Contraindicated in patients who have previously exhibited hypersensitivity to this medicine and in whom this medicines, aspirin, or other NSAIDs induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in suchpatients receiving NSAIDs. **Side Effects:** Diarrhea, dyspepsia, and abdominal pain, constipation, flatulence, nausea, positive stool guaiac, dry mouth, gastritis, stomatitis, vomiting. Central Nervous System: Dizziness, headache, fatigue, increased sweating, insomnia, nervousness, somnolence. **Warnings and precautions:** Risk of G.I. Ulceration, Bleeding, and Perforation with NSAID Therapy: Serious gastrointestinal toxicity such	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						as bleeding, ulceration, and perforation can occur at any time, with or without warning symptoms, in patients treated chronically with NSAID therapy. Although minor upper gastrointestinal problems, such as dyspepsia, are common, usually developing early in therapy, physicians should remain alert for ulceration and bleeding in patients treated chronically with NSAIDs even in the absence of previous G.I. tract symptoms.				
299.	Navana Pharmaceuticals Limited	Nebumetone 750 mg Tablet	Nebumetone 750 mg	Steroidal Anti inflammatory Therapeutic Code: 072	Indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis.	**Contraindications:** Contraindicated in patients who have previously exhibited hypersensitivity to this medicine and in whom this medicines, aspirin, or other NSAIDs induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in suchpatients receiving NSAIDs. **Side Effects:** Diarrhea, dyspepsia, and abdominal pain, constipation, flatulence, nausea, positive stool guaiac, dry mouth, gastritis, stomatitis, vomiting. Central Nervous System: Dizziness, headache, fatigue, increased sweating, insomnia, nervousness, somnolence. **Warnings and precautions:** Risk of G.I. Ulceration, Bleeding, and Perforation with NSAID Therapy: Serious gastrointestinal toxicity such as bleeding, ulceration, and perforation can occur at any time, with or without warning symptoms, in patients treated chronically with NSAID therapy. Although minor upper gastrointestinal problems, such as dyspepsia, are common, usually	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						developing early in therapy, physicians should remain alert for ulceration and bleeding in patients treated chronically with NSAIDs even in the absence of previous G.I. tract symptoms.				
300.	Navana Pharmaceuticals Limited	Pimavanserin INN 10 mg Tablet	Pimavanserin INN 10 mg	Antipsychotic Therapeutic Code: 028	Indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.	**Contraindications:** None **Side Effects:** Peripheral edema and confusional state **Warnings and precautions:** QT Interval Prolongation: Increases in QT interval; avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
301.	Navana Pharmaceuticals Limited	Clonazepam USP 0.25 mg ODT	Clonazepam USP 0.25 mg	Drug used in Epilepsy Therapeutic Code: 046	Used alone or with other medicines to treat: • certain types of seizure disorders (epilepsy) in adults and children • panic disorder with or without fear of open spaces (agoraphobia) in adults	**Contraindications:** Significant liver disease. Acute narrow-angle glaucoma. **Side Effects:** CNS effects (eg, somnolence, depression), confusion, amnesia, liver disorders, GI upset, blood dyscrasias, paradoxical reactions (discontinue gradually if occur); hypersalivation. **Warnings and precautions:** Increased risk of drug-related mortality from concomitant use with opioids. Suicidal thoughts or behavior (monitor). Depression. May increase or precipitate tonic-clonic seizures. Compromised respiratory function (eg, COPD, sleep apnea). Porphyria. Renal impairment. Avoid abrupt cessation. Monitor blood counts, liver function during long-term therapy. Elderly. Labor & delivery. Pregnancy. Nursing mothers.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
302.	**Navana Pharmaceuticals Limited**	Clonazepam USP 0.5 mg ODT	Clonazepam USP 0.5 mg	Drug used in Epilepsy Therapeutic Code: 046	Used alone or with other medicines to treat: • certain types of seizure disorders (epilepsy) in adults and children • panic disorder with or without fear of open spaces (agoraphobia) in adults	**Contraindications:** Significant liver disease. Acute narrow-angle glaucoma. **Side Effects:** CNS effects (eg, somnolence, depression), confusion, amnesia, liver disorders, GI upset, blood dyscrasias, paradoxical reactions (discontinue gradually if occur); hypersalivation. **Warnings and precautions:** Increased risk of drug-related mortality from concomitant use with opioids. Suicidal thoughts or behavior (monitor). Depression. May increase or precipitate tonic-clonic seizures. Compromised respiratory function (eg, COPD, sleep apnea). Porphyria. Renal impairment. Avoid abrupt cessation. Monitor blood counts, liver function during long-term therapy. Elderly. Labor & delivery. Pregnancy. Nursing mothers.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
303.	**Navana Pharmaceuticals Limited**	Clonazepam USP 1 mg ODT	Clonazepam USP 1 mg	Drug used in Epilepsy Therapeutic Code: 046	Used alone or with other medicines to treat: • certain types of seizure disorders (epilepsy) in adults and children • panic disorder with or without fear of open spaces (agoraphobia) in adults	**Contraindications:** Significant liver disease. Acute narrow-angle glaucoma. **Side Effects:** CNS effects (eg, somnolence, depression), confusion, amnesia, liver disorders, GI upset, blood dyscrasias, paradoxical reactions (discontinue gradually if occur); hypersalivation. **Warnings and precautions:** Increased risk of drug-related mortality from concomitant use with opioids. Suicidal thoughts or behavior (monitor). Depression. May increase or precipitate tonic-clonic seizures. Compromised respiratory function (eg, COPD, sleep apnea). Porphyria. Renal impairment. Avoid abrupt cessation. Monitor blood counts, liver function	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						during long-term therapy. Elderly. Labor & delivery. Pregnancy. Nursing mothers.				
304.	**Navana Pharmaceuticals Limited**	Clonazepam USP 2 mg ODT	Clonazepam USP 2 mg	Drug used in Epilepsy Therapeutic Code: 046	Used alone or with other medicines to treat: • certain types of seizure disorders (epilepsy) in adults and children • panic disorder with or without fear of open spaces (agoraphobia) in adults	**Contraindications:** Significant liver disease. Acute narrow-angle glaucoma. **Side Effects:** CNS effects (eg, somnolence, depression), confusion, amnesia, liver disorders, GI upset, blood dyscrasias, paradoxical reactions (discontinue gradually if occur); hypersalivation. **Warnings and precautions:** Increased risk of drug-related mortality from concomitant use with opioids. Suicidal thoughts or behavior (monitor). Depression. May increase or precipitate tonic-clonic seizures. Compromised respiratory function (eg, COPD, sleep apnea). Porphyria. Renal impairment. Avoid abrupt cessation. Monitor blood counts, liver function during long-term therapy. Elderly. Labor & delivery. Pregnancy. Nursing mothers.	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
305.	**Navana Pharmaceuticals Limited**	Desloratadine 2.5 mg ODT	Desloratadine 2.5 mg	Antihistamine Therapeutic Code: 021	Seasonal allergic rhinitis (for patients ≥2yrs old). Perennial allergic rhinitis, chronic idiopathic urticaria (for patients ≥6 months old).	**Contraindications:** Desloratadine orally disintegrating tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients or to loratadine. **Side Effects:** Pharyngitis, dry mouth or throat, myalgia, fatigue, somnolence, dysmenorrhea, headache, nausea, dizziness. Children: fever, diarrhea, upper respiratory infections, irritability, coughing.	5mg, 2.5mg/5ml	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
306.	**Navana Pharmaceuticals Limited**	Desloratadine 5 mg ODT	Desloratadine 5 mg	Antihistamine Therapeutic Code: 021	Seasonal allergic rhinitis (for patients ≥2yrs old). Perennial allergic rhinitis, chronic idiopathic urticaria (for patients ≥6 months old).	**Contraindications:** Desloratadine orally disintegrating tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients or to loratadine.	5mg, 2.5mg/5ml	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side Effects: Pharyngitis, dry mouth or throat, myalgia, fatigue, somnolence, dysmenorrhea, headache, nausea, dizziness. Children: fever, diarrhea, upper respiratory infections, irritability, coughing.				
307.	**Navana Pharmaceuticals Limited**	Perampanel INN 2 mg Tablet	Perampanel INN 2 mg	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।
308.	**Navana Pharmaceuticals Limited**	Perampanel INN 4 mg Tablet	Perampanel INN 4 mg	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency.				
309.	**Navana Pharmaceuticals Limited**	Perampanel INN 6 mg Tablet	Perampanel INN 6 mg	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।
310.	**Navana Pharmaceuticals Limited**	Perampanel INN 8 mg Tablet	Perampanel INN 8 mg	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
311.	**Navana Pharmaceuticals Limited**	Perampanel INN 10 mg Tablet	Perampanel INN 10 mg	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।
312.	**Navana Pharmaceuticals Limited**	Perampanel INN 0.5mg/ml Oral Solution	Perampanel INN 0.5mg/ml	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency.	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
313.	**Navana Pharmaceuticals Limited**	Perampanel INN 0.5mg/ml Oral Solution	Perampanel INN 0.5mg/ml	Drug used in Epilepsy Therapeutic Code: 046	A non-competitive AMPA glutamate receptor antagonist indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.	**Contraindications:** None **Side Effects:** Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder. **Warnings and precautions:** Suicidal Behavior and Ideation: Monitor for suicidal thoughts or behaviour *Neurologic Effects:* Monitor for dizziness, gait disturbance, somnolence, and fatigue. Patients should use caution when driving or operating machinery. *Falls:* Monitor needed for falls and injuries *Withdrawal of Antiepileptic Drugs:* In patients with epilepsy, there may be an increase in seizure frequency	New	USFDA	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুরের সুপারিশ করা হয়।	পদটির Warnings and precautions এর উপর ভিত্তি করে নামঞ্জুর করা হয়।
314.	**Navana Pharmaceuticals Limited**	Clonidine HCl USP 0.1 mg extended release Tablet	Clonidine HCl USP 0.1 mg	Antihypertensive Therapeutic Code: 022	1. A centrally acting alpha2-adrenergic agonist indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medications. 2. It is also approved for the treatment of hypertension	**Contraindications:** Clonidine hydrochloride tablets should not be used in patients with known hypersensitivity to clonidine. **Side Effects:** Somnolence, fatigue, upper respiratory tract infection (cough, rhinitis, sneezing), irritability, throat pain (sore throat), insomnia, nightmares, emotional disorder, constipation, nasal congestion, increased body temperature, dry mouth, and ear pain. **Warnings and precautions:** Hypotension/bradycardia: Use KAPVAY with caution in patients at risk for hypotension, bradycardia, and heart block. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Advise patients to avoid becoming dehydrated or overheated. •Somnolence/Sedation: Has been observed with KAPVAY. Consider the	0.1 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						potential for additive sedative effects with CNS depressant drugs. patients against operating heavy equipment or driving until they know how they respond to KAPVAY. • Abrupt Discontinuation: Patients should be instructed not to discontinue KAPVAY therapy without consulting their physician due to the potential risk of withdrawal effects. KAPVAY should be discontinued slowly in decrements of no more than 0.1 mg every 3 to 7 days. • Allergic Reactions: In patients who have developed localized contact sensitization or other allergic reaction to clonidine in a transdermal system, substitution of oral clonidine hydrochloride therapy may be associated with the development of a generalized skin rash, urticaria, or angioedema. • Use in patients with vascular disease, cardiac conduction disease, or chronic renal failure: Monitor carefully and uptitrate slowly. • Other clonidine containing products: Do not use KAPVAY concomitantly with other products containing clonidine.				
315.	**Navana Pharmaceuticals Limited**	Clonidine HCl USP 0.2 mg extended release Tablet	Clonidine HCl USP 0.2 mg	Antihypertensive Therapeutic Code: 022	1. A centrally acting alpha2-adrenergic agonist indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medications. 2. It is also approved for the treatment of hypertension	**Contraindications:** Clonidine hydrochloride tablets should not be used in patients with known hypersensitivity to clonidine. **Side Effects:** Somnolence, fatigue, upper respiratory tract infection (cough, rhinitis, sneezing), irritability, throat pain (sore throat), insomnia, nightmares, emotional disorder, constipation, nasal congestion, increased body temperature, dry mouth, and ear pain. **Warnings and precautions:** Hypotension/bradycardia: Use KAPVAY with caution in patients at risk	0.1 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						for hypotension, bradycardia, and heart block. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Advise patients to avoid becoming dehydrated or overheated. •Somnolence/Sedation: Has been observed with KAPVAY. Consider the potential for additive sedative effects with CNS depressant drugs. patients against operating heavy equipment or driving until they know how they respond to KAPVAY. • Abrupt Discontinuation: Patients should be instructed not to discontinue KAPVAY therapy without consulting their physician due to the potential risk of withdrawal effects. KAPVAY should be discontinued slowly in decrements of no more than 0.1 mg every 3 to 7 days. • Allergic Reactions: In patients who have developed localized contact sensitization or other allergic reaction to clonidine in a transdermal system, substitution of oral clonidine hydrochloride therapy may be associated with the development of a generalized skin rash, urticaria, or angioedema. • Use in patients with vascular disease, cardiac conduction disease, or chronic renal failure: Monitor carefully and uptitrate slowly. • Other clonidine containing products: Do not use KAPVAY concomitantly with other products containing clonidine.				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
316.	**Navana Pharmaceuticals Limited** Nuvista Pharma Ltd.	Methanamine Hippurate USP 1g Tablet	Methanamine Hippurate USP 1g	Anti-infective Therapeutic Code: 023	HIPREX is indicated for prophylactic or suppressive treatment of frequently recurring urinary tract infections when long-term therapy is considered necessary. This drug should only be used after eradication of the infection by other appropriate antimicrobial agents.	**Contraindications:** Methenamine hippurate tablets USP) is contraindicated in patients with renal insufficiency, severe hepatic insufficiency, or severe dehydration. Methenamine preparations should not be given to patients taking sulfonamides because some sulfonamides may form an insoluble precipitate with formaldehyde in the urine. **Side Effects:** Nausea, upset stomach, dysuria, and rash **Warnings and precautions:** Large doses of methenamine (8 grams daily for 3 to 4 weeks) have caused bladder irritation,painful and frequent micturition, albuminuria, and gross hematuria. Prescribing Methanamine in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
317.	**Navana Pharmaceuticals Limited**	Tavaborole INN (5%) 10 ml Topical Solution	Tavaborole INN (5%) 10 ml	Antifungl Agent Therapeutic Code: 020	An oxaborole antifungal indicated for the topical treatment of onychomycosis of the toenails.	**Contraindications:** None **Side Effects:** Application site exfoliation, ingrown toenail, application site erythema, and application site dermatitis. **Warnings and precautions:** Carcinogenesis, Mutagenesis, Impairment of Fertility may occur	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
318.	**Navana Pharmaceuticals Limited**	Levodopa INN 50mg + Benserazide INN 12.50mg dispersible tablet	Levodopa INN 50mg + Benserazide INN 12.50mg	Antiparkinsonism Therapeutic Code: 025	It is indicated for the treatment of all forms of Parkinson's syndrome with the exception of medicine-induced parkinsonism.	Contraindications: patients with known hypersensitivity to levodopa or benserazide or any of the excipients. • patients receiving non-selective monoamine oxidase (MAO) inhibitors due to the risk of hypertensive crisis.However, selective MAO-B inhibitors, such as selegiline and rasagiline, or selective MAO-A inhibitors, such as moclobemide, are	Levodopa 50mg + Benserazide 12.50mg tablet, Levodopa 100mg + Benserazide 25mg	BNF 76 Page 409 & 410	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						not contraindicated. Combination of MAO-A and MAO-B inhibitors is equivalent to non-selective MAO inhibition, and hence this combination should not be given concomitantly with it. • with decompensated endocrine, renal or hepatic function, cardiac disorders, psychiatric diseases with a psychotic component or closed angle glaucoma. levodopa may activate a malignant melanoma, It should not be used in patients with suspicious, undiagnosed lesions or a history of melanoma. • the management of patients with intention tremor and Huntington's chorea. • patients less than 30 years old. Side effects: Complications to long-term levodopa and benserazide combination therapy appear commonly and include motor fluctuations, dyskinesias, neuropsychiatric problems, and cardiovascular effects Involuntary movements (e.g., choreiform or movements) are associated with levodopa and benserazide combination therapy. Muscle twitching may signify early signs of overdosage	tablet, Levodopa 200mg plus Benserazide 50mg tablet			
319.	**Navana Pharmaceuticals Limited**	Levodopa INN 100mg + Benserazide INN 25mg dispersible tablet	Levodopa INN 100mg + Benserazide INN 25mg	Antiparkinsonism Therapeutic Code: 025	It is indicated for the treatment of all forms of Parkinson's syndrome with the exception of medicine-induced parkinsonism.	Contraindications: patients with known hypersensitivity to levodopa or benserazide or any of the excipients. • patients receiving non-selective monoamine oxidase (MAO) inhibitors due to the risk of hypertensive crisis.However, selective MAO-B inhibitors, such as selegiline and rasagiline, or selective MAO-A inhibitors, such as moclobemide, are not contraindicated. Combination of MAO-A and MAO-B inhibitors is equivalent to non-selective MAO	Levodopa 50mg + Benserazide 12.50mg tablet, Levodopa 100mg + Benserazide 25mg tablet, Levodopa 200mg	BNF 76 Page 409 & 410	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						inhibition, and hence this combination should not be given concomitantly with it. • with decompensated endocrine, renal or hepatic function, cardiac disorders, psychiatric diseases with a psychotic component or closed angle glaucoma. levodopa may activate a malignant melanoma, It should not be used in patients with suspicious, undiagnosed lesions or a history of melanoma. • the management of patients with intention tremor and Huntington's chorea. • patients less than 30 years old. Side effects: Complications to long-term levodopa and benserazide combination therapy appear commonly and include motor fluctuations, dyskinesias, neuropsychiatric problems, and cardiovascular effects Involuntary movements (e.g., choreiform or movements) are associated with levodopa and benserazide combination therapy. Muscle twitching may signify early signs of overdosage.	plus Benserazide 50mg tablet			
320.	**Navana Pharmaceuticals Limited**	Bifonazole BP 1% Cream	Bifonazole BP 1%	Antifungl Agent Therapeutic Code: 020	Treatment of athlete's foot.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients listed in section. Treatment of infants with nappy rash. Treatment of nail and scalp infections. **Side Effect:** Immune system disorders: Very rarely, systemic hypersensitivity reactions may occur. General disorders and administration site conditions: Administration site pain, oedema peripheral (at administration site), Skin and subcutaneous tissue disorders: Dermatitis contact, dermatitis	New	MHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						allergic, erythema, pruritus, rash, urticaria, blister, skin exfoliation, eczema, dry skin, skin irritation, skin maceration, skin burning sensation. These side effects are reversible after discontinuation of the treatment.				
321.	**Navana Pharmaceuticals Limited**	Sulconazole Nitrate 1.0% Cream	Sulconazole Nitrate 1.0%	Antifungl Agent Therapeutic Code: 020	Indicated for the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis, and for the treatment of tinea versicolor.	**Contra-indication:** Sulconazole nitrate Cream, 1.0% is contraindicated in patients who have a history of hypersensitivity to any of its ingredients. **Side-Effect:** Approximately 3% of these patients reported itching, 3% burning or stinging, and 1% redness.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
322.	NIPRO JMI Pharma Ltd, Comilla.	Clopidogrel Hydrogen Sulfate BP equivalent to Clopidogrel 150 mg Tablet	Clopidogrel 150 mg	Antiplatelete Therapeutic Code: 026	It is indicated for the patients with Acute coronary syndrome (ACS) who received Percutaneous coronary intervention (PCI) and CYP2C19 intermediate metabolizers.	**Contraindication** Clopidogrel is contraindicated in the following conditions: hypersensitivity to the drug substance or any component of the product, active pathological bleeding such as peptic ulcer or intracranial hemorrhage. **Side Effects:** Clopidogrel is generally well tolerated drug. Common side effects: bleeding, diarrhea, gastrointestinal discomfort, hemorrhage, skin reactions. Rare side effects: Acquired hemophilia, anemia, angioedema, arthralgia, arthritis, bone marrow disorders.	Clopidogrel 75 mg	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
323.	**Radiant Pharmaceuticals Limited** **B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh**	Vitamin C USP 1000mg Dispersible Granules in sachet	Vitamins and Combinations Therapeutic Code: 078	Scurvy, Bone and Tooth development, Gingivitis, infection (pneumonia, whooping cough, tuberculosis, diphtheria, sinusitis, rheumatic fever, etc.)	**Contraindication**: • a high amount of oxalic acid in urine • iron metabolism disorder causing increased iron storage • sickle cell anemia • anemia from pyruvate kinase and G6PD deficiencies	New		রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Side effects: Transient mild soreness may occur at the site of intramuscular or subcutaneous injection. Too-rapid intravenous administration of the solution may cause temporary faintness or dizziness.					
324.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Bacteriostatic Water for Injection USP 100%	Bacteriostatic Water for Injection USP	Water for Injection Therapeutic Code: 079	Bacteriostatic Water for injection is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.	**Contraindication:** Due to the potential toxicity of benzyl alcohol in neonates, solutions containing benzyl alcohol must not be used in this patient population. **Precaution:** Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture. Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration. Bacteriostatic Water for Injection, USP containing additives should be given to a pregnant woman only if clearly needed. **Warning:** Not for use in neonates. Intravenous administration of Bacteriostatic Water for Injection without a solute may result in hemolysis. **Side effects:** Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess,	Water for Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						tissue necrosis or infection at the site of injection.				
325.	**Silva Pharmaceuticals Ltd.**	Ascorbic Acid & Elemental Zinc Syrup	Ascorbic Acid & Elemental Zinc Syrup Each 5 ml of syrup contains Ascorbic Acid BP 100 mg & Zinc Sulfate Monohydrate USP 27.44 mg equivalent Elemental Zinc 10 mg.	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	Ascorbic Acid & Zinc Syrup works by both providing ascorbic acid and reversibly oxidizing to dehydroascorbic acid in the body; regulating the intestinal fluid transport, mucosal integrity, immunity, gene expression and oxidative stress.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Zinc. **Side-effects**: Temporary faintness, Dizziness, Injection site soreness, Vomiting, Loss of appetite, Stomach cramps, Diarrhea, Headache **PRECAUTIONS:** Concurrent administration of Zinc salt with penicillamine might diminish the effect of Penicillamine. The absorption of Zinc, although poor, may be decreased by various compounds including some foods. Chelation may occur with tetracyclines.	Existing Molecule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
326.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Netupitant 300 mg + Palonosetron 0.50 mg Capsule	Netupitant INN 300 mg + Palonosetron Hydrochloride INN 0.562 mg eqv. to Palonosetron 0.50 mg	Antiemetic Therapeutic code- 018	Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The combination of Palonosetron and Netupitant: Palonosetron prevents nausea and vomiting during the acute phase and Netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy	**Contra-indication:** None **Side-effects:** Allergic reactions, such as anaphylaxis, hives, swollen face, trouble breathing, or chest pain. Serotonin syndrome which can happen particularly with certain other medicines such as antidepressants and anti-migraine medicines and can lead to death. **Warnings & Precautions:** • Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron, one of the components of capsule, with or without known hypersensitivity to other 5-HT3 receptor antagonists. • Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs. If such symptoms occur, discontinue and initiate supportive treatment. If concomitant use of this drug with other serotonergic drugs is clinically warranted, patients should be made	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						aware of a potential increased risk for serotonin syndrome.				
327.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Minocycline 1.20 g/30 g (4%) Foam	Minocycline Hydrochloride USP 1.30 g eqv. to Minocycline 1.20 g/30 g (4%)	Anti-infective Therapeutic code- 023	Moderate to severe Acne Vulgaris	**Contra-indication:** This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines or any of the ingredients within this product. **Side-effects:** Headache, and application site reactions, including: redness, dryness, skin discoloration, peeling, and itching. **Warnings & Precautions:** • The propellant in Minocycline 4% topical foam is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application. • If liver injury is suspected, discontinue Minocycline 4% topical foam.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
328.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Mometasone Furoate 50 mcg + Formoterol Fumarate Dihydrate 5 mcg/puff, 120 puffs Metered Dose Inhaler (MDI)	Mometasone Furoate BP 50 mcg + Formoterol Fumarate Dihydrate BP 5 mcg/puff	COPD Therapeutic code-044	Asthma, COPD	**Contra-indication:** Primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures, hypersensitivity to any of the ingredients. **Side-effects:** Thrush in the mouth and throat, immune system effects and a higher chance for infections, adrenal insufficiency, serious allergic reactions, lower bone mineral density, eye problems including glaucoma, cataracts, and blurred vision. **Warnings & Precautions:** • LABA monotherapy increases the risk of serious asthma-related events. Deterioration of disease and acute episodes: Do not initiate in acutely deteriorating asthma or to treat acute symptoms. • Use with additional long-acting beta2-agonist: Do not use in combination because of risk of overdose. • Localized infections: Candida albicans infection of the mouth and	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						throat may occur. Monitor patients periodically for signs of adverse effects on the oral cavity. After dosing, advise patients to rinse their mouth with water and spit out contents without swallowing. • Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. • Use with caution in patients with these infections because of the potential for worsening of these infections.				
329.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Mometasone Furoate 100 mcg + Formoterol Fumarate Dihydrate 5 mcg/puff, 120 puffs Metered Dose Inhaler (MDI)	Mometasone Furoate BP 100 mcg + Formoterol Fumarate Dihydrate BP 5 mcg/puff	COPD Therapeutic code-044	Asthma, COPD	**Contra-indication:** Primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures, hypersensitivity to any of the ingredients. **Side-effects:** Thrush in the mouth and throat, immune system effects and a higher chance for infections, adrenal insufficiency, serious allergic reactions, lower bone mineral density, eye problems including glaucoma, cataracts, and blurred vision. **Warnings & Precautions:** • LABA monotherapy increases the risk of serious asthma-related events. Deterioration of disease and acute episodes: Do not initiate in acutely deteriorating asthma or to treat acute symptoms. • Use with additional long-acting beta2-agonist: Do not use in combination because of risk of overdose. • Localized infections: Candida albicans infection of the mouth and throat may occur. Monitor patients periodically for signs of adverse effects on the oral cavity. After dosing, advise patients to rinse their mouth with water and spit out contents without swallowing.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. • Use with caution in patients with these infections because of the potential for worsening of these infections.				
330.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Mometasone Furoate 200 mcg + Formoterol Fumarate Dihydrate 5 mcg/puff, 120 puffs Metered Dose Inhaler (MDI)	Mometasone Furoate BP 200 mcg + Formoterol Fumarate Dihydrate BP 5 mcg/puff	COPD Therapeutic code- -044	Asthma, COPD	**Contra-indication:** Primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures, hypersensitivity to any of the ingredients. **Side-effects:** Thrush in the mouth and throat, immune system effects and a higher chance for infections, adrenal insufficiency, serious allergic reactions, lower bone mineral density, eye problems including glaucoma, cataracts, and blurred vision. **Warnings & Precautions:** • LABA monotherapy increases the risk of serious asthma-related events. Deterioration of disease and acute episodes: Do not initiate in acutely deteriorating asthma or to treat acute symptoms. • Use with additional long-acting beta2-agonist: Do not use in combination because of risk of overdose. • Localized infections: Candida albicans infection of the mouth and throat may occur. Monitor patients periodically for signs of adverse effects on the oral cavity. After dosing, advise patients to rinse their mouth with water and spit out contents without swallowing. • Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex infections. More serious or even fatal	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						course of chickenpox or measles can occur in susceptible patients. • Use with caution in patients with these infections because of the potential for worsening of these infections.				
331.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Tiotropium 2.50 mcg + Olodaterol 2.50 mcg/puff, 120 puffs Metered Dose Inhaler (MDI)	Tiotropium Bromide Monohydrate BP 3.125 mcg eqv. to Tiotropium 2.50 mcg + Olodaterol Hydrochloride INN 2.736 mcg eqv. to Olodaterol 2.50 mcg/puff	COPD Therapeutic code-044	Asthma, COPD	**Contra-indication:** All LABAs are contraindicated in patients with asthma without use of a long-term asthma control medication, it is not indicated for the treatment of asthma, hypersensitivity to tiotropium, ipratropium, olodaterol, or any component of this product. **Side-effects:** People with asthma who take long-acting beta2-adrenergic agonist (LABA) medicines, such as olodaterol (one of the medicines in MDI), have an increased risk of death from asthma problems, It is not known if LABA medicines, such as olodaterol (one of the medicines in MDI) increase the risk of death in people with COPD, breathing problems worsen quickly. **Warnings & Precautions:** • LABA increase the risk of asthma related death. • Do not initiate the drug in acutely deteriorating COPD patients. • Do not use for relief of acute symptoms. Concomitant short-acting beta-2 agonists can be used as needed for acute relief. • Do not exceed the recommended dose. Excessive use of the drug, or use in conjunction with other medications containing LABA can result in clinically significant cardiovascular effects and may be fatal. • Immediate hypersensitivity reactions: Discontinue the drug at once and consider alternatives if immediate hypersensitivity reactions, including angioedema, bronchospasm, or anaphylaxis, occur.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Life-threatening paradoxical bronchospasm can occur, Discontinue immediately. • Use with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or sensitivity to sympathomimetic drugs. • Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to consult a physician immediately if this occurs. Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to consult a physician immediately if this occurs. Be alert to hypokalemia and hyperglycemia.				
332.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Lomitapide 5 mg Capsule	Lomitapide Mesylate INN 5.70 mg eqv. to Lomitapide 5 mg	Lipid Lowering Therapeutic code- -061	Homozygous Familial Hypercholesterolemia lomitapide is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDLC), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)	**Contra-indication:** Lomitapide is contraindicated in the following conditions: Pregnancy. Concomitant administration of lomitapide.with moderate or strong CYP3A4 inhibitors, as this can increase lomitapide exposure. Patients with moderate or severe hepatic impairment (based on Child-Pugh category B or C) and patients with active liver disease, including unexplained persistent elevations of serum transaminases. **Side-effects:** The following important adverse reactions have been observed and are discussed in detail in other sections of the label: • Risk of hepatotoxicity • Reduced absorption of fat-soluble vitamins, and serum fatty acids • Gastrointestinal adverse reactions **Warnings & Precautions:** • Embryo-Fetal Toxicity: Females of Reproductive Potential should have a negative pregnancy test before starting Lomitapide and use contraception during treatment.	Lomitapide 10 mg Capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Gastrointestinal adverse reactions occur in 93% of patients and could affect absorption of concomitant oral medications.				
333.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Lomitapide 20 mg Capsule	Lomitapide Mesylate INN 22.80 mg eqv. to Lomitapide 20 mg	Lipid Lowering Therapeutic code:061	Homozygous Familial Hypercholesterolemia lomitapide is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDLC), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)	**Contra-indication:** Lomitapide is contraindicated in the following conditions: Pregnancy. Concomitant administration of lomitapide.with moderate or strong CYP3A4 inhibitors, as this can increase lomitapide exposure. Patients with moderate or severe hepatic impairment (based on Child-Pugh category B or C) and patients with active liver disease, including unexplained persistent elevations of serum transaminases. **Side-effects:** The following important adverse reactions have been observed and are discussed in detail in other sections of the label: • Risk of hepatotoxicity • Reduced absorption of fat-soluble vitamins, and serum fatty acids • Gastrointestinal adverse reactions **Warnings & Precautions:** • Embryo-Fetal Toxicity: Females of Reproductive Potential should have a negative pregnancy test before starting Lomitapide and use contraception during treatment. • Gastrointestinal adverse reactions occur in 93% of patients and could affect absorption of concomitant oral medications.	Lomitapide 10 mg Capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
334.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Alogliptin 12.50 mg + Pioglitazone 45 mg Film Coated Tablet	Alogliptin Benzoate INN 16.99 mg eqv. to Alogliptin 12.50 mg + Pioglitazone Hydrochloride USP 49.9 mg eqv. to Pioglitazone 45 mg	Antidiabetes Therapeutic code:015	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of Use: Not for treatment of type 1 diabetes or diabetic ketoacidosis.	**Contra-indication:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, including anaphylaxis, angioedema or severe cutaneous adverse reactions. **Side-effects:** Nasopharyngitis, back pain and upper respiratory tract infection. **Warnings & Precautions:** • There have been reports of Congestive heart failure, acute	Pioglitazone 15 & 30 mg Pioglitazone 30 mg বাংলাদেশে নিষিদ্ধ করা হয়েছে ।	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						pancreatitis, hypersensitivity reactions, edema, Hypoglycemia.				
335.	**Acme Laboratories Ltd., Dhamrai, Dhaka**	Elemental Iron 500 mg/5 ml Injection	Ferric Derisomaltose INN 1678.16 mg eqv. to Elemental Iron 500 mg/5 ml	Vitamins and Combinations Therapeutic code: 078	Ferric Derisomaltose is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron & who have non-hemodialysis dependent chronic kidney disease.	**Contra-indication:** Serious hypersensitivity to Ferric Derisomaltose or iro overload. **Side-effects:** The most common side effects of Ferric Derisomaltose include rash and nausea. Symptoms of an allergic reaction including rash, itching, hives, dizziness, lightheadedness, breathing problems and low blood pressure have also happened during treatment with Ferric Derisomaltose. **Warnings & Precautions:** • Only administer Ferric Derisomaltose when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
336.	Acme Laboratories Ltd., Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur. Opsonin Pharma Limited, Rupatali, Barishal.	Elemental Iron 1000 mg/10 ml Injection	Ferric Derisomaltose INN 3356.32 mg eqv. to Elemental Iron 1000 mg/10 ml	Vitamins and Combinations Therapeutic code: 078	Ferric Derisomaltose is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron & who have non-hemodialysis dependent chronic kidney disease.	**Contra-indication:** Serious hypersensitivity to Ferric Derisomaltose or iro overload. **Side-effects:** The most common side effects of Ferric Derisomaltose include rash and nausea. Symptoms of an allergic reaction including rash, itching, hives, dizziness, lightheadedness, breathing problems and low blood pressure have also happened during treatment with Ferric Derisomaltose. **Warnings & Precautions:** • Only administer Ferric Derisomaltose when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
337.	Gonoshasthaya Pharmaceuticals Ltd	Furosemide BP 200 mg Tablet	Furosemide BP 200 mg	Diuretics Therapeutic code:042	Treatment of Edema associated with congestive heart failure, cirrhosis of the liver, and renal disease.	**Contraindications:** Furosemide is contraindicated in anuria, electrolyte deficiency and pre-comatose states associated with liver cirrhosis. Hypersensitivity to furosemide or sulphonamides.	Furosemide 20, 40 mg Tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side effects: Alkalosis, uric acid retention and may rarely produce acute gout. Furosemide may provoke hyperglycemia and glycosuria.				
338.	Gonoshasthaya Pharmaceuticals Ltd	Ascorbic Acid BP 250 mg Zinc Sulphate Monohydrate BP (as elemental zinc 2.5 mg) Tablet	Ascorbic Acid BP 250 mg Zinc Sulphate Monohydrate BP	Metals, Salts, Minerals and Calcium Preparations Therapeutic code:062	Treatment of vitamin C and Zinc deficiency.	**CONTRAINDICATIONS:** • Hypersensitivity to any of the active substances or to any of the excipients listed • Patients suffering from or having a history of Nephrolitiasis must not take this product. • Patients suffering from oxalate urolithiasis or oxaluria must not take this product. • Patients suffering from severe renal insufficiency or renal failure must not take the product. • This includes patients on dialysis. • Patients suffering from Hemochromatosis must not take this product. **SIDE EFFECTS:** • Gastrointestinal disorders • Immune System Disorders **WARNINGS AND PRECAUTIONS:** • Patients with rare hereditary problems of fructose intolerance should not take this medicine • Patients suffering from renal insufficiency • Patients suffering from glucose-6-phosphatase deficiency Do not exceed the recommended doses		রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
339.	Jayson Pharmaceuticals Limited, Tejgaon, Dhaka	Folic acid 2.5mg/5mL Oral Solution	Folic Acid Hydrate (Folic acid)BP 2.5mg (as anhydrous)/5mL Oral Solution	DRUG used in Anemia and other Blood disorder Therapeutic code: 045	1.Anaemia which can be caused by: - a lack of vitamins in adults and children -pregnancy -an addiction to alcohol	**Contra-indications:** -Known hypersensitivity to folic acid. -Known hypersensitivity to hydroxybenzoate esters. -Patients with malignant disease, unless megaloblastic anaemia due to folic deficiency	Folic acid 5 mg Tablet	BNF-76 page-993	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					-a medicine that is used to control fits 2. Sickle cell Anaemia or other anaemias caused by a lack of red blood cells. 3. Illnesses called "Tropical and Non-tropical Sprue". 4. Coeliac disease	**Side-effects:** The product can cause foe following side effects although not everybody gets them. An allergic reaction may include: - Any kind of skin rash, flaking skin, boils or sore lips and mouth - -Sudden wheezing, fluttering or tightness of the chest or collapse. - Frequency not known: Severe allergic reaction (anaphylactic reaction). - -Feeling sick (nausea), being sick (Vomiting) or an upset stomach.				
340.	Jayson Pharmaceuticals Limited, Tejgaon, Dhaka	Sodium Bicarbonate BP 50mg/mL Ear Drops	Sodium Bicarbonate BP 50mg/mL	Ear Preparation Therapeutic code: 051	Used to soften and help to remove hardened wax from the ear canal.	**Contra-indications:** Do not use for allergic to sodium bicarbonate or any other ingredients of this drops **Side-effects:** - Irritation or pain, loss of hearing, dizziness and tinnitus. Sometimes may cause dryness in ear canal. - Very rarely, an unpleasant taste has been reported when using ear drops.	Sodium Bicarbonate 7.5 mg/100 ml	BNF-76 Page-1164	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
341.	Popular Pharmaceuticals Limited 164, Tongi I/A, Tongi, Gazipur	Esketamine Hydrochloride BP 25 mg/ml Solution for Injection	Esketamine Hydrochloride BP 25 mg/ml	Anaesthetics (General) Therapeutic code: 004	Esketamine Hydrochloride is indicated in: Induction and maintenance of general anaesthesia, as the only anaesthetic or possibly in combination with hypnotics. Supplementation of regional or local anaesthesia Anaesthesia and pain relief (analgesia) in emergency medicine Pain control in artificial respiration (intubation)	**Contraindication:** Esketamine must not be used: ✓ in the case of hypersensitivity to the active substance or to any of the excipients ✓ in patients to whom elevation of blood pressure or intracranial pressure forms a serious risk ✓ if hypertension is poorly adjusted or not treated (arterial hypertension - systolic / diastolic blood pressure above 180/100 mmHg at rest) ✓ in eclampsia and pre-eclampsia ✓ in patients with hyperthyroidism (or insufficiently treated hyperthyroidism) ✓ in situations which require relaxed uterus myometrium (e.g.	New	**UK-MHRA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						threatening uterus rupture, prolapsed umbilical cord) ✓ as sole anesthetic agent in patients with manifest ischemic cardiac disorders ✓ in combination with xanthine derivatives (e.g. aminophylline or theophylline) (the convulsion threshold may become lower) ✓ in combination with ergometrine **Side-effects:** Adverse effects are usually dependent on the dose and speed of injection and are spontaneously reversible. Nervous system (CNS) and psychiatric adverse effects are more common if esketamine is administered as the only anaesthetic. The risk of psychic reaction occurring during recovery from anaesthesia can be greatly reduced by the co-administration of a benzodiazepine. **WARNING AND PRECAUTIONS** Esketamine should be used with caution in the following situations: ✓ unstable angina pectoris or myocardial infarction in the last 6 months ✓ cardiac insufficiency ✓ elevated intracranial pressure, except under appropriate ventilation, and in the case of central nervous system damages or diseases, since elevation of cerebrospinal pressure has been described in connection with ketamine anaesthesia ✓ in patients who have or have had severe psychiatric disturbances ✓ increased eye pressure (glaucoma) and perforating eye injuries as well as in connection				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						with eye examinations or eye surgery in which intraocular pressure should not increase ✓ surgery in the upper respiratory tract ✓ in patients under chronic or acute influence of alcohol ✓ in patients who have liver disease ✓ in patients who have a history of drug abuse or addiction				
342.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Metformin Hydrochloride 17gm/100ml (850mg/5ml) Oral Solution	Metformin Hydrochloride BP 17gm/100ml (850mg/5ml)	Antidiabetes Therapeutic code: 015	Metformin hydrochloride oral solution is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.	**Contra-indication:** Acute metabolic acidosis(including lactic acidosis and diabetic ketoacidosis), Common or very common:Abdominal pain, appetite decreased, diarrhoea, nausea, teste altered, vomiting	500mg/5 ml oral Solution	BNF-79 Page-714	পদটি sugar free উপাদান দিয়ে প্রস্তুত করতে হবে এই শর্তে অনুমোদনের সুপারিশ করা হয়।	পদটি sugar free উপাদান দিয়ে প্রস্তুত করতে হবে এই শর্তে অনুমোদন করা হয়।
343.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Benzonatate 100mg Soft Gelatin Capsule	Benzonatate USP 100mg	Antitussive Therapeutic code: 031	Indicated for the symptomatic relief of cough.	**Contra-indication:** Hypersensitivity to benzonatate or related compounds. **Side-effecct:** Potential side-effects to Benzonatate may include: **Hypersensitivity reactions:** bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule. **CNS:** sedation; headache; dizziness; mental confusion; visual hallucinations. **GI:** constipation; nausea; GI upset. **Dermatologic:** pruritus; skin eruptions. **Other:** nasal congestion; sensation of burning in the eyes; vague "chilly" sensation; numbness of the chest; hypersensitivity. **Warnings and Precautions:** Benzonatate is chemically related to anesthetic agents of the para-amino-benzoic acid class (e.g. procaine; tetracaine) and has been associated with adverse CNS effects possibly related to a prior sensitivity to related	New	USFDA তে শুধু Capsule হিসেবে অনুমোদিত।	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						agents or interaction with concomitant medication.				
344.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Aspirin 81mg Tablet	Aspirin USP 81mg	Anti-platelet Therapeutic code: 026	the most common dose used to prevent a heart attack or a stroke. Prevention of a first non-fatal myocardial infarction, Prior Myocardial Infarction or Unstable Angina Pectoris,	**Contra-indication:** DO NOT TAKE if you:•are allergic to ASA, salicylates, non-steroidal anti-inflammatory drugs (NSAIDs)/pain relievers/fever reducers, or other ingredients in the product•have an ulcer, history of ulcers or are prone to bleeding•have active or severe liver or kidney disease or congestive heart failure•have a history of asthma caused by salicylates or other NSAIDs •are using methotrexate at doses of 15mg/week or more•are in the last trimester of pregnancy because it may cause problems in the unborn child or complications during delivery Side-effect: You should call your doctor if you experience any of the following: nausea, vomiting; stomach irritation, or pain; if you notice that you are 'bruising' more easily than you were before starting a daily dose of ASPIRIN.Regular daily use of alcohol while on ASPIRIN daily therapy may increase your risk of developing gastrointestinal bleeding		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
345.	Acme Laboratories Ltd., Dhamrai, Dhaka	Aspirin 81 mg Delayed Release Tablet	Aspirin BP 81 mg	Antiplatelet Therapeutic code: 026	Unstable angina or cerebral transient ischemic attacks, prophylaxis in myocardial infarction	**Contra-indication:** Patients who are hypersensitive to ASA, Acute gastrointestinal ulcer,History of,gastrointestinal ulcers, Hemorrhagic diathesis, Active or Severe hepatic failure, renal failure, or congestive heart failure. **Side-effects:** Aspirin may induce hypersensitivity, asthma, urate kidney stones, chronic gastro-intestinal blood loss, tinnitus, nausea and vomiting. **Warnings & Precautions:** • It should be administered cautiously in	Aspirin 75 mg, 325 mg Tablet	USFDA approved aspirin 81mg tablet of OTC drug	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						asthma, uncontrolled blood pressure and pregnant women. • It is specially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in unborn child or complication during delivery. • It should be administered with caution to patients in nasal polyp and nasal allergy. Aspirin penetrates into breast milk. So, it should be administered with caution to lactating mothers.				
346.	Acme Laboratories Ltd., Dhamrai, Dhaka	Aspirin 81 mg Chewable Tablet	Aspirin BP 81 mg	Antiplatelet Therapeutic code: 026	Unstable angina or cerebral transient ischemic attacks, prophylaxis in myocardial infarction	**Contra-indication:** Patients who are hypersensitive to ASA, Acute gastrointestinal ulcer, History of gastrointestinal ulcers, Hemorrhagic diathesis, Active or Severe hepatic failure, renal failure, or congestive heart failure. **Side-effects:** Aspirin may induce hypersensitivity, asthma, urate kidney stones, chronic gastro-intestinal blood loss, tinnitus, nausea and vomiting. **Warnings & Precautions:** • It should be administered cautiously in asthma, uncontrolled blood pressure and pregnant women. • It is specially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in unborn child or complication during delivery. • It should be administered with caution to patients in nasal polyp and nasal allergy. Aspirin penetrates into breast milk. So, it should be administered with caution to lactating mothers.	Aspirin 75 mg	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
347.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Hydralazine Hydrochloride 25mg Tablet	Hydralazine Hydrochloride USP 25mg	Antihypertensive Therapeutic code: 022	Moderate to severe hypertension, Heart failure , Hypertensive emergencies (including during	**Contraindications:** Acute porphyrias, cor pulmonale, dissecting aortic aneurysm, high output heart failure, idiopathic systemic lupus erythematosus, myocardial		BNF-79, Page-186	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					pregnancy), Hypertension with renal complications	insufficiency due to mechanical obstruction, severe tachycardia. **Side-effects:** Angina pectoris, diarrhoea, dizziness, flushing, gastrointestinal disorders, headache, hypotension, joint disorders, lupus-like syndrome, myalgia, nasal congestion, nausea, palpitations, tachycardia, vomiting.				
348.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Sodium Alginate 225mg + Magnesium Alginate 87.50mg Powder in Sachet	Sodium Alginate BP 225mg + Magnesium Alginate INN 87.50mg	Antacids Therapeutic code: 007	Management of gastro-oesophageal reflux disease	**Contra-indications:** Intestinal obstruction. preterm neonates. Where excessive water loss likely (e.g. fever, diarrhoea, vomiting, high room temperature) **Warnings and precautions:** *Renal impairment*: In patients with fluid retention, avoid antacids containing large amounts of sodium		BNF-79, Page-69	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
349.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Triclosan 2%+Benzalkonium Chloride Solution 60% + Light Liquid Paraffin 52.5% Bath Additive	Triclosan USP 2gm+Benzalkonium Chloride Solution 50% BP 12gm eqv. to 6gm Benzalkonium Chloride + Light Liquid Paraffin BP 52.5gm/100gm	Skin and Mucous Membrane Preparations Therapeutic code: 071	Topical treatment of eczema, including eczema at risk from infection	**Contra-indications:** Contains Benzalkonium chloride which is irritant and may cause skin reactions; care to avoid slipping in the bath **Side Effects:** Application site reactions including-skin exfoliation, erythema, dermatitis, pruritus and burning sensation	New	BNF 79, Page 1259	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
350.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Light Liquid Paraffin 63.4% Bath Additive	Light Liquid Paraffin BP 63.40gm/100gm	Skin and Mucous Membrane Preparations Therapeutic code: 071	Dry skin conditions including dermatitis and ichthyosis; Pruritus of the elderly	**Contra-indications:** None **Side Effects:** Application site reactions including application site irritation, rash, erythema, pruritus	New	BNF 79, Page 1261	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
351.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Riociguat 0.5mg Tablet	Riociguat INN 0.5mg	Antihypertensive Therapeutic code: 022	Chronic thromboembolic pulmonary hypertension that is recurrent or persistent following surgery, or is inoperable (initiated under specialist supervision) Monotherapy or in combination with an endothelin receptor antagonist for idiopathic	**Contra-indication:** History of serious haemoptysis . previous bronchial artery embolisation . Pulmonary hypertension associated with idiopathic interstitial pneumonias pulmonary veno-occlusive disease	New	BNF-79, Page-192	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					or hereditary pulmonary arterial hypertension, or pulmonary arterial hypertension associated with connective tissue disease (initiated under specialist supervision)					
352.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Sodium Fluoride 0.050gm/100ml Solution Mouthwash	Sodium Fluoride USP 0.050gm/100ml	Throat Preparations, Mouth Washes and Gargles Therapeutic code: 073	Sodium fluoride is an antiseptic & anticavity mouthwash which- 1. Restores enamel to strengthen teeth 2. Protects teeth from cavity 3. Helps to prevent tooth decay 4. Controls tartar that can discolor teeth 5. whitens teeth safety	**Contra-indication:** Hypersensitivity to Sodium Fluoride or related compounds. **Side-effecct:** Hypersensitivity reactions, rash, nausea, vomiting. Products containing stannous fluoride may cause teeth staining. **Warnings and Precautions:** Prolonged treatment with large amounts of fluoride may result in dental fluorosis and osseous changes; do not exceed recommended dosage.	Sodium Fluoride 0.022%-Mouthwash	BNF-79, Page-1250	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
353.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Dexamethasone 0.100g + Neomycin Sulfate 0.500g + Glacia Acetic Acid USP 2.00g/100gm Ear Spray	Dexamethasone USP 0.100g + Neomycin SulfateUSP 0.500g + Glacia Acetic Acid 2.00g/100gm	Ear and Nose preparations Therapeutic code: 050	Eczematous inflammation in otitis externa	**Contra-indication:** Hypersensitivity to neomycin sulfate, dexamethasone, glacial acetic acid or to any of the excipients.The product should not be used in patients where a perforated tympanic membrane has been diagnosed or is suspected or where a tympanostomy tube (grommet) is in situ.The product should not be used in infants and neonates under 2 years of age. **Side-effecct:** **Eye disorders:** Blurred vision has been reported with corticosteroid use; for dexamethasone, the frequency is not known. **Skin and subcutaneous tissue disorders:** Some patients may experience a transient stinging or burning sensation for the first few days of treatment.Skin sensitisation / hypersensitivity reactions (immediate and delayed) leading to irritation, burning, stinging, itching and		BNF-79, Page-1236	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						dermatitis. **Warnings and Precautions:** Product use should be discontinued, and medical advice sought where appropriate, if irritation or rash occurs, or if the condition worsens or does not improve within 7 days. When otitis externa is treated topically with preparations containing aminoglycosides, in patients who have a perforation of the tympanic membrane, there is an increased risk of drug induced deafness. It is therefore important to ensure that there is no perforation in such patients				
354.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Treprostinil 1.74mg/2.9ml (0.6 mg/ml) Nebuliser Solution	Treprostinil INN 1.74mg/2.9ml	Antihypertensive Therapeutic code: 022	Treprostinil is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance.	**Contra-indications:** None **Warnings and Precautions:** • Safety and efficacy have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease). • In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension. • Tyvaso may increase the risk of bleeding, particularly in patients receiving anticoagulants. • Tyvaso dosage adjustments may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn. • Hepatic or renal insufficiency may increase exposure and decrease tolerability. **Adverse Reaction:** Most common adverse reactions (≥ 10%) are cough, headache, nausea, dizziness, flushing, throat irritation, pharyngolaryngeal pain and diarrhea.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
355.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Acetic Acid 2% Ear Spray	Acetic Acid USP 2gm/100gm	Ear and Nose preparations Therapeutic code: 050	Inflammation in otitis externa	**Contra-indication:** The product should not be used in patients with a known sensitivity to any of the ingredients.Not recommended for children under 12 years of age without medical advice.Do not use for more than 7 days. Avoid spraying near the eyes. **Side-effecct:** Some patients may experience a transient stinging or burning sensation after dosing for the first few days of treatment. **Warnings and Precautions:** If pain occurs during use, or if symptoms worsen or do not improve within 48 hours, or if your hearing becomes impaired, stop treatment and consult your doctor. Patients who are known to have a perforated ear drum should only use the product under medical supervision.	New	BNF-79, Page-1231	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
356.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Aztreonam (as Lysin) 75mg/Dose powder and solvent for Nebuliser solution	Aztreonam (as Lysin) Ph.Grade 75mg/Dose	Anti-infective Therapeutic code: 023	Chronic pulmonary *Pseudomonas aeruginosa* infection in patients with cystic fibrosis	**Contra-indication:** Contra-indicated in aztreonam hypersensitivity. Use with caution in patients with hypersensitivity to other beta-lactam antibiotics (although aztreonam may be less likely than other beta-lactams to cause hypersensitivity in penicillin-sensitive patients). **Side-effects:** **General Side-effects:** Common or very common Dyspnoea resiratory disorders **Specific Side-effects** Common or very common When used by inhalation Cough . haemoptysis . joint disorders . laryngeal pain . nasal complaints . rash Rare or very rare With parenteral use Anaemia . asthenia . breast tenderness . chest pain . confusion . diplopia . dizziness . eosinophilia . haemorrhage . headache	New	BNF-79, Page-559	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						. hepatic disorders . hypotension .insomnia . leucocytosis . myalgia . nasal congestion . neutropenia . oral disorders . pancytopenia . paraesthesia .pseudomembranous enterocolitis . seizure .thrombocytopenia . thrombocytosis . tinnitus . vertigo .vulvovaginal candidiasis Frequency not known With parenteral use Abdominal pain . angioedema . diarrhoea . nausea . skin reactions . taste altered . toxic epidermal necrolysis . vomiting				
357.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	Dornase alfa 2.5mg /2.5ml Nebuliser Solution	Dornase alfa INN 2.5mg /2.5ml	Mucolytic Therapeutic code: 031	Management of cystic fibrosis patients with a forced vital capacity (FVC) of greater than 40%of predicted to improve pulmonary function	**Side-effects:** Chest pain . conjunctivitis . dyspepsia . dysphonia . dyspnoea . fever . increased risk of infection, skin reactions	New	BNF-79, Page-301	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
358.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur Opsonin Pharma Limited, Rupatali, Barishal.	Povidone Iodine 0.45gm/100ml Solution for Throat Spray	Povidone Iodine USP 0.45gm/100ml	Throat Preparations, Mouth Washes and Gargles Therapeutic code: 073	As an antiseptic in the management of local infections of the mouth and oropharynx.	**Contra-indication:** Hypersensitivity to iodine, polyvinylpyrrolidone or to any excipient. History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis). Use in children under six years of age. Regular use should be avoided in patients on concurrent lithium therapy. **Side-effecct:** Idiosyncratic mucosal irritation and hypersensitivity reactions may occur.Anaphylactic reactions, anaphylactoid reactions and anaphylactic shock have been reported uncommonly with products containing povidone-iodine or povidone.Excess iodine can produce goitre and hypothyroidism or hyperthyroidism. Such effects have occasionally been seenwith extensive or prolonged use of povidone iodine.	Povidone-Iodine 1% Mouthwash Gargle	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Other effects that have been reported are metabolic acidosis and acute renal failure. **Warnings and Precautions:** Use of this preparation may interfere with tests of thyroid function. Regular use must be avoided as prolonged use may lead to the absorption of a significant amount of iodine particularly in patients with renal insufficiency. Do not use for more than 14 days. If symptoms occur suggesting changes in thyroid function, these should be investigated. In patients with impaired renal function, blood levels of iodine should be monitored.				
359.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	White Soft Paraffin 100gm/100gm Jelly	White Soft Paraffin BP 100gm/100gm	Skin and Mucous Membrane Preparations Therapeutic code: 071	Dry skin conditions; Eczema, Psoriasis, Ichthyosis, Pruritus	**Contra-indications:** Hypersensitivity to ingredient **Side Effects:** No known side effects	New	BNF 79, Page 1264	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
360.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	White Soft Paraffin 5gm/100gm Lotion	White Soft Paraffin BP 5gm/100gm	Skin and Mucous Membrane Preparations Therapeutic code: 071	Dry skin conditions; Eczema, Psoriasis, Ichthyosis, Pruritus	**Contra-indications:** Hypersensitivity to ingredient **Side Effects:** No known side effects	New	BNF 79, Page 1264	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
361.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	(Benzalkonium Chloride Solution 50% 0.20gm eqv. to 0.1gm Benzalkonium Chloride + Chlorhexidine Hydrochloride 0.10gm + Isopropyl Myristate 2.50gm + Liquid Paraffin 2.50gm)/100gm Lotion	(Benzalkonium Chloride Solution 50% BP 0.20gm eqv. to 0.1gm Benzalkonium Chloride + Chlorhexidine Hydrochloride BP 0.10gm + Isopropyl Myristate BP 2.50gm + Liquid Paraffin BP 2.50gm)/100gm	Skin and Mucous Membrane Preparations Therapeutic code: 071	Dry and pruritic skin conditions including eczema and dermatitis	Contra-indications: Known hypersensitivity to any ingredient Side Effects: Very rarely (<1/10,000) local skin reactions and hypersensitivity	New	BNF 79, Page 1262	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
362.	UniMed UniHealth Pharmaceuticals Limited B K Bari, Gazipur	(Benzalkonium Chloride Solution 50% 0.20gm eqv. to 0.1gm Benzalkonium Chloride + Isopropyl Myristate 0.10gm + Liquid Paraffin 10gm)/100gm Cream	(Benzalkonium Chloride Solution 50% BP 0.20gm eqv. to 0.1gm Benzalkonium Chloride + Isopropyl Myristate BP 0.10gm + Liquid Paraffin BP 10gm)/100gm	Skin and Mucous Membrane Preparations Therapeutic code: 071	Dry and pruritic skin conditions including eczema and dermatitis	Contra-indications: Known hypersensitivity to any ingredient Side Effects: Very rarely (<1/10,000) local skin reactions and hypersensitivity	New	BNF 79, Page 1262	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
363.	Acme Laboratories Ltd., Dhamrai, Dhaka	Anhydrous Fimasartan Potassium 60 mg Film Coated Tablet	Fimasartan Potassium Trihydrate INN 66.01 mg eqv. to anhydrous Fimasartan Potassium 60 mg	Antihypertensive Therapeutic code: 022	Essential hypertension	**Contra-indication:** Patients who are hypersensitive to any component of this product. Pregnant or nursing mothers. Patients with moderate to severe hepatic impairment. Patients with hepatobiliary obstruction. Patients with diabetes or renal impairment (GFR <60 mL/min) who are taking aliskiren. Patients with diabetic nephropathy who are taking angiotensin converting enzyme (ACE) inhibitors. **Side-effects:** Fimasartan can cause side effects such as dizziness, headache, abdominal pain, nausea, palpitation, fatigue, diarrhea, and coughing. **Warnings & Precautions:** • Renal Impairment: Patients who are sensitive to drugs inhibiting the renin angiotensin system may experience changes in the renal function. • Hepatic Impairment: The pharmacokinetics of Fimasartan was compared in patients with mild and moderate hepatic impairment to healthy volunteers. A 20% decrease in AUC and 10% increase in Cmax were observed in patients with mild hepatic impairment. The AUC and Cmax in moderate hepatic impairment were increased by 6.5-fold and 5-fold, respectively. • Fimasartan potassium is not recommended to moderate to severe hepatic impairment.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
364.	Acme Laboratories Ltd., Dhamrai, Dhaka	Anhydrous Fimasartan Potassium 120 mg Film Coated Tablet	Fimasartan Potassium Trihydrate INN 132.02 mg eqv. to anhydrous Fimasartan Potassium 120 mg	Antihypertensive Therapeutic code: 022	Essential hypertension	**Contra-indication:** Patients who are hypersensitive to any component of this product. Pregnant or nursing mothers. Patients with moderate to severe hepatic impairment. Patients with hepatobiliary obstruction. Patients with diabetes or renal impairment (GFR <60 mL/min) who are taking aliskiren. Patients with diabetic	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						nephropathy who are taking angiotensin converting enzyme (ACE) inhibitors. **Side-effects:** Fimasartan can cause side effects such as dizziness, headache, abdominal pain, nausea, palpitation, fatigue, diarrhea, and coughing. **Warnings & Precautions:** • Renal Impairment: Patients who are sensitive to drugs inhibiting the renin angiotensin system may experience changes in the renal function. • Hepatic Impairment: The pharmacokinetics of Fimasartan was compared in patients with mild and moderate hepatic impairment to healthy volunteers. A 20% decrease in AUC and 10% increase in Cmax were observed in patients with mild hepatic impairment. The AUC and Cmax in moderate hepatic impairment were increased by 6.5-fold and 5-fold, respectively. • Fimasartan potassium is not recommended to moderate to severe hepatic impairment.				
365.	Acme Laboratories Ltd., Dhamrai, Dhaka	Paracetamol 750 mg + Phenylephrine Hydrochloride 10 mg + Ascorbic Acid (Vitamin C) 60 mg/5 g Powder Sachet	Paracetamol BP 750 mg + Phenylephrine Hydrochloride INN 10 mg + Ascorbic Acid (Vitamin C) USP 60 mg/5 g	Analgesics and Antipyretics Therapeutic code: 006	Fever, Blocked nose, Sore throat, Body aches	**Contra-indications:** Paracetamol, phenylephrine, ascorbic acid combination is contraindicated for patients with hyperthyroidism, heart disease, high blood pressure, diabetes. If anyone is using or have used within the last two weeks medicines known as monoamine oxidase inhibitors (MAOIs), which are usually used in the treatment of depression. **Side-effects:** Headache, dizziness, anxiety, sleep problems, elevated blood pressure, nausea and vomiting. **Warnings and Precautions:** • Do not use this medicine concomitantly with other medicines containing paracetamol or medicines	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						used for relieving the symptoms of the common cold and the flu and nasal congestion. • Taking too much paracetamol may cause severe liver damage. Do not take this medicine if you are taking another prescription or over- the-counter medicine containing paracetamol for pain, fever, a cold, the flu or sleep disorders.				
366.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pranlukast Hydrate 112.50 mg Capsule	Pranlukast Hydrate INN 112.50 mg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic code :044	Asthma, Allergic Rhinitis	**Contra-indication:** Contraindication can be described as a special circumstance or a disease or a condition wherein you are not supposed to use the drug or undergo particular treatment as it can harm the patient; at times, it can be dangerous and life threatening as well. When a procedure should not be combined with other procedure or when a medicine cannot be taken with another medicine, it is called Relative contraindication. Contraindications should be taken seriously as they are based on the relative clinical experience of health care providers or from proven research findings. **Side-effects:** Headache, increased incidence of resp. tract infection, GI disturbances, induced generalized pain, fever, myalgia. **Warnings & Precautions:** • Hypersensitivity • Pregnancy	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
367.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pranlukast Hydrate 10 g/100 ml (10%) Dry Syrup	Pranlukast Hydrate INN 10 g/100 ml (10%)	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic code :044	Asthma, Allergic Rhinitis	**Contra-indication:** Contraindication can be described as a special circumstance or a disease or a condition wherein you are not supposed to use the drug or undergo particular treatment as it can harm the patient; at times, it can be dangerous and life threatening as well. When a procedure should not be combined with other procedure or when a medicine cannot be taken with another medicine, it is	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						called Relative contraindication. Contraindications should be taken seriously as they are based on the relative clinical experience of health care providers or from proven research findings. **Side-effects:** Headache, increased incidence of resp. tract infection, GI disturbances, induced generalized pain, fever, myalgia. **Warnings & Precautions:** • Hypersensitivity • Pregnancy				
368.	Acme Laboratories Ltd., Dhamrai, Dhaka	Montelukast Sodium 10 mg + Levocetirizine 5 mg Tablet	Montelukast Sodium USP 10 mg + Levocetirizine INN 5 mg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic code :044	Asthma, Allergic Rhinitis	**Contra-indication:** **Allergy:** This medicine is not recommended for use in patients with a known allergy to Levocetirizine, cetirizine, other piperazine derivatives, Montelukast, any other leukotriene modifiers, or any other inactive ingredients present along with these medicines. **Kidney Disease:** This medicine is not recommended for use in patients with end-stage kidney disease and creatinine clearance less than 10 ml/min due to the increased risk of severe adverse effects. It is not recommended for use in children below 12 years of age with an impaired kidney function. **Galactose intolerance:** This medicine is not recommended for use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Side-effects:** Headache, Stomach pain, Chest tightness, Joint pain, Difficulty in swallowing, Pus in urine, Indigestion, Skin rash, Heartburn, Nausea and Vomiting, Fever, Cough, Dizziness	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
369.	Acme Laboratories Ltd., Dhamrai, Dhaka	Montelukast Sodium 0.08 g + Levocetirizine Hydrochloride INN 0.05 g/100 ml Syrup	Montelukast Sodium USP 0.08 g + Levocetirizine Hydrochloride INN 0.05 g/100 ml	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic code:044	Asthma, Allergic Rhinitis	**Contra-indication:** **Allergy:** This medicine is not recommended for use in patients with a known allergy to Levocetirizine, cetirizine, other piperazine derivatives, Montelukast, any other leukotriene modifiers, or any other inactive ingredients present along with these medicines. **Kidney Disease:** This medicine is not recommended for use in patients with end-stage kidney disease and creatinine clearance less than 10 ml/min due to the increased risk of severe adverse effects. It is not recommended for use in children below 12 years of age with an impaired kidney function. **Galactose intolerance:** This medicine is not recommended for use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Side-effects:** Headache, Stomach pain, Chest tightness, Joint pain, Difficulty in swallowing, Pus in urine, Indigestion, Skin rash, Heartburn, Nausea and Vomiting, Fever, Cough, Dizziness	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
370.	Acme Laboratories Ltd., Dhamrai, Dhaka	Polmacoxib 2 mg Capsule	Polmacoxib INN 2 mg	Nonsteroidal antiinflamatory and drugs used in arthritis Therapeutic code : 064	Symptoms associated with arthritis	**Contra-indication:** This drug is mainly metabolized by CYP3A4 in the liver, so caution should be exercised when co-administered with a drug that inhibits CYP3A4. **Side-effects:** The common side effects are nasopharyngitis, anemia, headache, upper abdominal pain, pain and chest discomfort **Warnings & Precautions:** • If a person who drinks regularly more than three drinks a day should take this medication or other antipyretic pain medication, he or she should consult a	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						physician or pharmacist. If you take this medication, gastrointestinal bleeding may occur. • Cardiovascular risk: Non-steroidal anti-inflammatory analgesic drugs, including NSAIDs, can increase the risk of serious cardiovascular events, myocardial infarction and stroke, which can be fatal. Depending on the duration of the treatment, dose, and baseline cardiovascular risk factors, this risk may increase and may be even more dangerous in patients with cardiovascular disease. • Gastrointestinal risk: NSAIDs, including NSAIDs, can increase the risk of serious gastrointestinal adverse events, including gastric or intestinal bleeding, ulcers, and perforations, which can be fatal.				
371.	Acme Laboratories Ltd., Dhamrai, Dhaka	Umifenovir 100 mg Capsule	Umifenovir Hydrochloride INN 107.64 mg eqv. to Umifenovir 100 mg	Antiviral Therapeutic code:032	Umifenovir is currently licensed in China and Russia for the prophylaxis and treatment of influenza and other respiratory viral infections. It has demonstrated activity against a number of viruses and has been investigated in the treatment of Flavivirus, Zika virus, foot-and-mouth disease, Lassa virus, Ebola virus, and herpes simplex. In addition, it has shown in vitro activity against hepatitis B and C viruses, chikungunya virus, reovirus, Hantaan virus, and coxsackie virus. Umifenovir is currently being investigated as a potential treatment and prophylactic agent for the prevention of COVID-19 caused by SARS-CoV-2 infections.	**Contra-indication:** Hypersensitivity. **Side-effects:** Side effects in children include sensitization to the drug. No known overdose cases have been reported and allergic reactions are limited to people with hypersensitivity.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
372.	Acme Laboratories Ltd., Dhamrai, Dhaka	Calcium 750 mg + Menaquinone-7 (Vitamin K2) USP 40 mcg + Vitamin D3 500 IU Tablet	Calcium Carbonate (Coral Source) BP 1872.94 mg eqv. to Calcium 750 mg + Menaquinone-7 (Vitamin K2) USP 40 mcg + Cholecalciferol (100000 IU/g) USP 5 mg eqv. to Vitamin D3 500 IU	Vitamins & Combinations Therapeutic code :078	Osteoporosis, Osteomalacia, Osteopenia, Pregnancy & Lactation	**Contra-indication:** The following conditions are contraindicated with this drug: increased activity of the parathyroid gland a high amount of calcium in urine high amount of calcium in the blood dehydration, constipation, kidney stones, decreased kidney function. **Side-effects:** Hyperacidity, Hypercalcemia, Constipation, loss of appetite, low phosphate level, nausea, vomiting. **Warnings & Precautions:** • The following conditions are contraindicated with this drug: increased activity of the parathyroid gland, a high amount of calcium in urine, high amount of calcium in the blood, dehydration, constipation, kidney stones, decreased kidney function. When hypercalcemia occurs, discontinue the drug. • Patients with a history of stone formation should also be recommended to increase their fluid intake.	New Molecule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
373.	Acme Laboratories Ltd., Dhamrai, Dhaka	Calcium 180 mg + Menaquinone-7 (Vitamin K2) USP 25 mcg + Vitamin D3 400 IU Capsule	Calcium Carbonate (Algae Source) BP 449.53 mg eqv. to Calcium 180 mg + Menaquinone-7 (Vitamin K2) USP 25 mcg + Cholecalciferol (100000 IU/g) USP 4 mg eqv. to Vitamin D3 400 IU	Vitamins & Combinations Therapeutic code:078	Osteoporosis, Osteomalacia, Osteopenia, Pregnancy & Lactation	**Contra-indication:** The following conditions are contraindicated with this drug: increased activity of the parathyroid gland, a high amount of calcium in urine, high amount of calcium in the blood, dehydration, constipation, kidney stones decreased kidney function. **Side-effects:** Hyperacidity, Hypercalcemia, Constipation, loss of appetite, low phosphate level, nausea, vomiting. **Warnings & Precautions:** • The following conditions are contraindicated with this drug: increased activity of the parathyroid gland, a high amount of calcium in urine, high amount of calcium in the blood, dehydration, constipation, kidney	New Molecule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						stones, decreased kidney function. When hypercalcemia occurs, discontinue the drug. • Patients with a history of stone formation should also be recommended to increase their fluid intake.				
374.	Acme Laboratories Ltd., Dhamrai, Dhaka	Progesterone 80 mg/g (8%) Vaginal Gel	Progesterone USP 80 mg/g (8%)	Hormone Therapeutic code:056	Infertility	Contra-indication: Undiagnosed vaginal bleeding, Liver dysfunction or disease, Known or suspected malignancy of the breast or genital organs, Known or suspected progesterone-dependent neoplasia, Known sensitivity to Progesterone (progesterone or any of the other ingredients), Missed abortion Thrombophlebitis, thromboembolic disorders, cerebral apoplexy or patients with a history of these conditions, Acute porphyria. Side-effects: Infections and Infestations: genital candidiasis, urinary tract infection Immune System Disorders: hypersensitivity Nervous System Disorders: headache, migraine, dizziness, somnolence, Gastrointestinal Disorders: abdominal pain, constipation, diarrhea, nausea, vomiting, abdominal distension. Psychiatric Disorders: depression, memory impairment, aggression, nervousness. Renal and Urinary Disorders: enuresis, cystitis. Reproductive System and Breast Disorders: libido decreased, breast tenderness, breast pain, dyspareunia, pruritus genital, vulvovaginal dryness, vaginal discharge. Musculoskeletal and Connective Tissue Disorders: muscle spasms, arthralgia General Disorders and Administration Site Conditions: fatigue, pain Skin and Subcutaneous Tissue Disorders:	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						pruritis, rash, skin disorder, urticaria Warnings & Precautions: • Progesterone has moderate effect on the ability to drive and use machines. Drivers and users of machines are warned that risk of somnolence may occur. • Patients who have a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree. diabetic patients should be carefully observed while receiving progestin therapy.				
375.	Acme Laboratories Ltd., Dhamrai, Dhaka	Cannabidiol 10 g/100 ml Oral Solution	Cannabidiol INN 10 g/100 ml	Anti-epileptic Therapeutic code :046	Seizures associated with Lennox-Gastaut Syndrome (LGS) or Dravet Syndrome (DS) in patients 2 years of age and older.	**Contra-indication:** Cannabidiol is contraindicated in patients with a history of hypersensitivity to cannabidiol or any of the ingredients in the product. **Side-effects:** Liver problems, loss of appetite, nausea, vomiting, fever, feeling unwell, unusual tiredness, yellowing of the skin or the whites of the eyes (jaundice), itching, unusual darkening of the urine, right upper stomach area pain or discomfort, new or worse depression, new or worse anxiety, feeling agitated or restless, panic attack. **Warnings & Precautions:** • Precaution is needed in case of following factors: Hypersensitivity reactions, Somnolence and Sedation, Hepatocellular Injury.	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
376.	Acme Laboratories Ltd., Dhamrai, Dhaka	Paracetamol 500 mg + Phenylephirine Hydrochloride 5 mg + Caffeine 25 mg Film Coated Tablet	Paracetamol BP 500 mg + Phenylephirine Hydrochloride BP 5 mg + Caffeine BP 25 mg	Analgesics and Antipyretics Therapeutic code:006	Headache, fever, body aches, runny or stuffy nose, sneezing, itching, watery eyes, and sinus congestion caused by allergies, the common cold, or the flu.	**Contra-indication:** It should be avoided if you have closed angle glaucoma, diabetes, overactive thyroid (hyperthyroidism), any underlying serious heart condition or cardiovascular disorder. **Side-effects:** Nausea, Vomiting, Headache, Restlessness, Increased heart rate **Warnings & Precautions:** • This medicine is known to cause harm	New	UKMHRA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						to the liver especially when taken in the doses above the recommended level. Also, avoid drinking alcohol while taking this medicine, as it may further increase your risk of liver damage. • Use of this medicine should preferably be avoided in patients with underlying liver disease. • Contact your doctor immediately if you notice any early signs and symptoms of liver damage. • The symptoms may include fever, rash, loss of appetite, nausea, vomiting, fatigue, stomach pain, dark urine, yellow skin or eyes and abnormal live enzymes.				
377.	Acme Laboratories Ltd., Dhamrai, Dhaka	Diflucortolone Valerate 15 mg (0.1%) + Isoconazole Nitrate 150 mg (1%)/15 g Cream	Diflucortolone Valerate INN 15 mg (0.1%) + Isoconazole Nitrate INN 150 mg (1%)/15 g	Antifungl Agent Therapeutic code: 020	Fungal infections of hairless and hairy skin, e.g. in the region of the hands, the interdigital spaces of the feet, and in the inguinal and genital regions. Because of the addition of diflucortolone valerate, it is indicated for the initial or intermediate treatment of those fungal diseases which are accompanied by highly inflammatory or eczematous skin conditions.	**Contra-indication:** Hypersensitivity to the active substances or to any of the excipients. Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, Diflucortolone valerate + Isoconazole nitrate should not be used during pregnancy. **Side-effects:** Local symptoms such as itching, burning, erythema or Vesiculation may occur in isolated cases under treatment with Diflucortolone valerate + Isoconazole nitrate. The following side effects may occur in rare cases: Folliculitis, hypertrichosis, perioral dermatitis, skin discoloration, allergic skin reactions to any of the ingredients of the formulation. **Warnings & Precautions:** • Diflucortolone valerate + Isoconazole nitrate should not be allowed to come into contact with the eyes when being applied to the face.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Extensive application of topical corticosteroids such as Diflucortolone valerate + Isoconazole nitrate to large areas of the body or for prolonged periods of time, in particular under occlusion, significantly increases the risk of side effects. • Potent topical corticosteroids should be used for short courses only. Regular review should be made of the necessity for continuing therapy.				
378.	Acme Laboratories Ltd., Dhamrai, Dhaka Square Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur	Cefixime 50 mg + Clavulanic Acid 31.25 mg/5 ml Powder for Syrup	Cefixime Trihydrate USP 56.00 mg eqv. to Cefixime 50 mg + Diluted Potassium Clavulanate [Dry Mixture of Potassium Clavulanate & Colloidal Silicon Dioxide] BP 77.10 mg eqv. to Clavulanic Acid 31.25 mg/5 ml	Anti-infective Therapeutic code: 023	Cefixime & Clavulanic acid combination is indicated for Uncomplicated Urinary Tract Infections Otitis Media Pharyngitis and Tonsillitis Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis Uncomplicated gonorrhea (cervical/urethral)	**Contra-indication:** No adequate and well-controlled studies in pregnant women have been reported so Cefixime & Clavulanic acid combination should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician. **Side-effects:** The most frequent side effects seen with Cefixime & Clavulanic acid combination are diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hyper eosinophilia, neutropenia and agranulocytosis may also occur. **Warnings & Precautions:** • Before therapy with Cefixime & Clavulanic acid combination is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, Penicillin or other drugs. • Cefixime as with other broad-spectrum antibiotics should be prescribed with caution in individuals with a history of colitis. • Increases in prothrombin times may	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						occur and therefore care should be taken in patients receiving anticoagulant therapy.				
379.	Acme Laboratories Ltd., Dhamrai, Dhaka	L-Methylfolate Calcium 1 mg Film Coated Tablet	L-Methylfolate Calcium INN 1 mg	Vitamin Therapeutic code: 078	Polycystic ovary syndrome, Management of low plasma in certain patients, Management of low red blood cell folate in certain patients, Acts as medical food, Protective against Neural Tube Defects	**Contra-indication:** Allergic to any ingredient in L-methylfolate calcium. **Side-effects:** No common side effects have been reported with L-methylfolate. Seek medical attention right away if any of these severe side effects occur: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue) **Warnings & Precautions:** • Folic acid may mask symptoms of B12 deficiency (e.g., pernicious anemia), although this may be less likely with L-methylfolate • Use with caution in patients with bipolar disorder unless treated with concomitant mood-stabilizing agent • Monitor patients for activation of suicidal ideation, especially children and adolescents • Folic acid, when administered in doses above 800 mcg, may increase the amount of unmetabolized folic acid, which has been linked to accelerated growth of existing neoplasms in the colon; L-methylfolate may be less likely than folic acid to accelerate the growth of existing neoplasms	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
380.	Acme Laboratories Ltd., Dhamrai, Dhaka	Colecalciferol (Vitamin D3) 25 mcg + Menaquinone-7 (Vitamin K2) 75 mcg Tablet	Colecalciferol (Vitamin D3) BP 25 mcg + Menaquinone-7 (Vitamin K2) USP 75 mcg	Vitamins & Combinations Therapeutic code: 078	Maintenance of normal bones & teeth	**Contra-indication:** Anticoagulant effect of warfarin (Coumadin), functioning by its interference with the clotting effect of vitamin K, can be offset with as little as 1 mg of vitamin K. Vitamin D3 is contraindicated in sarcoidosis, high amount of phosphate in the blood, high amount of calcium in the blood, excessive amount of vitamin	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						D in the body, a blockage of the arteries called arteriosclerosis, obliterans, kidney stones, decreased kidney function. **Side-effects:** Vitamin K2 is likely safe for most people when taken appropriately. Some people may have an upset stomach or diarrhea. Vitamin D3 is also generally safe. Too much intact of Vitamin D3 may cause some problems like- Elevated blood levels, Elevated blood calcium levels, Nausea, vomiting, poor appetite, Stomach pain, constipation, diarrhea, Bone loss, Kidney failure. **Warnings & Precautions:** Before using this medication, Blood clotting level should be checked regularly, should take care of hypercalcemia/hypervitaminosis D, malabsorption syndrome, kidney disease, liver disease.				
381.	Acme Laboratories Ltd., Dhamrai, Dhaka	Colecalciferol (Vitamin D3) 25 mcg + Menaquinone-7 (Vitamin K2) 75 mcg Capsule	Colecalciferol (Vitamin D3) BP 25 mcg + Menaquinone-7 (Vitamin K2) USP 75 mcg	Vitamins & Combinations Therapeutic code: 078	Maintenance of normal bones & teeth	**Contra-indication:** Anticoagulant effect of warfarin (Coumadin), functioning by its interference with the clotting effect of vitamin K, can be offset with as little as 1 mg of vitamin K. Vitamin D3 is contraindicated in sarcoidosis, high amount of phosphate in the blood, high amount of calcium in the blood, excessive amount of vitamin D in the body, a blockage of the arteries called arteriosclerosis, obliterans, kidney stones, decreased kidney function. **Side-effects:** Vitamin K2 is likely safe for most people when taken appropriately. Some people may have an upset stomach or diarrhea. Vitamin D3 is also generally safe. Too much intact of Vitamin D3 may cause some problems like- Elevated blood levels, Elevated blood calcium levels, Nausea, vomiting, poor	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						appetite, Stomach pain, constipation, diarrhea, Bone loss, Kidney failure. **Warnings & Precautions:** Before using this medication, Blood clotting level should be checked regularly, should take care of hypercalcemia/hypervitaminosis D, malabsorption syndrome, kidney disease, liver disease.				
382.	Acme Laboratories Ltd., Dhamrai, Dhaka	Colecalciferol (Vitamin D3) 20 mcg + Menaquinone-7 (Vitamin K2 MK-7) 100 mcg + Calcium (Red Algae Calcium) 267 mg Capsule	Colecalciferol (Vitamin D3) BP 20 mcg + Menaquinone-7 (Vitamin K2 MK-7) USP 100 mcg + Calcium (Red Algae Calcium) Ph. Gr. 267 mg	Vitamins & Combinations Therapeutic code: 078	Maintenance of normal bones & teeth	**Contra-indication:** Anticoagulant effect of warfarin, functioning by its interference with the clotting effect of vitamin K, can be offset with as little as 1 mg of vitamin K. Vitamin D3 is contraindicated in sarcoidosis, high amount of phosphate in the blood, high amount of calcium in the blood, excessive amount of vitamin D in the body, a blockage of the arteries called arteriosclerosis, obliterans, kidney stones, decreased kidney function. Calcium intake is contraindicated in increased activity of parathyroid gland, hypercalcemia, constipation, kidney stone & extreme loss of body water. **Side-effects:** Vitamin K2 is likely safe for most people when taken appropriately. Some people may have an upset stomach or diarrhea. Vitamin D3 is also generally safe. Too much intact of Vitamin D3 may cause some problems like- Elevated blood levels, Elevated blood calcium levels, Nausea, vomiting, poor appetite, Stomach pain, constipation, diarrhea, Bone loss, Kidney failure. Side effects of calcium intake (rare) are flatulance, diarrhoea, constipation and allergic reactions. **Warnings & Precautions:** Before using this medication, Blood clotting level should be checked regularly, should be taken care of hypercalcemia/hypervitaminosis D,	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						malabsorption syndrome, kidney disease, liver disease. In case of calcium, in mild hypercalciuria reduction of dose is sufficient to return to normal serum calcium concentration. Patients with kidney stone should be recommended to increase their fluid intake.				
383.	Acme Laboratories Ltd., Dhamrai, Dhaka	Colecalciferol (Vitamin D3) 5 mcg + Menaquinone (Vitamin K2 MK-7) 37.5 mcg + Calcium (Red Algae Calcium) 320 mg + Potassium 320 mg + Magnesium 233 mg + Ascorbic Acid (Vitamin C) 50 mg + Zinc 3 mg Sachet	Colecalciferol (Vitamin D3) BP 5 mcg + Menaquinone (Vitamin K2 MK-7) USP 37.5 mcg + Calcium (Red Algae Calcium) BP 320 mg + Potassium Citrate BP 2507.71 mg eqv. to Potassium 320 mg + Magnesium (Red Algae Calcium, Magnesium Citrate) BP 2055.86 mg eqv. to Magnesium 233 mg + Ascorbic Acid (Vitamin C) BP 50 mg + Zinc Citrate BP 26.35 mg eqv. to Zinc 3 mg	Vitamins & Combinations Therapeutic code: 078	Maintenance of normal bones & teeth	**Contra-indication:** Anticoagulant effect of warfarin (Coumadin), functioning by its interference with the clotting effect of vitamin K, can be offset with as little as 1 mg of vitamin K. Vitamin D3 is contraindicated in sarcoidosis, high amount of phosphate in the blood, high amount of calcium in the blood, excessive amount of vitamin D in the body, a blockage of the arteries called arteriosclerosis, obliterans, kidney stones, decreased kidney function. Calcium intake is contraindicated in increased activity of parathyroid gland, hypercalcemia, constipation, kidney stone & extreme loss of body water. Or sensitivity to any other ingredients of this drug. **Side-effects:** Vitamin K2 is likely safe for most people when taken appropriately. Some people may have an upset stomach or diarrhea. Vitamin D3 is also generally safe. Too much intact of Vitamin D3 may cause some problems like- Elevated blood levels, Elevated blood calcium levels, Nausea, vomiting, poor appetite, Stomach pain, constipation, diarrhea, Bone loss, Kidney failure. Side effects of calcium intake (rare) are flatulance, diarrhoea, constipation and allergic reactions. **Warnings & Precautions:** Before using this medication, Blood clotting level should be checked regularly, should be taken care of	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						hypercalcemia/hypervitaminosis D, malabsorption syndrome, kidney disease, liver disease. In case of calcium, in mild hypercalciuria reduction of dose is sufficient to return to normal serum calcium concentration. Patients with kidney stone should be recommended to increase their fluid intake. Or patients have sensitivity to any other ingredients of this drug.				
384.	Acme Laboratories Ltd., Dhamrai, Dhaka	Methylcellulose 2 g/10.2 g Powder for Solution	Methylcellulose USP 2 g/10.2 g	Fiber supplement	Constipation, diverticulosis, hemorrhoids and irritable bowel syndrome. Methylcellulose fiber won't cause excess gas or bloating because the bacteria in the gut cannot break it down whereas Psyllium husk produces gas.	**Contra-indication:** It is not recommended to use in case of developing diarrhea which render the condition unsuitable for symptomatic medical treatment, e.g. infective bowel disease or bowel obstruction. **Side-effects:** Most common side effects are diarrhea, allergic reactions, abdominal pain, chest pain etc. **Warnings & Precautions:** • Administer with at least an 8-ounce glass of water or other fluid. Taking this product without enough liquid may cause it to swell and block the esophagus possibly resulting in choking. • Methylcellulose should not be used in patients with difficulty swallowing.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
385.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Vinorelbine 20mg Capsule.	Vinorelbine Tartrate USP 27.708mg eqv. to Vinorelbine 20mg	Anticancer Therapeutic Code: 010	First-line treatment of patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC), in combination with cisplatin. As a single agent, for the treatment of patients with metastatic NSCLC	**Contra-indication:** With oral use concurrent radiotherapy if treating the liver, long-term oxygen therapy. previous significant surgicalresection of small bowel previous significant surgical resection of stomach **Side-effect:** Common or very common Alopecia, anaemia. appetitedecreased arthralgia. Bone marrow depression (doselimiting) constipation. Diarrhoea. dyspnoea. fever. hypertension. hypotension. increased risk of infection. leucopenia. myalgia. nausea.	Vinorelbine 10 mg/ml inj	BNF-76 (page-906)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Neutropenia (dose-limiting). pain. reflexes absent stomatitis. thrombocytopenia. vomiting.				
386.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Capsule.	Vinorelbine 80mg Capsule.	Vinorelbine Tartrate USP 110.832mg eqv. to Vinorelbine 80mg	Anticancer Therapeutic Code: 010	First-line treatment of patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC), in combination with cisplatin. As a single agent, for the treatment of patients with metastatic NSCLC	**Contra-indication:** With oral use concurrent radiotherapy if treating the liver, long-term oxygen therapy. previous significant surgicalresection of small bowel previous significant surgical resection of stomach **Side-effect:** Common or very common Alopecia, anaemia. appetitedecreased arthralgia. Bone marrow depression (doselimiting) constipation. Diarrhoea. dyspnoea. fever. hypertension. hypotension. increased risk of infection. leucopenia. myalgia. nausea. Neutropenia (dose-limiting). pain. reflexes absent stomatitis. thrombocytopenia. vomiting.	Vinorelbine 10 mg/ml inj	BNF-76 (page-906)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
387.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Capsule.	Axitinib 1mg Tablet	Axitinib INN 1mg	Anticancer Therapeutic Code: 010	Axitinib is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.	**Contraindications:** None **Side effects:** The most common (≥20%) adverse reactions are diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, palmarplantar erythrodysesthesia (hand-foot) syndrome, weight decreased, vomiting, asthenia, and constipation. **WARNINGS AND PRECAUTIONS:** Hypertension including hypertensive crisis has been observed. Blood pressure should be well-controlled prior to initiating AXITINIB. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the AXITINIB dose. • Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk for these events.	5 Axitinib mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Hemorrhagic events, including fatal events, have been reported. AXITINIB has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. • Gastrointestinal perforation and fistula, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. • Hypothyroidism requiring thyroid hormone replacement has been reported. Monitor thyroid function before initiation of, and periodically throughout, treatment with AXITINIB. (5.6) • Stop AXITINIB at least 24 hours prior to scheduled surgery. • Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. Permanently discontinue AXITINIB if signs or symptoms of RPLS occur. • Monitor for proteinuria before initiation of, and periodically throughout, treatment with AXITINIB. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with AXITINIB. • Liver enzyme elevation has been observed during treatment with AXITINIB. Monitor ALT, AST and bilirubin before initiation of, and periodically throughout, treatment with AXITINIB. • The starting dose of AXITINIB should be decreased if used in patients with moderate hepatic impairment. AXITINIB has not been studied in patients with severe hepatic impairment. • AXITINIB can cause fetal harm when administered to a pregnant woman based on its mechanism of action. Women of childbearing potential should				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						be advised of the potential hazard to the fetus and to avoid becoming pregnant while receiving Axitinib.				
388.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Capsule.	Rasburicase 1.5mg/vial (as Lyophilized powder)	Rasburicase INN 1.5mg/vial.	Anticaner Therapeutic Code: 010	It is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid.	Contra-indication: it is contraindicated in individuals deficient in glucose-6-phosphatase dehydrogenase. Side-effects: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. The data described below reflect exposure to RASBURICASE in 703 patients [63% male, 37% female; median age 10 years (range 10 days to 88 years); 73% Caucasian, 9% African, 4% Asian, 14% other/unknown]. RASBURICASE was studied for adverse reactions, regardless of severity, in 347 patients (265 pediatric and 82 adults) enrolled in one active-controlled trial (Study 1), two uncontrolled trials (Studies 2 and 3), and one uncontrolled safety trial (N=82). Additionally, an expanded access experience enrolled 356 patients, for whom reliably collected data were limited to serious adverse reactions. Among the 703 patients for whom serious adverse reactions were assessed, the most serious adverse reactions caused byRASBURICASE were allergic reactions including anaphylaxis (10%) were vomiting	New	Usfda and BNF-76 (page-917)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						(50%), fever (46%), nausea (27%), headache (26%), abdominal pain (20%), constipation (20%), diarrhea (20%), mucositis (15%), and rash (13%). In Study 1, an active control study, the following adverse events occurred more frequently in RASBURICASE -treated subjects than allopurinol-treated subjects: vomiting, fever, nausea, diarrhea, and headache. Although the incidence of rash was similar in the two arms, severe rash (NCI CTC3 , Grade 3 or 4) was reported only in one RASBURICASE-treated patient. **WARNINGS:** Anaphylaxis The safety and efficacy of RASBURICASE have been established only for a single course of treatment [once daily for 5 days RASBURICASE may cause severe allergic reactions including anaphylaxis. Signs and symptoms of these reactions include chest pain, dyspnea, hypotension and/or urticaria. RASBURICASE administration should be immediately and permanently discontinued in any patient developing clinical evidence of a serious hypersensitivity reaction				
389.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Capsule.	Rasburicase 7.5mg/vial (as Lyophilized powder)	Rasburicase INN 7.5mg/vial (as Lyophilized powder)	Anticaner Therapeutic Code: 010	It is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid.	Contra-indication: it is contraindicated in individuals deficient in glucose-6-phosphatase dehydrogenase. Side-effects: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does,	New	Usfda and BNF-76 (page-917)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. The data described below reflect exposure to RASBURICASE in 703 patients [63% male, 37% female; median age 10 years (range 10 days to 88 years); 73% Caucasian, 9% African, 4% Asian, 14% other/unknown]. RASBURICASE was studied for adverse reactions, regardless of severity, in 347 patients (265 pediatric and 82 adults) enrolled in one active-controlled trial (Study 1), two uncontrolled trials (Studies 2 and 3), and one uncontrolled safety trial (N=82). Additionally, an expanded access experience enrolled 356 patients, for whom reliably collected data were limited to serious adverse reactions. Among the 703 patients for whom serious adverse reactions were assessed, the most serious adverse reactions caused byRASBURICASE were allergic reactions including anaphylaxis (10%) were vomiting (50%), fever (46%), nausea (27%), headache (26%), abdominal pain (20%), constipation (20%), diarrhea (20%), mucositis (15%), and rash (13%). In Study 1, an active control study, the following adverse events occurred more frequently in RASBURICASE -treated subjects than allopurinol-treated subjects: vomiting, fever, nausea, diarrhea, and headache. Although the incidence of rash was similar in the two arms, severe rash (NCI CTC3, Grade 3 or 4) was reported only in one RASBURICASE-treated patient. WARNINGS Anaphylaxis The safety and efficacy of RASBURICASE have been established				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						only for a single course of treatment [once daily for 5 days RASBURICASE may cause severe allergic reactions including anaphylaxis. Signs and symptoms of these reactions include chest pain, dyspnea, hypotension and/or urticaria. RASBURICASE administration should be immediately and permanently discontinued in any patient developing clinical evidence of a serious hypersensitivity reaction				
390.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Amisulpride 100mg Tablet.	Amisulpride BP 100mg	antipsychotic Therapeutic Code: 028	It is indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.	**Contra-indication:** CNSdepression.comatosestates. phaeochromocytoma. Prolactin-dependenttumours **Side-effects**: Anxiety.breastpain. hypersalivation. musclerigidity. nausea. oculogyr iccrisis. trismus. vomiting	Amisulpride 50mg Tablet.	BNF-76 (page-390)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
391.	M/S Beacon Pharmaceuticals Ltd Kathali, Bhaluka, Mymensingh	Amisulpride 200mg Tablet.	Amisulpride BP 200mg	antipsychotic Therapeutic Code: 028	It is indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.	**Contra-indication:** CNSdepression.comatosestates. phaeochromocytoma. Prolactin-dependenttumours **Side-effects**: Anxiety.breastpain. hypersalivation. musclerigidity. nausea. Oculogyr iccrisis. trismus. vomiting	Amisulpride 50mg Tablet.	BNF-76 (page-390)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
392.	M/S Beacon Pharmaceuticals Ltd	Amisulpride 400mg Tablet.	Amisulpride BP 400mg	antipsychotic Therapeutic Code: 028	It is indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as	**Contra-indication:** CNSdepression.comatosestates. phaeochromocytoma. Prolactin-dependenttumours	Amisulpride 50mg Tablet.	BNF-76 (page-390)	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Kathali, Bhaluka, Mymensingh				delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.	**Side-effects**: Anxiety.breastpain. hypersalivation. musclerigidity. nausea. Oculogyr iccrisis. trismus. vomiting				
393.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Mycophenolate Mofetil USP 250mg Tablet.	Mycophenolate Mofetil USP 250mg Tablet.	Immune-supressant Therapeutic Code: 058	Mycophenolate Mofetil in combination with corticosteroids and either ciclosporin or tacrolimus is indicated for • prophylaxis of acute organ rejection and treatment of first or refractory organ rejection in patients receiving allogeneic renal transplants • prophylaxis of acute organ rejection in patients receiving allogeneic cardiac transplants. (In the treated population, MMF improved survival in the first year after transplantation). • prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants. Mycophenolate Mofetil is indicated for induction and maintenance therapy of patients with Class III-V lupus nephritis (diagnosed according to International Society of Nephrology/Renal Pathology Society classification)	**Contra-indication:** Allergic reactions to Mycophenolate Mofetil have been observed. Therefore, Mycophenolate Mofetil is contraindicated in patients with a known hypersensitivity to mycophenolate mofetil or mycophenolic acid (MPA). Mycophenolate Mofetil is also contraindicated in patients with known hypersensitivity to polysorbate 80. Mycophenolate Mofetil is contraindicated during pregnancy due to its mutagenic and teratogenic potential. Mycophenolate Mofetil is contraindicated in women of childbearing potential not using highly effective contraceptive methods. . Mycophenolate Mofetil is contraindicated in women who are breastfeeding. Precution and Warning: Patients receiving immunosuppressive regimens involving combinations of medicinal products, including. Mycophenolate Mofetil, are at increased risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to the intensity and duration of immunosuppression rather than to the use of any specific agent. As general advice to minimise the risk for skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and	Mycophenolate Mofetil 500mg Tablet	রেফারেন্স নাই	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						using a sunscreen with a high protection factor. **Side-effects**: Constipation, nausea, headache, diarrhea, vomiting, stomach upset, gas, tremor, dizziness, drowsiness, or trouble sleeping may occur.				
394.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Lanthanum Carbonate Dihydrate INN 477.00mg eqv. to Elemental Lanthanum 250mg Tablet.	Lanthanum Carbonate Dihydrate INN 477.00mg eqv. to Elemental Lanthanum 250mg Tablet.	Diuretics Therapeutic Code: 042	It is indicated to reduce serum phosphate in patients with end stage renal disease.	**Contra-indication: None** **Side-effects**: The most common adverse events for LANTHANUM were gastrointestinal events, such as nausea and vomiting and they generally abated over time with continued dosing. In double-blind, placebo-controlled studies where a total of 180 and 95 ESRD patients were randomized to LANTHANUM and placebo, respectively, for 4-6 weeks of treatment, the most common events that were more frequent (>5% difference) in the LANTHANUM group were nausea, vomiting, dialysis graft occlusion, and abdominal pain PRECAUTIONS General: Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease or bowel obstruction were not included in LANTHANUM clinical studies. Caution should be used in patients with these conditions. Long-term Effects: There were no differences in the rates of fracture or mortality in patients treated with LANTHANUM compared to alternative therapy for up to 3 years. The duration of treatment exposure and time of observation in the clinical program are too short to conclude that LANTHANUM does not affect the risk of fracture or mortality beyond 3 years. Information for the Patient: LANTHANUM tablets should be taken with or immediately after meals. Tablets should be chewed completely before	Lanthanum 500mg Tablet.	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						swallowing. Intact tablets should not be swallowed. Drug Interactions: LANTHANUM is not metabolized. Studies in healthy subjects have shown that LANTHANUM does not adversely affect the pharmacokinetics of warfarin, digoxin or metoprolol. The absorption and pharmacokinetics of LANTHANUM are unaffected by coadministration with citrate-containing compounds (see CLINICAL PHARMACOLOGY: In Vitro/In Vivo Drug Interactions). An in vitro study showed no evidence that LANTHANUM forms insoluble complexes with warfarin, digoxin, furosemide, phenytoin, metoprolol and enalapril in simulated gastric fluid. However, it is recommended that compounds known to interact with antacids should not be taken within 2 hours of dosing with LANTHANUM.				
395.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Selinexor INN 20mg Tablet	Selinexor INN 20mg Tablet	Anticancer Therapeutic Code: 010	It is a nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial	Contra-indication: None **Side-effects:** The most common adverse reactions (incidence ≥20%) are thrombocytopenia, fatigue, nausea, anemia, decreased appetite, decreased weight, diarrhea, vomiting, hyponatremia, neutropenia, leukopenia, constipation, dyspnea, and upper respiratory tract infection **WARNINGS AND PRECAUTIONS** • Thrombocytopenia: Monitor platelet counts at baseline, during treatment, and as clinically indicated. Manage with dose interruption, reduction, and supportive care • Neutropenia: Monitor neutrophil counts at baseline, during treatment, and as clinically indicated. Manage with dose interruption and/or reduction and granulocyte colony-stimulating factors (G-CSFs)	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Gastrointestinal Toxicity: Nausea, vomiting, diarrhea, anorexia, and weight loss may occur. Provide antiemetic prophylaxis. Manage with dose interruption and/or reduction, antiemetics, and supportive care • Hyponatremia: Monitor serum sodium levels at baseline, during treatment, and as clinically indicated. Correct for concurrent hyperglycemia and high serum paraprotein levels • Infections: Monitor for signs/symptoms of infection and treat promptly • Neurological Toxicity: Avoid taking SELINEXOR with other medications that may cause dizziness or confusion. Avoid situations where dizziness or confusional state may be a problem. Optimize hydration status, blood counts and concomitant medications to avoid dizziness or confusion • Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential, and males with a female partner of reproductive potential, of the potential risk to a fetus and use of effective contraception				
396.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Afatinib 30mg Tablet	Afatinib Dimaleate INN 44.340mg eqv. to Afatinib 30mg Tablet	Anticancer Therapeutic Code: 010	It is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test **Limitation of Use:** Safety and efficacy of GILOTRIF have not been established in patients whose tumors have other EGFR mutations	**Contra-indication**: None **Side-effects**: Most common adverse reactions (≥20%) are diarrhea, rash/dermatitis acneiform, stomatitis, paronychia, dry skin, decreased appetite, pruritus **WARNINGS AND PRECAUTIONS** • Diarrhea: Diarrhea may result in dehydration and renal failure. Withhold GILOTRIF for severe and prolonged diarrhea not responsive to antidiarrheal agents. • Bullous and Exfoliative Skin Disorders: Severe bullous, blistering, and exfoliating lesions occurred in	Afatinib 20mg & 40mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						0.15% of patients. Discontinue for lifethreatening cutaneous reactions. Withhold GILOTRIF for severe and prolonged cutaneous reactions. • Interstitial lung disease (ILD): Occurs in 1.5% of patients. Withhold GILOTRIF for acute onset or worsening of pulmonary symptoms. Discontinue GILOTRIF if ILD is diagnosed. • Hepatic toxicity: Fatal hepatic impairment occurs in 0.18% of patients. Monitor with periodic liver testing. Withhold or discontinue GILOTRIF for severe or worsening liver tests. • Keratitis: Occurs in 0.8% of patients. Withhold GILOTRIF for keratitis evaluation. Withhold or discontinue GILOTRIF for confirmed ulcerative keratitis. • Embryofetal toxicity: Can cause fetal harm. Advise females of the potential hazard to the fetus and to use highly effective contraception.				
397.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Methotrexate BP 1000mg/10mL Injection.	Methotrexate BP 1000mg/10mL Injection.	Anticancer Therapeutic Code: 010	Acute leukemias, non-hodgkin's lymphoma, soft-tissue and osteogenic sarcomas andsolid tumors particularly breast, lung, head and neck, bladder, cervical, ovarian and testicular carcinoma. Methotrexate is also indicated in moderate to severe rheumatoid arthritis, psoriasis and effective in the treatment of advanced stages (III and IV Peters Staging System) of lymphosarcoma, particularly in those cases in children; and in advanced cases of mycosis fungoides	**Contra-indication:** Contra-indication: Pregnant psoriatic patients should not receive methotrexate. Psoriaticshould not receive methotrexate. Psoriatic patients with pre-existing blood dyscrasias, such as marrow hypoplasia, leukopenia, thrombocytopenia or anaemia, should not receive methotrexate. **Side-effects**: he most common adverse reactions include ulcerative stomatitis, leukopenia, nausea and abdominal distress. Others reported are malaise, undue fatigue, chills and fever, dizziness and decreased resistance to infection. In general, the incidence and severity of	1% & 10% IV Infusion 2 mg/ml Injection 50mg/vial injection	BNF-76 (page-890)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						side-effects are considered to be dose-related. Adverse reactions as reported for the various systems are as follows: Skin Erythematous rashes, pruritus, urticaria, photosensitivity, depigmentation, alopecia, ecchymosis, telangiectasia, acne, furunculosis. Lesions of psoriasis may be aggravated by concomitant exposure to ultraviolet radiation. Blood Bone marrow depression, leukopenia, thrombocytopenia, anaemia, hypogammaglobulinaemia, haemorrhage from various sites, septicaemia				
398.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Sodium Alginate USP500mg+ Sodium Bicarbonate USP 267mg+Calcium Carbonate BP 160mg Tablet	Sodium Alginate USP500mg+ Sodium Bicarbonate USP 267mg+Calcium Carbonate BP 160mg Tablet	Antacid Therapeutic Code: 007	Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and acid indigestion, for example, following meals or during pregnancy.	**Contra-indication:** This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients **Side-effect:** Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria. Respiratory effects such as bronchospasm. **Precution and Warnings:** If symptoms do not improve after seven days, the clinical situation should be reviewed. The sodium content of a two-tablet dose is 246 mg (10.6 mmol). This should be taken into account when a highly restricted salt diet is recommended. e.g. in some cases of congestive cardiac failure and renal impairment. Each two-tablet dose contains 320 mg (3.2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. Due to its aspartame content this product should not be given to patients with phenylketonuria.	Suspension	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
399.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Saroglitazar INN 4mg Tablet	Saroglitazar INN 4mg Tablet	Antidiabetic Therapeutic Code: 015	Saroglitazar Is indicated for the treatment of diabetic dyslipidemia and hyper Triglyceridemia with type II Diabetes mellitus not controlled by statin therapy. In clinical Studies Saroglitazar has demonstrated reduction of triglycerides (TG), Low Density Lipoprotein (LDL) Cholesterol andan increase in HDL Cholestereol.	**Contra-indication:** Hypersensitivity to Saroglitazar or any of the excipients used in the formulation. **Side Effects:** The Most Common Side Effects of Saroglitazar include: Gastritis, Asrhenia, and Pyrexia. **Warnings and Precutions:** Although clinical studies with Saroglitarzar have not demonstrated any potential for myopathies or derangement of liver and/or renal function, Saroglitarzar treatment should be initiated with caution in patients with abnormal liver or renal function, or history of myopathies. Saroglitarzar has not been studied in patients with established New York Heart Association (NYHA) Class III or IV heart failure. Saroglitarzar should be initiated with caution in patients with type 2 diabetes having cardiac disease with episodic congestive heart failure and such patients should be monitored for signs and symptoms of congestive heart failure. Although during the clinical studies, no significant weight gain and edema was reported with Saroglitarzar, patients who experience rapid increase in weight should be assessed for fluid accumulation and volume-related events such as excessive edema and congestive heart failure.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
400.	M/S Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Opsonin Pharma Limited, Rupatali, Barishal.	Paracetamol 250 mg +Ibuprofen 125mg Tablet	Paracetamol BP and Ibuprofen BP	Analoesics and Antipyretics Therapeutic Code-006	It is indicated for temporary relief of mild pain caused by Headache, Backache, Muscular aches, Toothache, Menstrual cramps, Minor pain of arthritis.	**Contra-indication:** Acetaminophen and Ibuprofen is contraindicated for patients who develop hypersensitivity to Acetaminophen and Ibuprofen. **Side-effect:** GI upset bleed, feel faint, rash, redness, symptoms of heart problems or stroke (eg. trouble breathing, chest pain, weakness, slurred speech, leg	Paracetamol 500 mg , 250 mg Tablet Ibuprofen 400,300, 200 mg Tablet	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						swelling), hepatotoxicity (overdose), allergic reactions (discontinue if occur). **Precution and Warnings:** Acetaminophen • Hepatotoxicity risk Risk of hepatotoxicity is higher in patients taking long-term high dose, or use of more than one acetaminophen-containing product Acetaminophen is available in many dosage forms and products; check label carefully to avoid overdose o Limit acetaminophen dose from all sources and routes to <4 g/day in adults o Consumption of 3 or more alcoholic drinks/day may increase risk of liver damage • Allergic reaction o Risk for rare, but serious skin reactions that can be fatal; these reactions Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous include Stevens pustulosis; symptoms may include skin redness, blisters, and rash o Discontinue if symptoms occur and seek medical help immediately Ibuprofen NSAID allergy May cause severe allergic reaction, especially in patients allergic Symptoms may include hives, asthma, skin redness, blisters, Cardiovascular risk o Higher risk if higher dose consumed or taken longer than directed				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Renal injury o Long-term administration of NSAIDs may result in renal papillary necrosis and other renal injury o Patients at greatest risk include elderly individuals and those with impaired renal function, hypovolemia, heart failure, liver dysfunction, or salt depletion O Risk increased if coadministered with diuretics, ACE inhibitors, or angiotensin receptor				
401.	Nuvista Pharma Ltd.	Acotiamide Hydrochloride Hydrate 100 mg Tablet	Acotiamide Hydrochloride Hydrate INN 100 mg Tablet	Antiemetic Therapeutic Code : 018	Bloating, nausea, belching, stomach pain and discomfort, early satiety, etc. associated with functional dyspepsia, a chronic disorder of the upper digestive tract.	Contraindication: Hypersensitivity Side Effects: Diarrhea, Constipation, Dizziness, Rash, Abnormal liver function	NEW	রেফারেন্স নাই Japan	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
402.	Nuvista Pharma Ltd.	Lactic acid, Citric Acid, Potassium Bitartrate 1%,1.8%,0.4% Gel	Lactic acid INN 18mg, citric acid INN 10mg and potassium Bitartrate INN 4mg	Contraceptive (including Device) Therapeutic Code : 039	Indications: Lactic acid, citric acid, potassium bitartrate gel is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.	Contraindication: 1. Cystitis, pyelonephritis, or other upper UTI may occur 2. Avoid use of in females of reproductive potential with a history of recurrent UTI or urinary tract abnormalities Side Effects: 1. Bladder infection (cystitis) and acute kidney infection (pyelonephritis). Urinary tract infections are common but can also be serious. You should not use Lactic Acid, Citric Acid, Potassium Bitartrate gel if you have a history of urinary tract infections that keep coming back or other problems with your urinary tract. Call your healthcare provider if you have burning with urination or other signs and symptoms of a urinary tract infection such as: burning feeling when passing urine, urine that looks cloudy, pain in the pelvis, or back pain. 2. Allergic reactions. Avoid using lactic acid, citric acid, potassium bitartrate	NEW	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদনের সুপারিশ করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						gel if you are a female who can become pregnant and are allergic to lactic acid, citric acid, potassium bitartrate or any of the ingredients in Lactic Acid, Citric Acid, Potassium Bitartrate Gel; or your sexual partners are allergic to any of the ingredients in Lactic Acid, Citric Acid, Potassium Bitartrate Gel". 1. Vulvovaginal reaction. 2. Vaginal burning 3. Vaginal Itching 4. Vaginal Yeast Infection 5. Discomfort Around The Vaginalarea 6. Bacterial Vaginosis WARNINGS AND PRECAUTIONS: Cystitis and Pyelonephritis: Avoid use in women with a history of recurrent UTI or urinary tract abnormalities.				
403.	Nuvista Pharma Ltd.	Linaclotide 72 mcg Capsule	Linaclotide 0.09% pellets eq. to Linaclotide INN 72 mcg.	Laxatives Therapeutic Code : 060	Indications: Linaclotide is a guanylate cyclase-C agonist indicated in adults for treatment of: 1. Irritable bowel syndrome with constipation. (IBS-C) 2. Chronic idiopathic constipation. (CIC)	Contraindication: 1. Patients less than 6 years of age due to the risk of serious dehydration [see Warnings and Precautions, Use in Specific Populations 2. Patients with known or suspected mechanical gastrointestinal obstruction Side Effects: Diarrhea, Stomach/Abdominal Pain Or Discomfort, Gas, Bloating, Heartburn, Vomiting, Headache, Or Cold Symptoms Such As Stuffy Nose, Sneezing, Or Sinus Pain.• Swelling, Or A Feeling Of Fullness Or Pressure In Your Abdomen (Distention)	NEW	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
404.	Nuvista Pharma Ltd. Opsonin Pharma Limited, Rupatali, Barishal.	Abametapir 0.74% Lotion	Abametapir INN 0.74% Lotion	Anthelmintics including schistosomiassis and filaricides Therapeutic Code : 008	Indications: Abametapir is indicated, in the context of an overall lice management program, for the topical treatment of head lice infestation in patients 6 months of age and older.	Contraindication: None. Side Effects: Skin redness, Rash, Skin burning sensation, Contact dermatitis, Vomiting, Eye irritation, Itching, and Hair color changes. WARNINGS AND PRECAUTIONS:	NEW	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Risk of Neonatal Benzyl Alcohol Toxicity: Systemic exposure to benzyl alcohol has been associated with serious adverse reactions and death in neonates and low birth-weight infants. Safety and effectiveness in pediatric patients below the age of 6 months have not been established. Use is not recommended in pediatric patients under 6 months of age because of the potential for increased systemic absorption. • Risk of Benzyl Alcohol Toxicity from Accidental Ingestion: Administer only under direct supervision of an adult.				
405.	Nuvista Pharma Ltd.	**Dequalinium chloride 5mg/ml oral solution**	Dequalinium chloride BP 5mg/ml oral solution	Anti-infective Therapeutic Code : 023	Indications: Effective local treatment for the treatment of mouth and throat infections, in the mouth like soar throat, tonsillitis, mouth ulcer. It has a soothing effect on pain.	Contraindication: Hypersensitivity to Dequalinium Chloride Mouth Paint is a contraindication. In addition, Dequalinium Chloride Mouth Paint should not be used if you have the following conditions: 1. Children under the age of 12 years 2. Open wounds or damaged areas Side Effects: Sore tongue, Allergic reaction to one of the ingredients, Dermatitis, Allergic reactions, Ulcers	Existing, 10mg Tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
406.	Nuvista Pharma Ltd.	**Ferumoxytol IV Injection**	Ferumoxytol INN 510mg/17ml IV Injection (30mg Iron/ml)	Drug used in Anemia and other blood disorder Therapeutic Code : 045	Indications: Ferumoxytol is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients: 1. Who have intolerance to oral iron or have had unsatisfactory response to oral iron (1) or 2. Who have chronic kidney disease (CKD)	Contraindication: Ferumoxytol is contraindicated in patients with: 1. Evidence of iron overload 2. Known hypersensitivity to Ferumoxytol or any of its components 3. Anemia not caused by iron deficiency Side Effects: Ferumoxytol Injection is a type of iron used to treat iron deficiency anemia in people with chronic kidney disease. Anemia is a lack of red blood cells caused by having too little iron in the	NEW	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						body. Common side effects of Ferumoxytol include: Dizziness, Fainting, Low blood pressure (hypotension), Injection site reactions (pain, swelling, or redness), Nausea, Vomiting, Stomach pain, Diarrhea, Constipation, Headache, Swelling in your hands or feet, Chest pain, or Cough. Tell your doctor if you have unlikely but serious side effects of Ferumoxytol including: Unusual bruising, Skin darkening (bronze tone), Swelling of lower legs, or Chest pain. **WARNINGS AND PRECAUTIONS:** • Hypersensitivity Reactions: Observe for signs and symptoms of hypersensitivity for at least 30 minutes following the administration of Ferumoxyto. • Hypotension: Ferumoxyto may cause hypotension. Monitor for signs and symptoms of hypotension following the administration of Ferumoxyto. (5.2) • Iron Overload: Regularly monitor hematologic responses during Ferumoxyto therapy. Do not administer Ferumoxyto to patients with iron overload. • Magnetic Resonance Imaging: Ferumoxyto can alter magnetic resonance imaging (MRI) studies.				
407.	Nuvista Pharma Ltd.	Coral Calcium 650 mg + Vitamin D3 500 IU +Vitamin K 40 mg Tablet	Coral Calcium INN 650mg + Vitamin D3 INN 500IU +Vitamin K INN 40mg Tablet	Metal, Salts, Minerals and Calcium Preparations Therapeutic Code : 062	Indications: This combination medication is used to prevent or treat low blood calcium levels in people who do not get enough calcium from their diets. It may be used to treat conditions caused by low calcium levels such as bone loss (osteoporosis), weak bones (osteomalacia/rickets), decreased activity of the	Contraindication: 1. Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria 2. Nephrolithiasis 3. Hypervitaminosis D Bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism Side Effects:	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					parathyroid gland (hypoparathyroidism), and a certain muscle disease (latent tetany). It may also be used in certain patients to make sure they are getting enough calcium (including women who are pregnant, nursing, or postmenopausal, people taking certain medications such as phenytoin, phenobarbital, or prednisone). Calcium plays a very important role in the body. It is necessary for normal functioning of nerves, cells, muscle, and bone. If there is not enough calcium in the blood, then the body will take calcium from bones, thereby weakening bones. Vitamin D helps your body absorb calcium and phosphorus. Having the right amounts of vitamin D, calcium, and phosphorus is important for building and keeping strong bones.	1. Nausea/vomiting 2. Loss of appetite 3. Unusual weight loss 4. Mental/mood changes 5. Signs of kidney problems (such as change in the amount of urine) 6. Bone/muscle pain 7. Headache 8. Increased thirst 9. Increased urination 10. Weakness 11. Tiredness 12. Fast/pounding heartbeat A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: 1. Rash 2. Itching/swelling (especially of the face/tongue/throat) 3. Severe dizziness 4. Trouble breathing				
408.	Nuvista Pharma Ltd.	Ferric Pyrophosphate 30 mg Tablet	Ferric Pyrophosphate INN eq. to Elemental iron 30 mg Tablet	Drug used in Anemia and other Blood disorder Therapeutic Code : 045	Indications: Ferric pyrophosphate is intended to be indicated for the treatment of iron loss or iron deficiency as a formulation with a milder gastrointestinal effect. Iron deficiency appears when the dietary intake does not meet the body's requirement or when there is chronic external blood loss. During acute blood loss, body iron stores are sufficient for accelerated erythropoiesis and restoration of iron homeostasis. But when the altered homeostasis remains for weeks to months then some supplement is needed. Some	Contraindication: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Side Effects:	NEW	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					causes of iron deficiency include ectoparasitism, endoparasitism, hematuria, epistaxis, hemorrhagic skin, coagulopathy, thrombocytopenia, thrombocytopathia and gastrointestinal hemorrhage.	1. Bleeding around your dialysis vein access point; 2. Blue-colored skin, bulging purple-colored veins that you can see through your skin; 3. Swelling in your arms, legs, or fingers; 4. Unusual bleeding or bruising, coughing up blood; 5. A light-headed feeling, like you might pass out; 6. Fever 7. Pain or burning when you urinate. 8. Common side effects may include: 9. Headache, dizziness; 10. Swelling in your hands or feet; 11. Weakness, tiredness; 12. Muscle pain; 13. Feeling short of breath; or 14. Pain in your back, arms, or legs.				
409.	Nuvista Pharma Ltd.	Ferrous Bisglycinate eq to 25mg elemental iron capsule	Ferrous Bisglycinate INN eq to 25mg elemental iron capsule	Drug used in Anemia and other Blood Disorder Therapeutic Code : 045	Indications: Mirogabalin has been used in the treatment of Post-herpetic Neuralgia, Pain Associated with Fibromyalgia, and Diabetic peripheral neuropathic pain.	Contraindication: 1. If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines. 2. If you have renal dysfunction. 3. If you are pregnant or breastfeeding. 4. If you are taking any other medicinal products. Side Effects: Dizziness, Sleepiness, Sleeping for unusually long periods, Headache.	NEW	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
410.	Nuvista Pharma Ltd.	Potassium Chloride 20mEq (1500mg) ER Tablet	Potassium Chloride USP 20mEq (1500mg) Tablet	Metals, Salts, Minerals and Calcium Preparations. Therapeutic Code : 062	Indications: For use as an electrolyte replenisher and in the treatment of hypokalemia. This medicine is a potassium salt indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.	Contraindication: Concomitant use with triamterene and amiloride. Side Effects: Upset stomach, nausea, vomiting, gas, or diarrhea may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Tell your doctor right away if you have any serious side effects, including:	Existing, 600 mg Tablet	US-FDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						difficult/painful swallowing, feeling as if the tablet is stuck in your throat.				
411.	One Pharma Ltd., Bogura	Ascorbic Acid BP 1000 mg + Zinc USP 13.725 mg eq to zinc 10 mg + Vitamin D3 BP 10 mg eq to 1000 IU Tablet	Ascorbic Acid BP 1000 mg + Zinc USP 13.725 mg eq to zinc 10 mg + Vitamin D3 BP 10 mg eq to 1000 IU	Vitamins and Combinations Therapeutic Code: 078	Treatment of vitamin-C, zinc, vitamin D deficiency, adjuvant in colds and influenza, healthy immune system, normal collagen formation for proper functioning of bones, teeth and skin, protect cells from oxidative stress.	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects:** Vitamin C: Larger dose may cause diarrhea or formation of renal calculi of calcium oxalate in patients with renal impairment. Zinc: Gastric ulcer, nausea, vomiting, metallic taste, headache and drowsiness. Vitamin D3: Hypercalcaemia syndrome or Calcium intoxication, anorexia, headache, nausea, vomiting, abdominal pain. **Precautions**: Vitamin C: Ingestion of megadose (more than 1000 mg daily) of vitamin C during pregnancy has resulted in scurvy in neonates. Zinc: Concurrent administration of Zinc salt with penicillamine might diminish the effect of Penicillamine. The absorption of Zinc, although poor, may be decreased by various compounds including some foods. Chelation may occur with tetracyclines. Vitamin D3: People with the following conditions should exercise caution when considering taking vitamin D supplements: High blood Calcium or Phosphorus level, Heart problems, Kidney disease Vitamin D must be taken with adequate amounts of both Calcium and Magnesium supplementation.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
412.	One Pharma Ltd., Bogura	Ascorbic Acid1000 mg + Zinc 13.725 mg eq to zinc 10 mg + Vitamin D3 10 mg eq to Vit D3 1000 IU /Sachet	Ascorbic Acid1000 mg + Zinc 13.725 mg eq to zinc 10 mg + Vitamin D3 10 mg eq to Vit D3 1000 IU	Vitamins and Combinations Therapeutic Code: 078	Treatment of vitamin-C, zinc, vitamin D deficiency, adjuvant in colds and influenza, healthy immune system, normal collagen formation for proper functioning of bones, teeth and	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects:** Vitamin C: Larger dose may cause diarrhea or formation of	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					skin, protect cells from oxidative stress.	renal calculi of calcium oxalate in patients with renal impairment. Zinc: Gastric ulcer, nausea, vomiting, metallic taste, headache and drowsiness. Vitamin D3: Hypercalcaemia syndrome or Calcium intoxication, anorexia, headache, nausea, vomiting, abdominal pain. **Precautions**: Vitamin C: Ingestion of megadose (more than 1000 mg daily) of vitamin C during pregnancy has resulted in scurvy in neonates. Zinc: Concurrent administration of Zinc salt with penicillamine might diminish the effect of Penicillamine. The absorption of Zinc, although poor, may be decreased by various compounds including some foods. Chelation may occur with tetracyclines. Vitamin D3: People with the following conditions should exercise caution when considering taking vitamin D supplements: High blood Calcium or Phosphorus level, Heart problems, Kidney disease Vitamin D must be taken with adequate amounts of both Calcium and Magnesium supplementation.				
413.	One Pharma Ltd., Bogura	Calcium BP 1.640 gm eq to elemental Calcium 82 mg + Vitamin D3 BP 4000 IU + Vitamin B12 BP 50mcg /100 ml Suspension	Calcium BP 1.640 gm eq to elemental Calcium 82 mg + Vitamin D3 BP 4000 IU + Vitamin B12 BP 50mcg /100 ml	Vitamins and Combinations Therapeutic Code: 078	Correction of combined calcium, vitamin D3 and vitamin B12 deficiencies, healthy immune system, for healthy bone & teeth, red blood cell formation and anemia prevention, improve mood and symptoms of depression, folic acid deficiency, macrocytic anaemia.	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects:** Calcium: In rare cases, flatulence, diarrhea or constipation. Vitamin D3: Few side-effects can generally occur including hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of hypercalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain. Vitamin B12: Arthralgia, Dizziness, Headache, Nasopharyngitis,	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Anaphylaxis, Angioedema, Congestive heart failure, Peripheral vascular disease, Pulmonary edema, Diarrhea, Dyspepsia, Polycythemia vera, Sore throat, Nervousness, Rhinitis, Glossitis, Hypoesthesia. **Precautions:** During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serumcreatinine. Monitoring is especiallyimportant in patients on concomitant treatment with cardiac glycosides or thiazide diuretics and in patients with a high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment discontinued. Therapy should be reduced or preliminary interrupted, if urinary calcium level exceeds 7.5 mmol/24 h (300 mg/24 h).				
414.	One Pharma Ltd., Bogura	Calcium 50 mg + Vitamin A 333.33 IU + Vitamin C 25 mg granules for solution Sachet	Calcium 50 mg + Vitamin A 333.33 IU + Vitamin C (Ascorbic Acid) 25 mg.	Vitamins and Combinations Therapeutic Code: 078	Healthy immune system, Normal collagen formation for proper functioning of bones, teeth and skin, Protect cells from oxidative stress.	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects:** Calcium: Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Vitamin A: Hypervitaminosis A characterised by fatigue, irritability, anorexia, weight loss, vomiting and other GI disturbances, low-grade fever, hepatosplenomegaly, skin changes, alopoecia, dry hair, cracking and bleeding lips, SC swelling, nocturia, pains in bones and joints. Vitamin C: Larger dose may cause diarrhea or formation of renal calculi of calcium oxalate in patients with renal	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						impairment. Ingestion of more than 600 mg daily has a diuretic action. **Precautions:** Calcium: In the presence of mild hypercalciuria, excretion levels must be carefully monitored and where necessary the dose of calcium carbonate should be reduced or treatment should be stopped. Patients with a history of stone formation should also be recommended to increase their fluid intake. High dosage of vitamin D should be avoided during Calcium therapy unless specifically indicated. Vitamin A: Cholestatic jaundice; fat-malabsorption conditions. Monitor patients closely for toxicity. Liver impairment and children. Vitamin C: Ingestion of megadose (more than 1000 mg daily) of vitamin C during pregnancy has resulted in scurvy in neonates. Vitamin C in mega-doses has been contraindicated for patients with hyperoxaluria. Vitamin C itself is a reactive substance in the redox system and can give rise to false positive reactions in certain analytical tests for glucose, uric acid, creatine and occult blood.				
415.	One Pharma Ltd., Bogura	Magnesium Citrate100 mg + Magnesium Glycinate75 mg+ Magnesium malate BP 50 mg + Zinc Citrate 5 mg+ Zinc Ascorbate BP 2.5 mg + Vitamin D3 BP 1000 IU Tablet	Magnesium Citrate100 mg + Magnesium Glycinate75 mg+ Magnesium malate BP 50 mg + Zinc Citrate 5 mg+ Zinc Ascorbate BP 2.5 mg + Vitamin D3 BP 1000 IU	Vitamins and Combinations Therapeutic Code: 078	Reinforces bone and muscle health, Prevents muscle cramping, Helps in immunity, enhances heart health, Elevate mood, Aids in enzyme function	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects:** Currently, no side effects have been reported. However, moderate to high doses of these individual nutrients are associated with various adverse effects, including- headaches, nausea and vomiting, diarrhea, constipation, stomach pain and cramps, loss of appetite, muscle weakness, numbness and tingling.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Precautions: Impaired calcium absorption in achlorhydria which is common in elderly. Increased risk of Hypercalcemia and Hypercalciuria in Hypothyroid patients on high doses of vitamin D3, History of kidney stones, Renal Impairment.				
416.	One Pharma Ltd., Bogura	Montelukast (as sodium) BP 10mg + Levocetirizine (as hydrochloride) BP 5 mg Tablet	Each film coated tablet contains Montelukast (as sodium) BP 10mg + Levocetirizine (as hydrochloride) BP 5 mg.	Vitamins and Combinations Therapeutic Code: 078	Montelukast plus Levocetirizine is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis.	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects: Montelukast**: Asthenia/ fatigue, Fever, Abdominal pain, Trauma, Digestive System Disorders, Dyspepsia, Infectious gastroenteritis, Dental Pain. **Levocetirizine**: Headache, Somnolence, Dry mouth, Fatigue. **Precautions**: The administration of Levocetirizine to infants and toddlers aged less than 2 years is not recommended. Therefore the use of Montelukast plus Levocetirizine is not recommended to infants and toddlers less than 2 years of age. In sensitive patients the simultaneous administration of cetirizine or Levocetirizine and alcohol or other CNS depressants may have effects on the central nervous system, although it has been shown that the racemate cetirizine does not potentiate the effect of alcohol. Comparative clinical trials have revealed no evidence that Levocetirizine at the recommended dose impairs mental alertness, reactivity or the ability to drive. Nevertheless, some patients do experience somnolence, fatigue and asthenia under therapy with Levocetirizine. Therefore, patients intending to drive, engage in potentially hazardous activities or operate	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						machinery should take their response to the medicinal product into account.				
417.	One Pharma Ltd., Bogura	Calcium Lysinate 250MG + Vitamin D3 500IU Tablet	Each film coated tablet contains Calcium Lysinate Equivalent to Elemental Calcium 250MG + Vitamin D3 500IU.	Vitamins and Combinations Therapeutic Code: 078	For treatment of vitamin D and calcium deficiency, For treatment of osteoporosis, In special populations like elderly, pregnancy, breast feeding who need vitamin D and calcium supplements	**Contra-indications:** Hypercalcaemia and/or hypercalciuria. Nephrolithiasis, hypervitaminosis D, hypophosphataemia. **Side effects:** Common side effects of Calcium Lysinate and Vitamin D3 include: Constipation, Vomiting, nausea, Loss of appetite, Feeling thirsty, Bone pain, Stomach pain, Frequent urination, Muscle weakness, High level of calcium in urine **Precautions:** Impaired calcium absorption in elderly. Increased risk of hypercalcaemia and hypercalciuria in hypoparathyroid. Caution when using in patients with history of kidney stones, renal impairment.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
418.	One Pharma Ltd., Bogura	Paracetamol BP 250 mg + Aspirin BP 250 mg + Caffeine BP 65mg Tablet	Paracetamol BP 250 mg + Aspirin BP 250 mg + Caffeine BP 65mg.	Analgesics and Antipyretics Therapeutic Code: 006	Mild aches and pains, arthritis, headache (including migraine), menstrual cramps, toothache, common cold or nasal congestion	**Contra-indications:** It is contraindicated in patients with known hypersensitivity to any component of the formulation. **Side effects:** Common side effects are severe skin reactions, Severe liver damage, severe stomach bleeding. **Precautions:** Risk of hepatotoxicity (higher in alcoholics and with use of >1 Paracetamol-containing product), glucose-6-phosphate dehydrogenase (G6PD) deficiency, gastrointestinal (GI) bleeding; exercise particular caution in patients with history of GI bleeding, alcoholism, or bleeding disorders, avoid with active peptic ulcer disease, avoid with severe renal impairment (ie, CrCl<10 mL/min), avoid with severe hepatic impairment, Paracetamol: Risk for rare, but serious skin reactions that	New	USFDA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						can be fatal; these reactions include Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP); symptoms may include skin redness, blisters and rash.				
419.	One Pharma Ltd., Bogura	Loxoprofen INN 60mgTablet	Loxoprofen INN 60mg	Analgesics and Antipyretics Therapeutic Code: 006	Loxoprofen is non-steroidal anti-inflammatory medication (NSAID) indicated for pain and inflammation related to musculoskeletal and joint disorders. In addition to its effects on pain, it is an antipyretic and anti-inflammatory medication.	**Contra-indications:** History of aspirin-induced asthma attack , History of nonsteroidal anti-inflammatory drugs [NSAIDs]-induced asthma attack , Hypersensitivity to arylcarboxylic acids, Hypersensitivity to nonsteroidal anti-inflammatory drugs [NSAIDs], Hypersensitivity to one of the components, Hypersensitivity to salicylates, Progressive peptic ulcer, Severe congestive heart failure, Severe hematologic disease, Severe hepatic failure, Severe renal failure, Lactation, Last 4 months of pregnancy. **Side effects:** The most commonly reported side effect include gastric discomfort, pain in the pit of the stomach, stomachache, nausea/vomiting, loss of appetite, edema/swelling, rash, hives, drowsiness, fever, and itch. **Precautions:** Asthma, Hematologic disease, Hepatic failure, History of gastrointestinal ulcer, Infection, Prolonged treatment, Renal failure, Pregnancy.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
420.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Dextromethorphan Hydrobromide 0.6gm)/100ml Extended Release Oral Suspension	Dextromethorphan Polistirex Ph. Grade 0.800 gm (Eqv. to 0.600 gm Dextromethorphan Hydrobromide)/100ml	Antitussives, Expeqtorants and Mucolytic Therepeutic Code: 031	It is indicated for temporary relief of cough due to minor throat and bronchial irritation as may occur with the common cold or with inhaled irritants.	**Side-effect**: Confusion, Constipation, Dizziness, Drowsiness, Nausea, Vomiting **Contraindications and warnings**: Concomitant use of monoamine oxidase inhibitors is contraindicated. Dextromethorphan is extensively metabolised in the liver and should be prescribed with caution to patients with liver disease.	Dextromethorphan Hydrobromide 10 mg/5 ml Syrup	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
421.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Elemental Calcium 10.00 gm + Cholecalciferol (Vitamin D3) 0.0005 gm/100ml Oral Liquid	Hydroxyapatite Powder In-house37.736 gm (eqv. to 10.00 gm of elemental Calcium) + Cholecalciferol (Vitamin D3) BP 0.0005 gm/100ml	Metals, Salts, Minerals and Calcium Preparations Therepeutic Code: 062	It helps the development and maintenance of strong bones & teeth in children.	**Contra-indication:** Hypercalcemia and hyperparathyroidism, Hypercalciuria and nephrolithiasis, Hypersensitivity to any component of this product, Severe renal insufficiency, Concomitant digoxin therapy (requires careful monitoring of serum calcium level) **Side-effects:** Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of calcium alone, but may occur when large doses are given to patients with chronic renal failure.	Cholecalciferol (Vit. D3) 25 mcg/5 ml Syrup	রেফারেন্স নাই TGA	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
422.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Paracetamol 750 mg+ Phenylephrine HCl 10 mg+ Ascorbic acid 60 mg/5gm Sachet Powder for Solution	Paracetamol BP 750 mg+ Phenylephrine HCl BP 10 mg+ Ascorbic acid BP 60 mg/5gm	Analqesics and Antiovretics Therepeutic Code: 006	This medication is recommended for the short-term relief of the symptoms of flu, colds and chills. These symptoms include headache, shivers, aches and pains, blocked nose and painful sinuses and sore throat.	**Side effects:** Excitability, dizziness, headache, nervousness, insomnia, restlessness, anxiety, irritability, palpitations, gastrointestinal disturbances, hypertension, rash, dysuria, urinary retention, weight loss, loss of appetite, thrombocytopenia, agranulocytosis, bronchospasm & anaphylaxis. **Contraindications:** The drug is Known hypersensitivity to Paracetamol or any of the other constituents, concomitant use of monoamine oxidase inhibitors, patients with hyperthyroidism, hepatic or severe renal impairment, hypertension, diabetes, and heart disease.	Paracetamol 120 mg/5 ml Syrup,	MHRA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
423.	NAAFCO PHARMA LTD	Bacillus clausii spores (suspension)	Bacillus clausii UBBC-07 2Billion cfu/5ml	Proton Pump inhibitor Therepeutic Code: 067	• Restores the intestinal bacterial flora disorders caused by intestinal infections, intoxications, food disorders, unbalanced diet, and use of antibiotics. • Relieves Diarrhea, abdominal pain, gas.	Not Known **Warning:** Do not use if hypersensitive to the active ingredient or excipients. **Precautions for use:** During treatment with antibiotics, it is recommended that *Bacillus clausii* spores suspension be administered	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						during the interval between antibiotic administrations.				
424.	Popular Pharmaceuticals Limited 164, Tongi I/A, Tongi, Gazipur	Obeticholic Acid INN 25mg Tablet	Obeticholic Acid INN 25mg Tablet	Other Classification Therepeutic Code: 075	Obeticholic Acid is indicated for the treatment of primary biliary cholangitis (PBC) in combination with Ursodeoxycholic Acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, cholestatic liver disease & non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH). •	**Contraindication:** Contraindicated in patients known to have hypersensitivity to the drug or any of its components & in patients with complete biliary obstruction. . **ADVERS REACTION** The most common side effects of Obeticholic Acid include: Pruritus, Fatigue & Stomach pain and discomfort. Other common side effects include rash, arthralgia (joint pain), oropharyngeal pain (pain in the middle part of the throat), dizziness, constipation, abnormal thyroid function, and eczema (inflammation of the skin).	Obeticholic Acid INN 5mg Tablet & Obeticholic Acid INN 10mg Tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
425.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Alkyl Dimethyl Benzyl Ammonium Chloride BP 2.37%, w/v Alkyl Dimethyl Ethylbenzyl Ammonium Chloride Pharma Grade 2.37%,w/v Solution	Alkyl Dimethyl Benzyl Ammonium Chloride BP 2.37%, w/v Alkyl Dimethyl Ethylbenzyl Ammonium Chloride Pharma Grade 2.37%,w/v Solution	Antiseptic and Disinfectants Therepeutic Code: 29	It is recommended for use as a non-porous hard surface disinfectant in healthcare facilities.	Contraindications: N/A Side Effects: N/A	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
426.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Sodium Dichloroisocyanurate INN 1.7 g Tablet	Sodium Dichloroisocyanurate INN 1.7 g Tablet	Antiseptic and Disinfectants Therepeutic Code: 29	It is indicated in • Terminal, isolation and outbreak deep cleaning • Regular environmental cleaning of rooms, bays, wards, bed spaces and patient areas • Commodes, toilets and bathroom areas • Mattresses and mattress covers	Contraindications: Side Effects: The product contains a substance which is toxic to aquatic organisms and which may cause long-term adverse effects in the aquatic environment.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					• Bed frames and enamelled surfaces • Stainless steel • Sealed floors • Worktops and other hard surfaces					
427.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Didecyl dimethyl ammonium chloride Pharma Grade 8.7%, n Alkly dimethyl benzyl ammonium Pharma Grade 8.19% Solution	Didecyl dimethyl ammonium chloride Pharma Grade 8.7%, n Alkly dimethyl benzyl ammonium Pharma Grade 8.19% Solution	Antiseptic and Disinfectants Therepeutic Code: 29	Effective biocidal action against bacteria, fungi, mycobacteria, viruses and spores on hard surfaces like Hospitals, Nursing home, laboratory etc. It will effectively kill and control the growth of mold and mildew plus the odor caused by them, when applied to hard and non porous surfaces, OT, Critical care, foot ware etc.	Contraindications: N/A Side Effects: N/A	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
428.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Potassium pentasulfate INN 51%, Hydrogen peroxide (Powder) USP 30%, Titanium Dioxide (Crystalline Powder) BP 10%, Sulfamic Acid USP 5% and Sodium Chloride BP 4% Powder	Potassium pentasulfate INN 51%, Hydrogen peroxide (Powder) USP 30%, Titanium Dioxide (Crystalline Powder) BP 10%, Sulfamic Acid USP 5% and Sodium Chloride BP 4% Powder	Antiseptic and Disinfectants Therepeutic Code: 29	It is indicated to disinfection in Hospitals, Airports, Public Places, Personal Hygiene, Animal Transport, Animal Health, Food Processing, Aquaculture, Horticulture, Water Delivery Systems, Equipment & Surfaces.	Contraindications: N/A Side Effects: N/A	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
429.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Chlorhexidine Gluconate Solution 7.5% v/v & Equivalent to Cetrimide 15% w/v	Chlorhexidine Gluconate Solution 7.5% v/v & Equivalent to Cetrimide 15% w/v	Antiseptic and Disinfectants Therepeutic Code: 29	This solution is used for Infection of cuts, Grazes, Insect bites, Minor burns, Wounds, Dental plaque and bacteria, Gingivitis, Skin cleansing, Keratitis, Infection before any surgical procedure and other conditions.	Contraindications: N/A Side Effects: These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Such as, • Skin rash • Skin irritation • Red or itchy skin • Hypersensitivity reactions • Photophobia • Slurred speech • Allergic skin reactions • Nausea • Vomiting • Allergic reactions	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
430.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Propanol-1BP 30 g, Propanol-2 BP 45 g, Didecyl dimethyl ammonium chloride 0.5 g, N, alkyl dimethyl benzyl ammonium chloride 0.5 g, Poly-hexamethylene biguanide hydro-chloride 0.5 g Solution	Propanol-1BP 30 g, Propanol-2 BP 45 g, Didecyl dimethyl ammonium chloride 0.5 g, N, alkyl dimethyl benzyl ammonium chloride 0.5 g, Poly-hexamethylene biguanide hydro-chloride 0.5 g Solution	Antiseptic and Disinfectants Therepeutic Code: 29	For usage in NICU • Syringe pump • Infusion pump • ECG monitor • Pulse oxymeter • Photo therapy unit • Ventilator • Accessories – cables, cords, adaptors, • connectors, wires • Incubators & warmers For usage in Dental homes • Dental chair, equipment & accessories, • waste receivers • Hand pieces in kidney plates • Spitting areas of dental chairs Usage in operation theatres • Operation tables • Overhead lights • Operation theatres between surgeries • Monitors • Fibrilator • Heart-lung machine Usage in AKD • Haemodialysis system • Blood pump • Respirator Monitor Usage in Opthalmology • Tornometers, microscopes, scan probes etc. Others • Imaging machines • C.T. scanners	Contraindication: Hypersensitivity, Allergies. Sideeffect: These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Such as, • Skin rash • Skin irritation • Red or itchy skin • Hypersensitivity reactions • Photophobia • Slurred speech • Allergic skin reactions • Nausea • Vomiting • Allergic reactions	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					• HIV endangered areas • Pharmaceutical sterile sections					
431.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP 0.5% Cream	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP 0.5%	Skin and Mucous Membrane Preparations Therapeutic Code: 071	First aid to help prevent skin infection, and for temporary relief of pain and itching associated with minor - cuts - scrapes – burns.	• For external use only. • Keep out of reach of children. • When using this product - do not use in or near the eyes, do not apply over large areas of the body or in large quantities - do not apply over raw surfaces or blistered areas. • Ask a doctor before use if you have - deep or puncture wounds- animal bites - serious burns. • If swallowed, get medical help or contact a Poison Control Center right away immediately. • Stop use and ask a doctor if - condition worsens , symptoms persist for more than 7 days, or clear up and occur again within a few days.	New	USA তে OTC হিসেবে ব্যবহৃত হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
432.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP 4 % Cream	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP 4 %	Skin and Mucous Membrane Preparations Therapeutic Code: 071	First aid to help prevent skin infection, and for temporary relief of pain and itching associated with minor - cuts - scrapes – burns.	• For external use only. • Keep out of reach of children. • When using this product - do not use in or near the eyes, do not apply over large areas of the body or in large quantities - do not apply over raw surfaces or blistered areas. • Ask a doctor before use if you have - deep or puncture wounds- animal bites - serious burns. • If swallowed, get medical help or contact a Poison Control Center right away immediately. • Stop use and ask a doctor if - condition worsens , symptoms persist for more than 7 days, or clear up and occur again within a few days.	New	USA তে OTC হিসেবে ব্যবহৃত হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
433.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP 4% Spray	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP 4%	Skin and Mucous Membrane Preparations Therapeutic Code: 071	First aid to help prevent skin infection, and for temporary relief of pain and itching	• For external use only. • Keep out of reach of children.	New	USA তে OTC হিসেবে ব্যবহৃত হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					associated with minor - cuts - scrapes – burns.	• When using this product - do not use in or near the eyes, do not apply over large areas of the body or in large quantities - do not apply over raw surfaces or blistered areas. • Ask a doctor before use if you have - deep or puncture wounds- animal bites - serious burns. • If swallowed, get medical help or contact a Poison Control Center right away immediately. • Stop use and ask a doctor if - condition worsens , symptoms persist for more than 7 days, or clear up and occur again within a few days.				
434.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur.	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP2.5% Spray	Benzalkonium Chloride BP 0.13% and Lidocain HCL BP2.5%	Skin and Mucous Membrane Preparations Therapeutic Code: 071	First aid to help prevent skin infection, and for temporary relief of pain and itching associated with minor - cuts - scrapes – burns.	• For external use only. • Keep out of reach of children. • When using this product - do not use in or near the eyes, do not apply over large areas of the body or in large quantities - do not apply over raw surfaces or blistered areas. • Ask a doctor before use if you have - deep or puncture wounds- animal bites - serious burns. • If swallowed, get medical help or contact a Poison Control Center right away immediately. • Stop use and ask a doctor if - condition worsens , symptoms persist for more than 7 days, or clear up and occur again within a few days.	New	USA তে OTC হিসেবে ব্যবহৃত হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
435.	Mundipharma (Bangladesh) Pvt. Ltd. Mirzapur, Gazipur	Macrogol 3350 (Polyethylene Glycol) BP 6.563 g + Sodium Chloride BP 175.4 mg + Sodium Bicarbonate BP 89.3 mg + Potassium Chloride BP 25.1 mg / 6.85 g sachet (paediatric plain oral powder)	Macrogol 3350 (Polyethylene Glycol) BP 6.563 g + Sodium Chloride BP 175.4 mg + Sodium Bicarbonate BP 89.3 mg + Potassium Chloride BP 25.1 mg / 6.85 g sachet	Laxative	Treatment of children with chronic constipation and faecal impaction	**Contraindication**: Gut obstruction, paralytic ileus, perforated gut wall, ulcerative colitis, Crohn's disease or toxic megacolon and allergy to the active substances of Movicol Paediatric. **Side effect:** Stomach pains, diarrhea, vomiting, Nausea, anal discomfort. **Warning and precautions:** The fluid content of Movicol Paediatric when re-constituted with water does not replace regular fluid intake and	Existing Macrogol (3350) 13.125 gm + Sodium Bicarbonate 178.5 mg+ Sodium Chloride	BNF 79, March-September 2020 Page No. 57-59.	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						adequate fluid intake must be maintained.	350.70mg + Potassium Chloride 46.6 mg/Sachet			
436.	Beximco Pharmaceuticals Ltd.	Cefiderocol 1gm Injection	Cefiderocol INN 1gm	Anti-infective Therapeutic Code: 023	It is indicated in patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Enterobacter cloacae complex. It is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible Gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens..	Contraindications: It is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol and other beta-lactam antibacterial drugs. Side effects: The most frequently occurring adverse reactions in greater than or equal to 2% of patients treated with Cefiderocol were diarrhea, infusion site reactions, constipation, rash, candidiasis, cough, elevations in liver tests, headache, hypokalemia, nausea, and vomiting. Warning and precautions: Increase in All-Cause Mortality in Patients With Carbapenem-Resistant Gram-Negative Bacterial Infections: An increase in all-cause mortality was observed in Cefiderocol-treated patients compared to those treated with best available therapy . Reserve Cefiderocol for use in patients who have limited or no alternative treatment options for the treatment of cUTI. Closely monitor the clinical response to therapy in patients with cUTI Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta lactam antibacterial drugs. Hypersensitivity was observed with Cefiderocol . Cross-hypersensitivity	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদনের সুপারিশ করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						may occur in patients with a history of penicillin allergy. If an allergic reaction occurs, discontinue Cefiderocol. Clostridioides difficile-Associated Diarrhea (CDAD): CDAD has been reported with nearly all systemic antibacterial agents, including Cefiderocol. Evaluate if diarrhea occurs. Seizures and Other Central Nervous System (CNS) Adverse Reactions: CNS adverse reactions such as seizures have been reported with Cefiderocol . If focal tremors, myoclonus, or seizures occur, evaluate patients to determine whether Cefiderocol should be discontinued.				
437.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Chlorhexidine Gluconate Solution (20% w/v) 1%+ Ethanol (96%) 61% hand rub	Chlorhexidine Gluconate BP Solution (20% w/v) 1%+ Ethanol (96%) USP 61% hand rub	Antiseptic and Disinfectants Theraputic Code: 029	It is indicated for use as a surgical hand and as a healthcare personnel hand.	**Contra-indication:** its should not be used by persons who ae known to be hypersensitive to chlorhexidine gluconate or any of its components**.** **Side effect:** There were two adverse events probably or possibly related to Avagard antiseptic hand prep use in the 85 subjects who used this product in pivotal clinical trials. One subject suffered conjunctivitis and blurred vision after he rubbed his eye with a hand that had been treated with Avagard antiseptic hand prep The other subject developed a maculopapular rash.	**New**	**USFDA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
438.	Healthcare Pharmaceuticals Ltd	Canagliflozin 300 mg Tablet	Canagliflozin Hemihydrate INN 306 mg equivalent to Canagliflozin 300 mg.	**Anti-diabetic** **Therapeutic Code:** 015	• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction	**Contraindication:** • History of serious hypersensitivity reaction. • Severe renal impairment (eGFR less than 30 mL/min/1.73 m2), end stage renal disease or patients on dialysis. **Side effects:**	Existing: 100 mg Tablet	USFDA BNF 79 (Page-724)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). To reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day.	Most common adverse reactions associated with Canagliflozin are Female genital mycotic infections, urinary tract infection and increased urination. **Warnings and Precautions:** • Hypotension: Before initiating Canagliflozin, assess volume status and correct hypovolemia in patients with renal impairment, the elderly, in patients with low systolic blood pressure, or if on diuretics, ACEi, or ARB. Monitor for signs and symptoms during therapy. • Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue Canagliflozin, evaluate and treat promptly. Before initiating Canagliflozin, consider risk factors for ketoacidosis. Patients on Canagliflozin may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. • Acute kidney injury: Consider temporarily discontinuing in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue and promptly treat. Monitor renal function during therapy. • Urosepsis and pyelonephritis: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated. • Hypoglycemia: Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with Canagliflozin. • Necrotizing fasciitis of the perineum (Fournier's gangrene): Serious, life-threatening cases have occurred in both females and males. Assess				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment. • Genital mycotic infections: Monitor and treat if indicated.				
439.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pitolisant hydrochloride equivalent to Pitolisant 4.45 mg Tablet	Pitolisant hydrochloride INN equivalent to Pitolisant 4.45 mg Tablet	অহী রজ্জু ংরপ	• Pitolisant hydrochloride is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.	**Contra-indication:** Pitolisant hydrochloride is contraindicated in patients with severe hepatic impairment. **Side-effect:** এঝব স ড়ংঃ পড়স স ড়হ ধফা বৎংব ৎবধপঃরড়ুং ধৎব রহঃড়স হরধ,হধঁ ংবধ, ধহফ ধহী রবুঃ . **WARNINGS AND PRECAUTIONS:** ছএ ওঃবথ ধষচ ৎড়ষড়হমধঃরড়ু: ওপৎবধংবং রহ ছএ রহঃবথ ধষ.আ ড়রুফ ঁংব িরিয়ফঁ মং ংযধঃ ধষংড় রহপৎবধংব ংযব ছএ রহঃবথ ধষধহফ রহ ঢ়ধঃরহঃং িরুয ৎরংশ ভাপঃড়ৎং ভড়ৎ ঢ়ৎড়ষড়হমবফ ছএ রহঃবথ ধষ.গড় হরঢ়ড়ৎ ঢ়ধঃরবহঃং িরুয যবঢ়ধঃরপড়ৎ ৎবহধষ রূস ঢ়ধরঙ্গ বহঃ ভড়ৎ রহপৎবধংবফ ছএপ.	New	USFDA	ডিসিসি-২৫১ তম সভার সিদ্ধান্ত মোতাবেক ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়।	ডিসিসি-২৫১ তম সভার সিদ্ধান্ত মোতাবেক ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়। কোন মতামত পাওয়া যায়নি বিধায় পুনরায় ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়।
440.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd,	Pitolisant hydrochloride equivalent to Pitolisant 17.8 mg Tablet	Pitolisant hydrochloride INN equivalent to Pitolisant 17.8 mg Tablet	Anxiolytic	• Pitolisant hydrochloride is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.	**Contra-indication:** Pitolisant hydrochloride is contraindicated in patients with severe hepatic impairment. **Side-effect:**	New	USFDA	ডিসিসি-২৫১ তম সভার সিদ্ধান্ত মোতাবেক ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়।	ডিসিসি-২৫১ তম সভার সিদ্ধান্ত মোতাবেক ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়। কোন মতামত পাওয়া যায়নি বিধায় পুনরায় ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Kathali, Bhaluka, Mymensingh					এক্সব স ড়ংঃ পড়স স ড়হ ধফা বৎংব ৎবধপঃরড়হং ধৎব রহঃড়স হরধ,হধঁ ংবধ, ধহফ ধহী রবুঃ **WARNINGS AND PRECAUTIONS:** ছএঃ ওহঃবথ ধষচ ৎড়ষড়হমধঃরড়হ: ওহপঙ্গধংবং রহ ছএঃ রহঃবথ ধষ.আ ড়রুফ ঁংব িরিয়ু ফহুঁ মং ঃযধঃ ধষংড়রহপঙ্গধংব ঃযব ছএঃ রহঃবথ ধষ ধহফ রহ ঢ় ধঃরবহ্ণং িরিয়ু ৎরংশ ভাপঃড়ৎং ভড়ৎ ঢ় ৎড়ষড়হুমবফ ছএঃ রহঃবথ ধষ.গড় হরঃড়হ ঢ় ধঃরবহ্ণং িরিয়ু যবঢ় ধঃরপড়ৎ ৎবহ ধষ রস ঢ় ধরঙ্গস বহঃ ভড়ৎ রহপঙ্গধংবফ ছএঃপ.				
441.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Tiopronin 100 mg delayed release tablet	Tiopronin INN 100 mg	Renal-Urologic Agent	• Tiopronin is a reducing and complexing thiol indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone	**Contraindication:** Hypersensitivity to tiopronin or any component of tiopronin **Warning and Precautions:** •Proteinuria, including nephrotic syndrome, and membranous nephropathy, has been reported with tiopronin use. Pediatric patients receiving greater than 50 mg/kg of tiopronin per day may be at increased risk for proteinuria. •Hypersensitivity reactions have been reported during tiopronin treatment.	New	USFDA	ডিসিসি-২৫১ তম সভার সিদ্ধান্ত মোতাবেক ঔষধটির বিষয়ে ইউরোলজিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়।	ডিসিসি-২৫১ তম সভার সিদ্ধান্ত মোতাবেক ঔষধটির বিষয়ে ইউরোলজিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়। কোন মতামত পাওয়া যায়নি বিধায় পুনরায় ঔষধটির বিষয়ে ইউরোলজিস্ট এর মতামত নেওয়ার সিদ্ধান্ত গৃহীত হয়।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name with strength	Therapeutic Class & Code	Indication	Contraindication, Side-effects, Precautions & Warnings	Status (New Molecule/ Existing)	USFDA/ BNF /EMA/UK-MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Side effect: Most common adverse reactions (≥10%) are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.				

Imported Medicine (Human): Annex-B

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	Emcure Pharmaceuticals Ltd, Plot No.P-1, P-2, I.T.B.T. Park, Phase-II, M.I.D.C, Hinjawadi, Pune, Maharashtra, State, IN 411 037, India, **Local Agent:** Renata Limited Mirpur, Dhaka	Carmustine 100mg Powder and Solvent for Solution for Infusion	Carmustine Ph. Eur. 100mg/Vial Powder and Solvent for Solution for Infusion	Anti Cancer Therapeutic Code: 010	Carmustine 100 mg-Powder and solvent for solution for infusion is a medicine which contains carmustine Carmustine belongs to a group of anticancer substances known as nitrosourea that act by slowing the growth of cancer cells Carmustine is used as palliative therapy (relieving and preventing the suffering of patients) as a single agent or in established combination therapy with other approved anticancer substances in certain types of cancers, like: • Brain tumours - glioblastoma, medulloblastoma, astrocytoma and metastatic brain tumours • Multiple myeloma (malignant tumours developing from bone marrow) • Hodgkin's disease (lymphoid tumour) Non-Hodgkin's lymphomas (lymphoid tumour)	Carmustine should not be given to individuals who : • have demonstrated a previous hypersensitivity to the active, to other nitrosoureas or to any other of the excipients • Suffer from decereased circulating platelets, leucocytes or erythrocytes either from previous chemotherapy or other causes	New	UK India	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
2.	Emcure Pharmaceuticals Ltd, Plot No.P-1, P-2, I.T.B.T. Park, Phase-II, M.I.D.C, Hinjawadi, Pune, Maharashtra, State, IN 411 037, India, **Local Agent:** Renata Limited Mirpur, Dhaka	Treosulfan 5g Powder for Solution for Infusion Powder for Solution for Injection/Infusion	Treosulfan INN 5gm/vial After reconstitution, 1ml of solution contains 50 mg of treosulfan	Anti Cancer Therapeutic Code: 010	Treosulfan is indicated for the palliative treatment of advanced epithelial ovarian cancer after at least one line of standard therapy	• Hypersensitivity to the active substance. • Severe and lasting bone marrow depression. • Breast-feeding Side Effects : The most commonly reported undesirable effects are myelosuppression and gastrointestinal complaints. These are usually mild and resolve after therapy with treosulfan. Bone marrow suppression is the dose-limiting side effect of treosulfan.	New	UK India	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
3.	EVER Pharma Jena GmbH Otto-Schott-Str.15 07745 Jena Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Terlipressin acetate EVER Pharma 0.2 mg/ml (solution for injection.)	Terlipressin Acetate 0.2 mg/ml solution for injection.	Hormone Therapeutic Code: 056	Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection is used for- The treatment of: bleeding from dilated (widening) veins in the food pipe leading to your stomach (called bleeding oesophageal varices). Emergency treatment of type 1 hepatorenal syndrome (rapidly progressive renal failure) in patients with liver cirrhosis (scarring of the liver) and ascites (abdominal dropsy).	**Contraindication:** Pregnancy. Hypersensitivity to terlipressin or any other excipients of the product **Side Effect:** there may be severe side effects when you are given Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection. severe shortness of breath due to an asthma attack • severe difficulty with or stopping breathing • severe pain in the chest (angina) • severe and persistent irregular heart beats • dead skin around the injection site	New	CPP- Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						(necrosis) • convulsions (seizure)				
4.	Piramal Enterprises Limited Sy. Nos.7-70,70/1 And 70/2 Digwal Village, Kohir Mandal, ,Sangareddy District, 502321, Telangana, India **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Fluothane 250ml (Inhalation Liquid)	Halothane BP 100%	Anesthetic Therapeutic Code: 004	Halothane is indicated for the induction and maintenance of general anesthesia.	**Contraindication:** Halothane is not recommended for obstetrical anesthesia except when uterine relaxation is required. **Side Effect:** Muscle rigidity , hypercapnia, tachycardia, ventricular arrhythmias, cyanosis, tachypnea, unstable blood pressure, malignant hyperthemia, post-operative nausea and vomiting, mild hepatotoxicity, massive centrilobular necrosis leading to fulminant liver failure		CPP-India & UK	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
5.	DEMO SA Pharmaceutical Industry, 21st km National Road Athens – Lamia GR-145 68 Krioneri Attiki, Greece **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Zitamin 5 mg/ml (Solution for Injection/Infusion)	Ropivacaine hydrochloride 5mg/ml	Anesthetic Therapeutic Code: 004	Ropivacaine Hydrochloride is indicated for the production of local or regional anesthesia for surgery and for acute pain management	**Contraindication:** Ropivacaine solutions are contraindicated in patients with hypersensitivity to local anaesthetics of the amide-type. **Side effect:** The most common side effects include: • changes in your sense of taste • feeling short of breath • constipation • decreased appetite • changes in fingernails or toenails		CPP-Greece & Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
6.	DEMO SA Pharmaceutical Industry, 21st km National Road Athens – Lamia GR-145 68 Krioneri Attiki, Greece Local Agent: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Zitamin 7.5 mg/ml (Solution for Injection/Infusion)	Ropivacaine hydrochloride 7.5mg/ml	Anesthetic Therapeutic Code: 004	Ropivacaine Hydrochloride is indicated for the production of local or regional anesthesia for surgery and for acute pain management	**Contraindication:** Ropivacaine solutions are contraindicated in patients with hypersensitivity to local anaesthetics of the amide-type. **Side effect:** The most common side effects include: • changes in your sense of taste • feeling short of breath • constipation • decreased appetite • changes in fingernails or toenails		CPP-Greece & Germany.	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
7.	Siegfried Hameln GmbH Langes Feld 13 31789 Hameln Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor)	Hydromorphon-hameln 2mg/ml (Solution for Injection or infusion)	Hydromorphon 2mg/ml	Opioid Analgesics Therapeutic Code: 065	Hydromorphon For the treatment of severe pain.	**Contraindication** hypersensitivity to the active substance or to any of the excipients - significant respiratory depression with hypoxia or elevated carbon dioxide levels in the blood - severe chronic obstructive pulmonary disease - cor pulmonale		CPP-Germany.	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Dhaka-1000, Bangladesh.					- coma - acute abdomen - paralytic ileus - concurrent administration of mono-amine oxidase inhibitors or within two weeks of discontinuation of their use **Side effects** The most common adverse effects are lightheadedness, dizziness, sedation, nausea, vomiting, sweating, flushing, dysphoria, euphoria, dry mouth, and pruritus. These effects seem to be more prominent in ambulatory patients and in those not experiencing severe pain				
8.	Siegfried Hameln GmbH Langes Feld 13 31789 Hameln Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Hydromorphon-hameln 10mg/ml (Solution for Injection or infusion)	Hydromorphon 10mg/ml	Opioid Analgesics Therapeutic Code: 065	Hydromorphon For the treatment of severe pain.	**Contraindication** hypersensitivity to the active substance or to any of the excipients - significant respiratory depression with hypoxia or elevated carbon dioxide levels in the blood - severe chronic obstructive pulmonary disease - cor pulmonale - coma - acute abdomen - paralytic ileus - concurrent administration of mono-amine oxidase inhibitors or within two weeks of discontinuation of their use **Side effects** The most common adverse effects are lightheadedness, dizziness, sedation, nausea, vomiting, sweating, flushing, dysphoria, euphoria, dry mouth, and pruritus. These effects seem to be more prominent in ambulatory patients and in those not experiencing severe pain		CPP-Germany.	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
9.	Ardeypharm GmbH Lofeldstrabe 20 58313 Herdecke – Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Yomogi 250 mg (Hard Capsule)	250 mg dry yeast from Saccharomyces cerevisiae HANSEN CBS 5926, corresponding to at least 2*1010 viable cells/g, lyophilized	OtherClassification Therapeutic Code: 075 (Probiotics)	For the relief / management of Diarrhea. It belong to antidiarrheal group. From treatment of symptom of acute diarrhea, also in case of traveler's diarrhea, and diarrhea during feeding by stomach tube.	**Contraindication** Congenital galactosemia, glucose and lactose intolerance, lactase deficiency in patients with disabling. Hypersensitivity to this drug or one of its components Gynecological: Hypersensitivity. Estrogen-dependent tumors, endometriosis, vag hemorrhaging of unknown origin, females who are not yet sexually mature **Side effects** An increase in stomach gas .Many people		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						using this medication do not have serious side effects. serious side effects, including: signs of infection (such as high fever, chills).A very serious allergic reaction to this product is rare.				
10.	Ardeypharm GmbH Lofeldstrabe 20 58313 Herdecke – Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Yomogi (Capsule)	250 mg lyophilisate 221.25 mg active substance dry yeast from Saccharomyces cerevisiae HANSEN CBS 5926, corresponding to min 10^{10} viable cells/g, lyophilisate	OtherClassification Therapeutic Code: 075 (Probiotics)	For the relief / management of Diarrhea. It belong to antidiarrheal group. From treatment of symptom of acute diarrhea, also in case of traveler's diarrhea, and diarrhea during feeding by stomach tube.	**Contraindication** Congenital galactosemia, glucose and lactose intolerance, lactase deficiency in patients with disabling. Hypersensitivity to this drug or one of its components Gynecological: Hypersensitivity. Estrogen-dependent tumors, endometriosis, vag hemorrhaging of unknown origin, females who are not yet sexually mature **Side effects** An increase in stomach gas .Many people using this medication do not have serious side effects. serious side effects, including: signs of infection (such as high fever, chills).A very serious allergic reaction to this product is rare.		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
11.	Ardeypharm GmbH Lofeldstrabe 20 58313 Herdecke – Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Mutaflor (Capsule)	E.coli strain nissle 1917 corresponding to 2.5 - 25× 10^9 viable cells (CFU)/capsule	OtherClassification Therapeutic Code: 075 (Probiotics)	Mutaflor indication of increase the number of bowel movements per day and the number of days on which bowel movements occur in patients with chronic constipation.	**Contraindication** Congenital galactosemia, glucose and lactose intolerance, lactase deficiency in patients with disabling. Hypersensitivity to this drug or one of its components Gynecological: Hypersensitivity. Estrogen-dependent tumors, endometriosis, vag hemorrhaging of unknown origin, females who are not yet sexually mature. **Side effects** An increase in stomach gas .Many people using this medication do not have serious side effects. serious side effects, including: signs of infection (such as high fever, chills).A very serious allergic reaction to this product is rare.		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
12.	Ardeypharm GmbH Lofeldstrabe 20 58313 Herdecke – Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor)	Paidoflor (Chewable Tablet)	Dry Powder of Lactobacillus acidophilus corresponding to 10^9-10^{10} viable bacteria per g	OtherClassification Therapeutic Code: 075 (Probiotics)	Paidoflor is used as a mild medicine for support to the function of Intestine. In case of under activity of the Intestine and Diarrhea.	**Contraindication** Congenital galactosemia, glucose and lactose intolerance, lactase deficiency in patients with disabling. Hypersensitivity to this drug or one of its components Gynecological: Hypersensitivity. Estrogen-dependent tumors, endometriosis, vag hemorrhaging of unknown origin, females who are not yet		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Dhaka-1000, Bangladesh.					sexually mature. **Side effects** An increase in stomach gas .Many people using this medication do not have serious side effects. serious side effects, including: signs of infection (such as high fever, chills).A very serious allergic reaction to this product is rare.				
13.	Wasserburger Arzneimittelwerk GmbH Herderstrasse 2, 83512 Wasserburg Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Selenase T peroral (Oral Solution)	Sodium selenite pentahydrate 1.67 mg corresponding to 500 µg selenium	Metals, Salts, Minerals Therapeutic Code: 062	Proven selenium deficiency, which cannot be offset by alimentation. • Diseases which can be treated with a selenium therapy, e.g.: sepsis, critically ill patients (ICU patients), cardiovascular diseases, cancer, chronic inflammatory diseases, general immunosuppression, viral infection.	**Contraindication** – Hypersensitivity to sodium selenite pentahydrate or to any of the excipients – Selenosis **Side effects** Selenium can cause muscle tenderness, tremor, lightheadedness, facial flushing, blood clotting problems, liver and kidney problems, and other side effects. High doses of selenium can cause significant side effects including nausea, vomiting, nail changes, loss of energy, and irritability		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
14.	Wasserburger Arzneimittelwerk GmbH Herderstrasse 2, 83512 Wasserburg Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	selenase® T pro injection (solution for Injection) 10 ml vial.	Sodium selenite pentahydrate 1.67 mg, corresponding to 500 µg selenium	Metals, Salts, Minerals Therapeutic Code: 062	Proven selenium deficiency, which cannot be offset by alimentation. • Diseases which can be treated with a selenium therapy, e.g.: sepsis, critically ill patients (ICU patients), cardiovascular diseases, cancer, chronic inflammatory diseases, general immunosuppression, viral infection.	**Contraindication** – Hypersensitivity to sodium selenite pentahydrate or to any of the excipients – Selenosis **Side effects** Selenium can cause muscle tenderness, tremor, lightheadedness, facial flushing, blood clotting problems, liver and kidney problems, and other side effects. High doses of selenium can cause significant side effects including nausea, vomiting, nail changes, loss of energy, and irritability		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
15.	Wasserburger Arzneimittelwerk GmbH Herderstrasse 2, 83512 Wasserburg Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	selenase® 100 µg pro injection (Solution for Injection) 2ml Vial	Sodium selenite pentahydrate 0.333 mg corresponding to 100 µg selenium	Metals, Salts, Minerals Therapeutic Code: 062	Proven selenium deficiency, which cannot be offset by alimentation. • Diseases which can be treated with a selenium therapy, e.g.: sepsis, critically ill patients (ICU patients), cardiovascular diseases, cancer, chronic inflammatory diseases, general immunosuppression, viral infection.	**Contraindication** – Hypersensitivity to sodium selenite pentahydrate or to any of the excipients – Selenosis **Side effects** Selenium can cause muscle tenderness, tremor, lightheadedness, facial flushing, blood clotting problems, liver and kidney problems, and other side effects. High doses of selenium can cause significant side effects including nausea, vomiting, nail changes, loss of energy, and		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						irritability				
16.	Wasserburger Arzneimittelwerk GmbH Herderstrasse 2, 83512 Wasserburg Germany. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Selenase 100 µg peroral (Oral Solution)	Sodium selenite pentahydrate 0.333 mg corresponding to 100 µg selenium	Metals, Salts, Minerals Therapeutic Code: 062	Proven selenium deficiency, which cannot be offset by alimentation. • Diseases which can be treated with a selenium therapy, e.g.: sepsis, critically ill patients (ICU patients), cardiovascular diseases, cancer, chronic inflammatory diseases, general immunosuppression, viral infection.	**Contraindication** – Hypersensitivity to sodium selenite pentahydrate or to any of the excipients – Selenosis **Side effects** Selenium can cause muscle tenderness, tremor, lightheadedness, facial flushing, blood clotting problems, liver and kidney problems, and other side effects. High doses of selenium can cause significant side effects including nausea, vomiting, nail changes, loss of energy, and irritability		CPP-Germany	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
17.	ADIENNE S.r.l. S.U., Via Galileo Galilei, 19, 20867 Caponago (MB), Italy. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	TEPADINA (Powder for concentrate for solution for infusion)	Thiotepa 15mg/vial	Anti Cancer Therapeutic Code: 010	TEPADINA is indicated, in combination with other chemotherapy)- medicinal! Products: with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous hematopoietic progenitor cell transplantation (HPCT) in hematological diseases in adult and pediatric patients; • when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatric patients	**Contraindication** Thiotepa is contraindicated in patients with a known hypersensitivity (allergy) to this preparation.Therapy is probably contraindicated in cases of existing hepatic, renal, or bone-marrow damage. However, if the need outweighs the risk in such patients, thiotepa may be used in low dosage, and accompanied by hepatic, renal and hemopoietic function tests **Side effects** General: Fatigue, weakness. Febrile reaction and discharge from a subcutaneous lesion may occur as the result of breakdown of tumor tissue. Hypersensitivity Reactions: Allergic reactions - rash, urticaria, laryngeal edema, asthma, anaphylactic shock, wheezing. Gastrointestinal: Nausea, vomiting, abdominal pain, anorexia. Neurologic: Dizziness, headache, blurred vision.		EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
18.	**Manufacturer:** Alcon-Couvreur, Puurs, Belgium **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Beovu PFS	Brolucizumab INN 120 mg/ml Solution for Injection in Pre-Filled Syringe (PFS)	Eye Preparations **Therapeutic Code:052**	Beovu is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD)	**Contraindication** • Hypersensitivity to the active substance or to any of the excipients. • Active or suspected ocular or periocular infection. • Active intraocular inflammation. **Side Effects:** **Eye disorders:** Visual acuity reduced,	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Retinal haemorrhage, Uveitis, Iritis, Vitreous detachment, Retinal tear, Cataract, Conjunctival haemorrhage, Vitreous floaters, Eye pain, Intraocular pressure increase, Conjunctivitis, Retinal pigment epithelial tear, Vision blurred, Corneal abrasion, Punctate keratitis. **Immune system disorders:** Hypersensitivity				
19.	**Manufacturer:** Novartis Pharma AG, Switzerland **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Beovu Vial	Brolucizumab INN 120 mg/ml Solution for Injection in Vial	Eye Preparations **Therapeutic Code:052**	Beovu is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD)	**Contraindication** -do- **Side Effects** -do-	New	EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
20.	**Manufacturer:** Novartis Pharma AG, Switzerland **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Atectura Breezhaler	Indacaterol INN150 mcg +Mometasone INN 80mcg inhalation powder hard capsules	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code:044	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.	**Contraindication** Hypersensitivity to any of the active substances or excipients. **Side Effects** Infections and infestations: Nasopharyngitis, Upper respiratory tract infection, Immune system disorders: Hypersensitivity, Nervous system disorders: Headache, Respiratory, thoracic and mediastinal disorders: Oropharyngeal Pain & Dysphonia, Musculoskeletal and connective tissue disorders: Musculoskeletal Pain.	New	EMA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
21.	**Manufacturer:** Novartis Pharma AG, Switzerland **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Atectura Breezhaler	Indacaterol INN 150 mcg and Mometasone INN 160mcg inhalation powder hard capsules	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code:044	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.	**Contraindication** -do- **Side Effects** -do-	New	EMA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
22.	**Manufacturer:** Novartis Pharma AG, Switzerland	Atectura Breezhaler	Indacaterol INN 150 mcg + Mometasone INN 320mcg inhalation powder hard capsules	Drug used in Bronchial Asthma,Chronic	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-	**Contraindication** -do- **Side Effects**		EMA	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Local Representative: Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.			obstructive pulmonary disease(COPD) Therapeutic Code:044	acting beta2-agonists.	-do-				
23.	**Manufacturer:** Novartis Pharma AG, Switzerland **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Enerzair Breezhaler	Indacaterol INN 150 mcg + Glycopyrronium INN 50 mcg +Mometasone INN 80mcg inhalation powder hard capsules	COPD Therapeutic Code: 044	Enerzair Breezhaler is indicated as a once-daily maintenance treatment of asthma, and to reduce asthma exacerbations, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and an inhaled corticosteroid.	**Contraindication** Hypersensitivity to any of the active substances or excipients. **Side Effects** Infections and infestations: Nasopharyngitis, Upper respiratory tract infection, Candidiasis & urinary tract infection, Immune system disorders: Hypersensitivity, Nervous system disorders: Headache, Cardiac disorders: Tachycardia, Respiratory, thoracic and mediastinal disorders: Asthma, Oropharyngeal Pain, Cough & Dysphonia, Gastrointestinal disorders: Gastroenteritis & Dry Mouth, Skin and subcutaneous tissue disorders: Rash, Musculoskeletal and connective tissue disorders: Musculoskeletal Pain & Muscle Spasms, General disorders and administration site conditions: Pyrexia	New	Japan	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
24.	**Manufacturer:** Novartis Pharma AG, Switzerland **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A Dhaka 1208, Bangladesh.	Enerzair Breezhaler	Indacaterol INN 150mcg+ Glycopyrronium INN 50 mcg +Mometasone INN 160mcg inhalation powder hard capsules	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code:044	Enerzair Breezhaler is indicated as a once-daily maintenance treatment of asthma, and to reduce asthma exacerbations, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and an inhaled corticosteroid.	**Contraindication** -do- **Side Effects** -do-	New	EMA & Japan	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
25.	**Manufacturer:** Mipharm S.p.A., Italy **Local Representative:** Novartis (Bangladesh) Limited Tower One One Seven (Level 5) Plot # 117/A, Tejgaon I/A	Voltfast	Diclofenac Potassium Ph. Eur. 50 mg Powder for oral solution	Steroidal Anti inflammatory Therapeutic Code: 072	Voltfast is indicated for the short-term treatment in the following acute conditions: • Post-operative pain, inflammation and swelling, e.g. following dental or orthopedic surgery. • Post-traumatic pain, inflammation and swelling, e.g. due to sprains. • Painful and/or inflammatory conditions in gynecology, e.g. primary dysmenorrhea or	**Contraindication:** • Known hypersensitivity to the active substance or to any of the excipients. • Hypersensitivity to acetylsalicylic acid and to other analgesics, antipyretics, non-steroidal anti-inflammatories • Active gastric or intestinal ulcer, bleeding or perforation • Last trimester of pregnancy	New	Italy & Swiss	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Dhaka 1208, Bangladesh.				adnexitis. • Migraine attacks, with or without aura • As an adjuvant in severe painful inflammatory infections of the ear, nose, or throat, e.g. pharyngotonsillitis, otitis. • Painful syndromes of the vertebral column. • Non-articular rheumatism. • In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.	• Hepatic failure • Renal failure (GFR <15 mL/min/1.73m2) • Severe cardiac failure • Like other non-steroidal anti-inflammatory drugs (NSAIDs), Voltfast is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs **Side Effects:** Headache, dizziness, Vertigo, Nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, Transaminases increased & Rash.				
26.	Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland. By F. Hoffmann - La Roche Ltd, CH-4303 Kaiseraugst, Switzerland **Local agent:** Roche Bangladesh Limited	Tecentriq 840 mg / 14 ml (vial)	Atezolizumab INN	Anticancer Therapeutic Code: 010	***Metastatic urothelial carcinoma*** Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC): after prior chemotherapy, or who are considered cisplatin ineligible and whose tumours have a PD-L1 expression ≥ 5%, or who are not eligible for any platinum-containing chemotherapy regardless of level of tumor PD-L1 expression. ***Non-small cell lung cancer*** Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC). Patients with EGFR or ALK genomic tumor aberrations should have received targeted therapy if clinically indicated prior to receiving Tecentriq. Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. Tecentriq is indicated for the treatment of patients with locally advanced or metastatic NSCLC after prior chemotherapy. ***Small cell lung cancer*** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). ***Triple-negative breast cancer*** Tecentriq, in combination with nab-paclitaxel, is	**Contraindication**: Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. **Side effects:** Immune-related pneumonitis Immune-related hepatitis Immune-related colitis, Immune-related endocrinopathies, Immune-related meningoencephalitis, Immune-related neuropathies, Immune-related pancreatitis, etc.	New	Swissmedic CPP	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease.					
27.	Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland, by BSP Pharmaceuticals S.p.A., Latina Scalo, Italy **Local agent:** Roche Bangladesh Limited	Polivy 140 mg/ 20 ml vial	Polatuzumab Vedotin INN	Anticancer Therapeutic Code: 010	Polivy in combination with bendamustine and rituximab is indicated for the treatment of adult patients with diffuse large B-cell lymphoma who have received at least one prior therapy.	**Contraindication** Polivy is contraindicated in patients with a known hypersensitivity to polatuzumab vedotin or any of the excipients. **Side effects**: Anemia, thrombocytopenia, neutropenia, fatigue, diarrhea, nausea, and pyrexia	New	EMA, CPP	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
28.	Made in Switzerland by F. Hoffmann-La Roche Ltd, Basel **Local agent:** Roche Bangladesh Limited	Cotellic 20 mg film-coated tablets	Cobimetinib INN	Anticancer Therapeutic Code: 010	Cotellic is indicated for use in combination with Zelboraf for the treatment of patients with unresectable or metastatic melanoma with BRAF V600 mutation.	**Contraindication**: Cotellic is contraindicated in patients with known hypersensitivity to cobimetinib or any of the excipients. **Side effects**: Common or very common: Anemia, Chorioretinopathy, Vision blurred,Retinal detachment, Diarrhea, Nausea, Vomiting, Pyrexia, Chills, Dehydration, Hyponatremia Photosensitivity Maculo-papular, rash, Acneiform dermatitis, etc.	New	Swissmedic CPP	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
29.	Boehringer Ingelheim Pharma GmbH and Co. KG, Germany. **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road CNo-3, Sector-12, Uttara, Dhaka 1230, Bangladesh.	Glyxambi Film Coated Tablet	Empagliflozin Company Standard 10mg + Linagliptin Company Standard 5mg	Antidiabetes Therapeutic Code: 015	Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus: to improve glycaemic control when metformin and/or sulphonylurea (SU) one of the monocomponents of Glyxambi do not provide adequate glycaemic control when already being treated with the free combination of empagliflozin and linagliptin.	**Contraindication:** Hypersensitivity to empagliflozin or linagliptin or any of the excipients. **Side effects:** Common side effects of Glyxambi: Urinary tract infection, common cold symptoms, upper respiratory tract infections, genital yeast infection, increased urination, joint pain, nausea, runny or stuffy nose, diarrhoea, cough **Adverse Drug reactions:** **Infections and infestations** Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections Urinary tract infection(including pyelonephritis and urosepsis) Nasopharyngitis **Immune system disorders** Hypersensitivity Angioedema Urticaria	New	USFDA approved CPP (EMA)	পদটি ডিসিসি-২৫০ এ বাতিল করা হয়েছিল। ডিসিসি-২৫০ তম সভার সিদ্ধান্ত মোতাবেক কোন ডিসিসিতে বাতিলকৃত ঔষধ পরপর দুই ডিসিসিতে উপস্থাপিত হবে না, এর পর উপস্থাপিত হবে। সে মোতাবেক পদটি আবেদনের ভিত্তিতে ডিসিসি-২৫৩ এর টেকনিক্যাল সাব	পদটি ডিসিসি-২৫০ এ বাতিল করা হয়েছিল। ডিসিসি-২৫০ তম সভার সিদ্ধান্ত মোতাবেক কোন ডিসিসিতে বাতিলকৃত ঔষধ পরপর দুই ডিসিসিতে উপস্থাপিত হবে না, এর পর উপস্থাপিত হবে। সে মোতাবেক পদটি আবেদনের ভিত্তিতে ডিসিসি-২৫৩ এর টেকনিক্যাল সাব কমিটির সভায় উপস্থাপতি হবে।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Metabolism and nutrition disorders Hypoglycaemia (when used with sulphonylurea or insulin) Ketoacidosis **Renal and urinary disorders** Increased urination Dysuria **Respiratory, thoracic & mediastinal disorders** Cough **Skin and subcutaneous tissue disorders** Rash Pruritus			কমিটির সভায় উপস্থাপতি হবে।	
30.	Boehringer Ingelheim Pharma GmbH and Co. KG, Germany. **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road CNo-3, Sector-12, Uttara, Dhaka 1230, Bangladesh.	Glyxambi Film Coated Tablet	Empagliflozin Company Standard 25mg + Linagliptin Company Standard 5mg	Antidiabetes Therapeutic Code: 015	Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus: to improve glycaemic control when metformin and/or sulphonylurea (SU) one of the monocomponents of Glyxambi do not provide adequate glycaemic control when already being treated with the free combination of empagliflozin and linagliptin.	**Contraindication:** Hypersensitivity to empagliflozin or linagliptin **or** any of the excipients. **Side effects:** **Common side effects of** Glyxambi: Urinary tract infection, common cold symptoms, upper respiratory tract infections, genital yeast infection, increased urination, joint pain, nausea, runny or stuffy nose, diarrhoea, cough **Adverse Drug reactions:** **Infections and infestations** Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections Urinary tract infection(including pyelonephritis and urosepsis) Nasopharyngitis **Immune system disorders** Hypersensitivity Angioedema Urticaria **Metabolism and nutrition disorders** Hypoglycaemia (when used with sulphonylurea or insulin) Ketoacidosis **Renal and urinary disorders** Increased urination Dysuria **Respiratory, thoracic & mediastinal disorders** Cough **Skin and subcutaneous tissue disorders** Rash Pruritus	New	USFDA approved CPP-EMA	পদটি ডিসিসি-২৫০ এ বাতিল করা হয়েছিল। ডিসিসি-২৫০ তম সভার সিদ্ধান্ত মোতাবেক কোন ডিসিসিতে বাতিলকৃত ঔষধ পরপর দুই ডিসিসিতে উপস্থাপিত হবে না, এর পর উপস্থাপিত হবে। সে মোতাবেক পদটি আবেদনের ভিত্তিতে ডিসিসি-২৫৩ এর টেকনিক্যাল সাব কমিটির সভায় উপস্থাপতি হবে।	পদটি ডিসিসি-২৫০ এ বাতিল করা হয়েছিল। ডিসিসি-২৫০ তম সভার সিদ্ধান্ত মোতাবেক কোন ডিসিসিতে বাতিলকৃত ঔষধ পরপর দুই ডিসিসিতে উপস্থাপিত হবে না, এর পর উপস্থাপিত হবে। সে মোতাবেক পদটি আবেদনের ভিত্তিতে ডিসিসি-২৫৩ এর টেকনিক্যাল সাব কমিটির সভায় উপস্থাপতি হবে।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
31.	Manufacturer: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway, Halol-389350, Gujarat State, India Importer: Sun Pharmaceutical (Bangladesh) ITD	Doxorubicin Hydrochloride Liposome Injection, 20 mg/10 mL	Doxorubicin Hydrochloride Liposome Injection, 20 mg/10 mL	Anticancer Therapeutic Code: 010	Doxorubicin HCL Liposome Injection, as monotherapy, is indicated for the treatment of metastatic breast cancer. Doxorubicin HCL Liposome Injection is also indicated for the treatment of: · Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen. · AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (<200 lymphocytes/mm3) and extensive mucocutaneous or visceral disease. Doxorubicin HCL Liposome Injection may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and doxorubicin (or other anthracycline). Doxorubicin HCL Liposome Injection is also indicated, in combination with bortezomib, for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.	Contra-indication: Doxorubicin HCL Liposome Injection is contraindicated in patients who have a history of hypersensitivity reactions to its components or to doxorubicin HCl. Doxorubicin HCL Liposome Injection should not be administered during pregnancy or while breast feeding. Doxorubicin HCL Liposome Injection should not be used to treat AIDS-KS that may be effectively treated with local therapy or systemic alfa-interferon. Side effects: Very common (≥10%): asthenia, mucous membrane disorder, Infusion reactions, Common (>1% and <10%): fever, pain, headache, peripheral oedema, allergic reaction, dehydration, chills, infection, chest pain, back pain, malaise, sweating, taste perversion, herpes zoster, cachexia, hypertonia Uncommon (>0.1% and <1%): enlarged abdomen, facial oedema. (Details in Dossier)	Doxorubicin Hydrochloride Liposome Injection, 10 mg, 50 mg/ml	CPP= USA, Origin: India	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।
32.	**ONY Biotech Inc.** 1576 Sweet Home Rd, Amherst, NY 14228, USA **Local Agent:** City Overseas Ltd. 218 Mitford Road, Dhaka-1100, Bangladesh	**1. Infasurf 3ml,** (Calfactant 35mg/1ml) Intratracheal Suspension **2. Infasurf 6ml,** (Calfactant 35mg/1ml) Intratracheal Suspension	**Calfactant** 35mg/ml Sterile, Non-Pyrogenic Suspension for Intratracheal Use Only	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Infasurf is indicated for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS and for the treatment of premature infants who develop RDS. Infasurf decreases the incidence of RDS, mortality due to RDS, and air leaks associated with RDS. Prophylaxis therapy at birth with Infasurf is indicated for premature infants <29 weeks of gestational age at significant risk for RDS. Infasurf prophylaxis should be administered as soon as possible, preferably within 30 minutes after birth. Treatment: Infasurf therapy is indicated for infants ≤72 hours of age with RDS (confirmed by clinical and radiologic findings) and requiring endotracheal intubation.	**Side effects**: The most common adverse reactions associated with Infasurf dosing procedures in the controlled trials were cyanosis (65%), airway obstruction (39%), bradycardia (34%), reflux of surfactant into the endotracheal tube (21%), requirement for manual ventilation (16%), and reintubation (3%). These events were generally transient and not associated with serious complications or death. **Contraindications:** None	New	**CPP: USA** **Country of Origin: USA**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
33.	Guerbet Bp 57400 95943 Roissy Charles De Gaulle Cedex France	**Dotarem**	**Gadoteric Acid 0.5 mmol/ml , solution for injection**	Other Classification Therapeutic Code: 075	This medicinal product is for diagnostic use only. Dotarem should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI) • Magnetic resonance imaging for: • Cerebral and spinal diseases	**Contraindications:** • Hypersensitivity to gadoteric acid, to meglumine or to any medical products containing gadolinium. **Side-effects:**	New	FSC-FRANCE	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Local Agent Unicorn Healthcare Solution Limited. Rupayan karim Tower, Floor 14/D 80 Kakrail, Dhaka-1000				• Diseases of the vertebral column • And other whole body pathologies (including angiography)	Side effects in association with the use of gadoteric acid are usually mild to moderate in intensity and transient in nature. Injection site reactions, nausea and headache are the most frequently observed reactions.				
34.	Guerbet Bp 57400 95943 Roissy Charles De Gaulle Cedex France Local Agent Unicorn Healthcare Solution Limited. Rupayan karim Tower, Floor 14/D 80 Kakrail, Dhaka-1000	XENETIX 350 (350 mg Iodine/mL), solution for injection	Iobitridol EP 76.78 g/ 100 ml, solution for injection	Other Classification Therapeutic Code: 075	This medicinal product is for diagnostic use only. Contrast agent for use in: • intravenous urography • computed tomography • intravenous digital subtraction angiography • arteriography • angiocardiography.	Contraindications: • Hypersensitivity to iobitridol or any of the excipients. • History of a major immediate reaction or delayed skin reaction to a Xenetix 350 injection. • Manifest thyrotoxicosis. Side-effects: The adverse reactions most commonly reported during administration of Xenetix since marketing are feeling of warmth, and pain and oedema at the injection site. The hypersensitivity reactions are usually immediate (during the injection or over the hour following the start of the injection) or sometimes delayed (one hour to several days after the injection), and then appear in the form of adverse skin reactions. Immediate reactions comprise one or several, successive or concomitant effects, usually including skin reactions, respiratory and/or cardiovascular disorders, which may be the first signs of shock, which can rarely be fatal. Severe rhythm disorders including ventricular fibrillation have been very rarely reported in heart disease patients, in as well as out of a context of hypersensitivity	New	FSC-FRANCE	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
35.	Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland. By F. Hoffmann - La Roche Ltd, CH-4303 Kaiseraugst, Switzerland **Local agent:** Roche Bangladesh Limited	Tecentriq 840 mg/14 ml (vial)	Atezolizumab INN 840 mg/14ml, Concentrate for Solution for Infusion	Anti-cancer Therapeutic Code: 010	***1. Metastatic urothelial carcinoma*** Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC): after prior chemotherapy, or who are considered cisplatin ineligible and whose tumours have a PD-L1 expression ≥ 5%, or who are not eligible for any platinum-containing chemotherapy regardless of level of tumor PD-L1 expression. ***Non-small cell lung cancer*** Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC). Patients with EGFR or ALK genomic tumor aberrations should have received targeted therapy if clinically indicated prior to receiving Tecentriq. Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. Tecentriq is indicated for the treatment of patients with locally advanced or metastatic NSCLC after prior chemotherapy. ***Small cell lung cancer*** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). ***Triple-negative breast cancer*** Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease.	**Contraindication**: Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. **Side effects:** Immune-related pneumonitis Immune-related hepatitis Immune-related colitis, Immune-related endocrinopathies, Immune-related meningoencephalitis, Immune-related neuropathies, Immune-related pancreatitis, etc.	New	USFDA, EMA & Swissmedic approved	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
36.	Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland, by BSP Pharmaceuticals S.p.A., Latina Scalo, Italy **Local agent:** Roche Bangladesh Limited	Polivy 140 mg/20 ml vial	(Polatuzumab Vedotin INN 140 mg/20 ml)/vial	Anti-cancer Therapeutic Code: 010	Polivy in combination with bendamustine and rituximab is indicated for the treatment of adult patients with diffuse large B-cell lymphoma who have received at least one prior therapy.	**Contraindication** Polivy is contraindicated in patients with a known hypersensitivity to polatuzumab vedotin or any of the excipients. **Side effects**: Anemia, thrombocytopenia, neutropenia, fatigue, diarrhea, nausea, and pyrexia	New	USFDA & EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
37.	Made in Switzerland by F. Hoffmann-La Roche Ltd, Basel **Local agent:** Roche Bangladesh Limited	Cotellic 20 mg film-coated tablets	Cobimetinib INN 20 mg film-coated tablets	Anti-cancer Therapeutic Code: 010	Cotellic is indicated for use in combination with Zelboraf for the treatment of patients with unresectable or metastatic melanoma with BRAF V600 mutation.	**Contraindication**: Cotellic is contraindicated in patients with known hypersensitivity to cobimetinib or any of the excipients. **Side effects**: Common or very common: Anemia, Chorioretinopathy, Vision blurred,Retinal detachment, Diarrhea, Nausea, Vomiting, Pyrexia, Chills, Dehydration, Hyponatremia Photosensitivity Maculo-papular, rash, Acneiform dermatitis, etc.	New	USFDA, EMA & Swissmedic	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
38.	Mylan Laboratories Limited (FDF-2) H-12 and H-13, MIDC, Waluj, Aurangabad-431136, Maharashtra, India Local agent: S.S. Scientific Corporation 107, Begum Rokeya Sarani, Mirpur-10, Dhaka-1216	Dovprela 200mg	Pretomanid 200mg Tablet	Antitubercular and Antileprotic Therapeutic Code: 030	Limited Population: Pretomanid Tablet is indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.	CONTRAINDICATIONS Pretomanid Tablets used in the combination regimen with bedaquiline and linezolid are contraindicated in patients for whom bedaquiline and/or linezolid are contraindicated. Refer to the bedaquiline and linezolid prescribing information. SIDE EFFECTS The following serious adverse reactions are discussed here and elsewhere in the labeling: Hepatotoxicity Myelosuppression Peripheral and Optic Neuropathy QT Prolongation Reproductive Effects Lactic Acidosis	New	CPP-USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
39.	Ferring International Center SA, Chemin de la Vergognausaz, 1162 Saint-Prex, Switzerland Local Agent : Interhealth & Devices Ltd., Bangladesh	Menopur multidose 600 IU solution for Inj.	Highly Purified Menotrophin (Human Menopausal Gonadotrophin, HMG) solution for Inj	Hormone Therapeutic Code: 056	For the treatment of infertility in the following clinical situations: Anovulation, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g. in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)). Stimulation of follicular development in women with hypogonadotropic hypogonadism.	Contra – Indications: Contraindicated in women who have: - Tumors of the pituitary gland or hypothalamus - Ovarian, uterine or mammary carcinoma - Pregnancy and lactation - Gynaecologicalhaemorrhage of unknown aetiology - Hypersensitivity to the active substance or to any of the excipients listed in section List of Excipients of package insert - Ovarian cysts or enlarged ovaries not due to polycystic ovarian disease. In the following situations treatment outcome is unlikely to be favourable, and therefore MENOPUR™ should not be administered: - Primary ovarian failure	New	CPP-Switzerland	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						- Malformation of sexual organs incompatible with pregnancy - Fibroid tumors of the uterus incompatible with pregnancy Side-effects: The most frequently reported adverse drug reactions (ADR) during treatment with MENOPUR™ in clinical trials are Ovarian Hyperstimulation Syndrome, OHSS, headache, abdominal pain, abdominal distension and injection site pain. None of these ADRs have been reported with an incidence rate of more than 5%.				
40.	Manufacturer: Novo Nordisk A/S Novo Allé 2880 Bagsværd Denmark Local Representative: Novo Nordisk Pharma (Private) Limited Nina Kabbo, Level -9, 227/A, Gulshan Tejgaon Link Road,Tejgaon, Dhaka 1208	Saxenda®	Liraglutide 6 mg/ml Solution for injection in pre-filled pen	Other Classification Theraputic Code: 075	Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of • ≥30 kg/m² (obese), or• ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.	Contraindications: Hypersensitivity to liraglutide or to any of the excipients listed in List of excipients. Adverse reactions Very Common: Nausea, Vomiting, Diarrhoea, Constipation Common: Hypoglycaemia*, Insomnia**, Dizziness, Dysgeusia, Dry mouth, Dyspepsia, Gastritis, Gastro-oesophageal reflux disease, Abdominal pain upper, Flatulence, Eructation, Abdominal distension, Cholelithiasis***, Injection site reactions, Asthenia, Fatigue, Increased lipaseIncreased amylase Uncommon: Dehydration, Tachycardia, Pancreatitis***, Delayed gastric emptying****, Cholecystitis***, Urticaria, Malaise Rare: Anaphylactic reaction, Acute renal failure, Renal impairment * Hypoglycaemia (based on self-reported symptoms by patients and not confirmed by blood glucose measurements) reported in patients without type 2 diabetes mellitus treated with Saxenda® in combination with diet and exercise. Please see Description of selected adverse reactions for further information. ** Insomnia was mainly seen during the	New	EMA CPP-Denmark	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						first 3 months of treatment. *** See Special warnings and precautions for use. **** From controlled phase 2, 3a and 3b clinical trials.				
41.	AstraZeneca AB Local Agent: MGH Health Care Ltd.	CALQUENCE® CAPSULES	Acalabrutinib 100 mg Capsule	Anti-Cancer Theraputic Code: 010	1. Mantle cell lymphoma (MCL) who have received at least one prior treatment for their cancer. 2. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).	**Contra-indication:** None CALQUENCE may cause serious side effects, including: Serious infections can happen during treatment with CALQUENCE and may lead to death. Bleeding problems (hemorrhage) may happen during treatment with CALQUENCE, and can be serious and may lead to death. Patient's risk of bleeding may increase if he is also taking a blood thinner medicine. Patient should contact healthcare provider if he has any signs or symptoms of bleeding, including: o blood in stools or black stools (looks like tar) o pink or brown urine o unexpected bleeding, or bleeding that is severe o vomit blood or vomit that looks like coffee grounds o cough up blood or blood clots o dizziness o weakness o confusion o changes in speech o headache that lasts a long time o bruising or red or purple skin marks Decrease in blood cell counts. Decreased blood counts (white blood cells, platelets, and red blood cells) are common with CALQUENCE, but can also be severe. Second primary cancers. New cancers have happened in people during treatment with CALQUENCE, including cancers of the skin or other organs. Heart rhythm problems (atrial	New	CPP-USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						fibrillation and atrial flutter) have happened in people treated with CALQUENCE. Patient should tell healthcare provider if he has any of the following signs or symptoms: o fast or irregular heartbeat o dizziness o feeling faint o chest discomfort o shortness of breath The most common side effects of CALQUENCE include: o headache o diarrhea o muscle and joint pain o upper respiratory tract infection o bruising				
42.	Sanofi S.p.A. Viale Europa, 11 21040 Origgio (VA) Italy **Importer** (Sanofi Bangladesh Limited, Station Road, Tongi, Gazipur-1710, Bangladesh For Contact 6/2/A Segun Bagicha, Dhaka-1000)	Enterogermina 2 Billion/5 ml *[One 5ml mini bottle contains spores of polyantibiotic-resistant Bacillus clausii - 2 billion]*	Bacillus clausii spores (strains O/C, N/R, SIN and T) Oral Suspension	Anti-diarrhoeal microorganisms **Therapeutic Class:** Other Classification **Therapeutic Code:** 075	• Prevention and treatment of altered intestinal microflora (dysbiosis) and associated symptoms such as diarrhea, abdominal pain/discomfort and subsequent dysvitaminosis • Therapeutic aid for recovery of the intestinal microflora during treatment with antibiotics or chemotherapeutic agents • Acute and chronic gastrointestinal (GI) disorders in breast-feeding infants, due to GI toxic states or intestinal dysbiosis or dysvitaminosis **Latest clinical study/ outcome:** • **Rota Viral Diarrhea [2019]**: Enterogermina facilitates faster recovery from Rota Viral Diarrhea and helps in normalization of immune markers, contributing to protect children against future infections. *Reference: Smiyan Ol. Et al. Optimization of the treatment of rotavirus infection in children by using Bacillus Clausii. Wiad Lek 2019;72(7):1320-1323* • **Childhood Diarrhea [2018]:** Enterogermina have statistically significant beneficial effects on pediatric clinical outcomes. Faster recovery of Paediatric Diarrhea. *Reference: Ianiro G. et al. Nutrients 2018; 10:1074* **Meets WHO Recommendation of an Ideal Probiotic [2018]:** WHO recommends standard	**Contraindications:** Hypersensitivity to the active ingredient or any of the excipients. **Side-effects:** In post-marketing experience cases of hypersensitivity reactions including rash and urticaria have been reported. **Pregnancy and lactation**: Limited data are available on the use of probiotics including Enterogermina® in pregnant women. Enterogermina® should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus. There are limited available data on the presence of Enterogermina® in human milk, milk production, or the effects on the breastfed infant. Enterogermina® should be used during breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.	New	CPP- Italy	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					criteria of an ideal probiotics as: be consistent to label, contaminant-free, acid resistant in in the GI tract. In line with WHO recommendations, Enterogermina was found to meet all standard criteria of an ideal probiotic. *Reference: Vecchione A et al. Front Med (Lausanne), 2018:5,59*					
43.	**Mfgr :** Korea Fertilizer Co. Ltd., Korea **Local Agent :** Multiple Health Pharma Ltd., House-122, Road-21, Mohakhali DOHS, Dhaka-1206	Virus Zero	Pure Chlorine Dioxide 0.6% (6000 PPM)	Therapeutic Class: Antiseptic and Disinfectants Therapeutic Code: 029	• Disinfection, Sterilization, Deodorization		New	FSC- South Korea USFDA Regulation Number: 880.6890 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm EU Registration Number: N-92265 https://www.baua.de/DE/Biozid-Meldeverordnung/Offen/offen.html	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
44.	Medivators Inc, 14605 28th Avenue North Minneapolis, MN 55447, USA. **Local Agent**: Zas Industries Ltd., 80/22 Mymenshing Road, Nurjahan Tower, Banglamotor, Dhaka-1000, Bangladesh.	Rapicide Disinfactan	High Level Disinfactant & Sterilant Glutaraldehyde 2.5%	Therapeutic Class: Antiseptic and Disinfectants Therapeutic Code: 029	• High-level Disinfactant solution for medical devices Sanitization.		New	CFG - USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
45.	**Manufacturer :** Lek Pharmaceuticals, d.d. Verovškova 57, 1526 Ljubljana, Slovenia **Local Agent**: Novartis (Bangladesh) Limited Squibb Road, Tongi Industrial Area, Gazipur-1711, Bangladesh	**Dailiport 2 mg** prolonged release capsules, hard	Tacrolimus Monohydrate Ph. Eur. 2.045 mg eqv. to Tacrolimus 2 mg	Transplant & Immunosuppressant Therapeutic Code: 058	**Indication:** Dailiport is indicated: • for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients	**Contraindication:** Hypersensitivity to the active substance, soya, peanut, or to any of the excipients of drug product. Hypersensitivity to other macrolides. **Adverse effect:** The adverse reaction profile associated with immunosuppressive agents is often difficult to establish owing to the underlying disease and the	New	**CPP:** Germany and Slovenia	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						concurrent use of multiple medicinal products. The most commonly reported adverse reactions (occurring in > 10% of patients) are tremor, renal impairment, hyperglycaemic conditions, diabetes mellitus, hyperkalaemia, infections, hypertension and insomnia. The frequency of adverse reactions is defined as follows: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness. <u>Infections and infestations</u> As is well known for other potent immunosuppressive agents, patients receiving tacrolimus are frequently at increased risk for infections (viral, bacterial, fungal, protozoal). The course of preexisting infections may be aggravated. Both generalised and localised infections can occur. Cases of BK virus associated nephropathy, as well as cases of JC virus associated progressive multifocal leukoencephalopathy (PML), have been reported in patients treated with immunosuppressants, including tacrolimus. <u>Neoplasms benign, malignant and unspecified</u> Patients receiving immunosuppressive therapy are at increased risk of developing malignancies. Benign as well as malignant neoplasms including EBV-associated lymphoproliferative disorders and skin malignancies have been reported in association with tacrolimus treatment. <u>Immune system disorders.</u> Allergic and anaphylactoid reactions have been observed in patients receiving tacrolimus. <u>Description of selected adverse reactions</u>				

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Pain in extremity has been described in a number of published case reports as part of Calcineurin- Inhibitor Induced Pain Syndrome (CIPS). This typically presents as a bilateral and symmetrical, severe, ascending pain in the lower extremities and may be associated with supra-therapeutic levels of tacrolimus. The syndrome may respond to tacrolimus dose reduction. In some cases, it was necessary to switch to alternative immunosuppression.				
46.	**Manufacturer :** Lek Pharmaceuticals, d.d. Verovškova 57, 1526 Ljubljana, Slovenia **Local Agent**: Novartis (Bangladesh) Limited Squibb Road, Cherag Ali Market, Tongi Industrial Area, Gazipur-1711, Bangladesh	**Dailiport 3 mg** prolonged release capsules, hard	Tacrolimus Monohydrate Ph. Eur. 3.067 mg eqv. to Tacrolimus 3 mg	Transplant & Immunosuppressant Therapeutic Code: 058	**Indication:** Dailiport is indicated: for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients	-Do-	New	**CPP:** Germany and Slovenia	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
47.	*Manufactured for* AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850. *By* AstraZeneca UK Limited, 1 Francis Crick Ave, Cambridge, England CB2 0AA. US License Number 2043. **Local Agent**: **MGH Health Care**	IMFINZI® INJECTION 120mg/2.4ml	Durvalumab 50mg/1ml	Anti-Cancer	1.1 Urothelial Carcinoma: Imfinzi is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who: • Have disease progression during or following platinum- containing chemotherapy. • Have disease progression within 12 months of neoadjuvants or adjuvant treatment with platinum containing chemotherapy. 1.2 Non-Small Cell Lung Cancer: Imfinzi is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. 1.3 Small Cell Lung Cancer: Imfinzi in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).	Contra-indication: None **INFINZI can cause serious side effects, including:** The most common side effects of IMFINZI in people with urothelial carcinoma include: • Feeling tired • Muscle or bone pain • Constipation • Decreased appetite • Nausea • Swelling of your arms and legs • Urinary tract infection The most common side effects of IMFINZI in people with NSCLC include: • Cough	New	USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						• Feeling tired • Inflammation in the lungs (pneumonitis) • Upper respiratory tract infections • Shortness of breath • Rash The most common side effects of IMFINZI when used with other anticancer medicines in people with ES-SCLC include: • Nausea • Hair loss • Feeling tired or weak.				
48.	*Manufactured for* AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850. *By* AstraZeneca UK Limited, 1 Francis Crick Ave, Cambridge, England CB2 0AA. US License Number 2043. **Local Agent**: **MGH Health Care**	IMFINZI® INJECTION 500mg/10ml	Durvalumab 50mg/1ml	Anti-Cancer	1.4 Urothelial Carcinoma: Imfinzi is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who: • Have disease progression during or following platinum- containing chemotherapy. • Have disease progression within 12 months of neoadjuvants or adjuvant treatment with platinum containing chemotherapy. 1.5 Non-Small Cell Lung Cancer: Imfinzi is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. 1.6 Small Cell Lung Cancer: Imfinzi in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). ○	Contra-indication: None **INFINZI can cause serious side effects, including:** The most common side effects of IMFINZI in people with urothelial carcinoma include: • Feeling tired • Muscle or bone pain • Constipation • Decreased appetite • Nausea • Swelling of your arms and legs • Urinary tract infection The most common side effects of IMFINZI in people with NSCLC include: • Cough • Feeling tired • Inflammation in the lungs (pneumonitis) • Upper respiratory tract infections • Shortness of breath • Rash The most common side effects of IMFINZI when used with other anticancer	New	USA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

Sl. No.	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class and Code	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						medicines in people with ES-SCLC include: • Nausea • Hair loss • Feeling tired or weak.				

অহহবী -ঈ: ঐঁসধ হ ঠধ পপরহব ভড়ৎষড়পঁষ ঢ়ৎড়ফঁপ ঃরড়হ

Sl No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Terapeutic Class and code	Indication	Source of Product (Fill Finished/ API)	Registration Status of the Product (Fill Finished manufacturing Country))	GMP Certificate	Lot Release Certificate of the Product	Registration Status of the Product (Internationally)/ Name of the Countries where this Product Export	WHO Prequalification (If any)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF / MHRA Ref.
১	ওহ্পবঢ়ঃধ ঠ ধপপরহব খঃফ. ; তরুধনড়, ঝধা ধৎ, উয ধশধ চড়ঢ়ঁ ষধৎ চযধৎস ধপবঁ ঃরপধষ ং খরুস রঃবফ ১৬৪, এঢ়ড়হমর ণ্ডঅ,এঢ়ড়হমর, এধু রঢ়ঁ ৎ	জবপড়স নরহধহঃ ঐঁ স ধহ চ ধঢ়রহ্মড়ভ ধা রৎঁ ং ঠ ধপপরহব	জবপড়স নরহধহঃ ঐঁ স ধহ চ ধঢ়রহ্মড়ভ ধা রৎঁ ং এঃু ঢ়ব-১৬ খ১ চ ৎড়ঃবরহ ই চ ৪০ ক্রম + জবপড়স নরহধহঃ ঐঁ স ধহ চ ধঢ়রহ্মড়ভ ধা রৎঁ ং এঃু ঢ়ব-১৮ খ১ চ ৎড়ঃবরহ ই চ ২০ ক্রম / ০.৫স খ া রধষ	ঠ ধপপরহবং, এঞ্ঝী রহং, এঞ্ঝী ড়রফং ধহফ ঝবৎধ এঞ্রবৎধঢ়বঁ ঃরপ ঈড়ফব: ০৬৯	এঞ্রংরং ঠ ধপপরহব রং ংবফ ভ্ভূৎ নবঃৃি ববহ ঃযব ধমব ড়ভ ৯-৪৫ ু বধৎং ভ্ভূৎ ঃযব ঢ়ৎবা বহঃরড়হ ড়ভ ঢ়ৎবস ধষরাহধহঃ ধহড়-মবহরপ্লষ যবড়্লভ্ংং (পবৎা রপঋ, ঠঁ ষা ধৎ, া ধমরহধষ ধহফ ধহধষ) ধহফ পবৎা রপঋ ধহফ ধহধষ পধহপবৎং পধঁ ংধষুষ ৎবষধঃঋ ঃড় পবৎংধরহ ড়হপড়মবহরপ ঐঁ স ধহ চ ধঢ়রহ্মড়ভ ধা রৎঁ ং (ঐচঠ) ঃু ঢ়ব, এ ৎধফব ২ ধহফ ৩ পবৎা রপঋ ওহ্ণৎধবঢ়রপ্লাবষরপ্লষ হবড়ঢ়ষধড়্লধ (ঈওঘ ২/৩) ধহফ ধফবহড়পধৎপ্লহড়স ধ রহ-ংরঃ (অওঝ), এ ৎধফব ১ পবৎা রপঋষ রহঃৎধবঢ়রপ্লাবষরপ্লষ হবড়ঢ়ষধড়্লধ (ঈওঘ ১), ঢ়বৎংরংঃবহঃ রুভপঃরড়হ পধঁ ংবফ নু ঐচঠ ঃু ঢ়বং ১৬ ধহফ ১৮.	ঢ রধসবহ ওহ্হড়া ধী ইরড়ঃবপষ ঈড়., খঃফ., ঈয রহধ	ণব ং	ণব ং	ণব ং	ঘ/অ	ঘ/অ	ঐঁ স ধহ চ ধঢ়রহ্মড়ভ ধা রৎঁ ং এঃু ঢ়ব-১৬ খ১ চ ৎড়ঃবরহ ২০ স পম + ঐঁ স ধহ চ ধঢ়রহ্মড়ভ ধা রৎঁ ং এঃু ঢ়ব-১৮ খ১ চ ৎড়ঃবরহ ২০ স পম **(DCC 237)**	ইঘঋ ৮০ চ ধমব: ১৩৬৮
বিশেষজ্ঞ কমিটির সভার সিদ্ধান্তঃ	**ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়।**												
টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত ঃ	**ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়।**												
ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ	**ভ্যাক্সিনটি অনুমোদন করা হয়।**												
২	ওহ্পবঢ়ঃধ ঠ ধপপরহব খঃফ. ; তরুধনড়, ঝধা ধৎ, উয ধশধ	উরঢ়যঃযবৎরধ ধহফ এঞ্রঃধহঁ ং ঠ ধপপরহব (অফড়ৎনবফ, জবফঁ পবফ অহঃরূবহ(ং) ঈড়হঃবহঃ)	চঁ ৎরভবফ উরঢ়যঃযবৎরধ এঞ্ঝী ড়রফই চ ২ খভ (≥ 2 ওট ধহফ <৩০ ওট) + চঁ ৎরভবফ এঞ্রঃধহঁ ং এঞ্ঝী ড়রফ ইচ ৭ খভ(≥ ৪০ ওট) / ০.৫স খ া রধষ	ঠ ধপপরহবং, এঞ্ঝী রহং, এঞ্ঝী ড়রফং ধহফ ঝবৎধ এঞ্রবৎধঢ়বঁ ঃরপ ঈড়ফব: ০৬৯	এঞ্রংরং া ধপপরহব রং ধহ রসসঁ হড়মবহরপ ধহফ ংধভ্ভ ড়ঢ়ঃরড়হ ভ্ভূৎ নড়ড়ংঃবৎ রসসঁ হরুধ ঃরড়হ ধমধরহংঃ ংবঃধহঁ ং ধহফ ফরঢ়যঃযবৎরধ রহ ধফড়ষবংপবহঃ ধহফ ধফঁ ষঃু. এঞ্রব া ধপপরহব পধহ ংধভ্লষু ধহফ বভভলাঃর বষু নব মরা বহ ংরসঁ ষপ্লহবড়ঁ ংষু ি রিপ্ল ইঈএ , গ বধংষবং, চ ড়ষরু ঠ ধপপরহব, ঐবঢ়ধঃরহ ই, ণব ষফ্ি ভ্লা বৎ া ধপপরহব, ঐধবস ড়ঢ়যরঁষ ং রহঞ্জ বহু ধ-ই ধহফ ঠ রপ্লাস রহ অ ং ঢ়ঢ়ষবস বহঃ. ওহ্ফরা রফঁ ধষং রুভপঃবফ ি রিপ্ল যঁ স ধহ রসসঁ হড়ফবভ্রাপরব্পু া রৎঁ ং (ঐওঠ), নড়ঃয ধু স ঢ়ঃড়স ধঃরূা ধহফ ু স ঢ়ঃড়স ধঃরূা, ংযড়ঁ ষফ নব রসসঁ হরুব ফ ি রিপ্ল ঃযব া ধপপরহব ধপপড়ৎফরহম ঃড় ংঃধহফধৎফ ংপযবফঁ ষবং.	চ .ঞইওঙ ঋঅজগ অ (চ বৎংবৎড়)., ওহ্ফড়হবংরধ	ণব ং	ণব ং	ণব ং	**List of countries where this product is Registered:** উমু ঢ়ঃ, ওহ্ফড়হবংরধ, এঞ্রধরহ্মহফ **Supply and Marketed countries:** ঈব হঃৎধষ অভৎরপ্ধ, ঈয রহধ, এ যধহধ, ঐধরপ্ল, ওহ্ফড়হবংরধ, কব হু ধ, ঘড় ৎঃয ক ড়ৎবধ, ঝধঁ ফর অৎধনরধ, এঞ্রধরহ্মহফ.	ড ঐঙ চ ৎবয়ঁ ধষরভ্রবফ	চঁ ৎরভবফ ফরঢ়যঃযবৎরধ ঃড়ী ড়রফ পড়হপবহঃংধঃব চ য. ঊ ৎ. হড়ঃ ষবংং ঃযধহ ২ ওট+ চঁ ৎরভবফ ংবঃধহঁ ং ঃড়ী ড়রফ পড়হপবহঃংধঃব চ য. ঊ ৎ. হড়ঃ ষবংং ঃযধহ ২০ ওট/০.৫ স ষ **(DCC 240)**	

Sl No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Terapeutic Class and code	Indication	Source of Product (Fill Finished/ API)	Registration Status of the Product (Fill Finished manufacturing Country))	GMP Certificate	Lot Release Certificate of the Product	Registration Status of the Product (Internationally)/ Name of the Countries where this Product Export	WHO Prequalification (If any)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF / MHRA Ref.
বিশেষজ্ঞ কমিটির সভার সিদ্ধান্ত ঃ		<u>নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়ঃ</u> ১. ভ্যাক্সিনটির ক্লিনিক্যাল ট্রায়াল যেহেতু ধফড়ষবংপ্মহঃ এবং ধফঁষঃ এর উপর করা হয়েছে, সেহেতু ভ্যাক্সিনটির প্রয়োগও শুধুমাত্র ধফড়ষবংপ্মহঃ এবং ধফঁষঃ এর উপর করতে হবে, যা লেবেল ক্লেইম এ উল্লেখ করতে হবে। ২. ভ্যাক্সিনটির কাঁচামাল আমদানির পর য়ঁধ ষব্ধু ধংংবংংসবহঃ করতে হবে এবং ফধঃধ ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে।											
টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত ঃ		<u>নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়ঃ</u> ১. ভ্যাক্সিনটির ক্লিনিক্যাল ট্রায়াল যেহেতু ধফড়ষবংপ্মহঃ এবং ধফঁষঃ এর উপর করা হয়েছে, সেহেতু ভ্যাক্সিনটির প্রয়োগও শুধুমাত্র ধফড়ষবংপ্মহঃ এবং ধফঁষঃ এর উপর করতে হবে, যা লেবেল ক্লেইম এ উল্লেখ করতে হবে। ২. ভ্যাক্সিনটির কাঁচামাল আমদানির পর য়ঁধ ষব্ধু ধংংবংংসবহঃ করতে হবে এবং ফধঃধ ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে। ৩. ভ্যাক্সিনটি উৎপাদনের পর ২ বছর পর্যন্ত চ যধংব ওঁ ঈষ রহরপাধষ এঃৎরাষ/অপঃরব চ যধৎসধ পড়ার মরহ্মধহপ্ম করতে হবে।											
ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ		**<u>নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদন করা হয়ঃ</u>** ১. ভ্যাক্সিনটির ক্লিনিক্যাল ট্রায়াল যেহেতু ধফড়ষবংপ্মহঃ এবং ধফঁষঃ এর উপর করা হয়েছে, সেহেতু ভ্যাক্সিনটির প্রয়োগও শুধুমাত্র ধফড়ষবংপ্মহঃ এবং ধফঁষঃ এর উপর করতে হবে, যা লেবেল ক্লেইম এ উল্লেখ করতে হবে। ২. ভ্যাক্সিনটির কাঁচামাল আমদানির পর য়ঁধ ষব্ধু ধংংবংংসবহঃ করতে হবে এবং ফধঃধ ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে। ৩. ভ্যাক্সিনটি উৎপাদনের পর ৫ বছর পর্যন্ত চ যধংব ওঁ ঈষ রহরপাধষ এঃৎরাষ/অপঃরব চ যধৎসধ পড়ার মরহ্মধহপ্ম করতে হবে।											
৩.	ওহ্পবঢ়ঃধ ঠ ধপপরহব খঃফ. ; তরুধনড়, ঝধা ধৎ, উয ধশধ	জবপড়স নরহধহঃ ঐবঢ়ধঃরুঃ উ ঠ ধপপরহব (উ.পড়ষর)	ঐউঠ ২৩৯ চৎড়ঃবরহ ওহঐউঁ ংব্ ড ঐঙ ৩০ক্রম/ ০.৫স খ া রধষ	ঠ ধপপরহবং, এঞ্ী রহং, এঞ্ী ড়রফং ধহফ ঝবৎধ এঝবৎধঢ়বঁ ঃরপ ঈড়ফব: ০৬৯	এঝরং া ধপপরহব ঁ ংবফ ভ্ড়ৎ ঢ়ৎবা বহঃরড়হ ড়ভ যবঢ়ধঃরুঃ উ (ধ হড়হ-বহা বষড়্বফ ঢ়ড়ংরঃর ব-ংবহংব জঘ অ া রৎং ং ড়ভ ঃযব ঐবঢ়বা রৎঝাধব ভ্রূস রূষ) া রধ ঃযব ভ্রূপধষ-ড়ৎধষ ৎড়ঁ ঃব. ঐবঢ়ধঃরুঃ উ া রৎং ং (ঐউঠ) রংধ স ধলড়্পধঁ ংব ড়ভংঢ়ড়ৎধফরূপ ধহফ বঢ়রফষস রূপ যবঢ়ধঃরুঃ ঃযধঃ রু ভ্ড়ঁ হফ ি ড়ৎষফি রফষ. ঐউঠ রংড়্ষধঃবং ি বৎব পষধংরভ্রূবফ রহঃড় ভ্ড়ঁ ৎ র্য স ধহ মবহড়ঃু ঢ়বং (মবহড়ঃু ঢ়বং ১-৪). এঝবংব ভ্ড়ঁ ৎ মবহড়ঃু ঢ়বং ভ্ড়ৎস ধ ংরহমষব ংবৎড়ঃু ঢ়ব নধংবফ ড়হ ঃযবরৎ ওসস ঁ হব ৎবধপাঃর রুঃ .	ঢ রধস বহ ওহ্হড়া ধী ইরড়ঃবপ্ম ঈড়., খঃফ, ঈষ রহধ	ণব ং	ণব ং	ণব ং	ঘ/অ	ঘ/অ	ঘব ি	ড ঐঙ চ ড়ংরঃরুঢ়হ ঢ়ধঢ়বৎ ধা ধরহ্মনষব
বিশেষজ্ঞ কমিটির সভার সিদ্ধান্ত ঃ		<u>নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়ঃ</u> ১. ভ্যাক্সিনটির ক্লিনিক্যাল ট্রায়াল যেহেতু ১৬ হতে ৬৫ বছরের সাবজেক্ট এর উপর করা হয়েছে সেহেতু ভ্যাক্সিনটির প্রয়োগও শুধুমাত্র ১৬ হতে ৬৫ বছরের এর উপর করতে হবে, যা লেবেল ক্লেইম এ উল্লেখ করতে হবে। ২. ভ্যাক্লিটির ক্লিনিক্যাল ট্রায়ালের ডাটা লিভার ডিজিজ, ফ্যাটি লিভার, হেপাটাইটিস রোগী, প্রেগনেন্ট মহিলাদের উপর নেই বিধায় লেবেল ক্লেইম এ বিষয়টি উল্লেখ করতে হবে এবং উল্লিখিত ক্ষেত্রে ভ্যাক্সিনটি প্রয়োগে সতর্ক হতে হবে। ৩. ভ্যাক্সিনটি অত্যন্ত ৎধৎব ভ্যাক্সিন এবং বিভিন্ন রিজিওনে ভ্যাক্সিনের রেসপন্স া ধু করে বিধায় বাংলাদেশে ভ্যাক্সিনটি উৎপাদনের পর চ যধংব ওঁ ঈষ রহরপাধষ এঃৎরাষ/অপঃরব চ যধৎসধ পড়ার মরহ্মধহপ্ম করতে হবে।											

Sl No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Terapeutic Class and code	Indication	Source of Product (Fill Finished/ API)	Registration Status of the Product (Fill Finished manufacturing Country))	GMP Certificate	Lot Release Certificate of the Product	Registration Status of the Product (Internationally)/ Name of the Countries where this Product Export	WHO Prequalification (If any)	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF / MHRA Ref.
টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত ঃ		**নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়ঃ** ১. ভ্যাক্সিনটির ক্লিনিক্যাল ট্রায়াল যেহেতু ১৬ হতে ৬৫ বছরের সাবজেক্ট এর উপর করা হয়েছে সেহেতু ভ্যাক্সিনটির প্রয়োগও শুধুমাত্র ১৬ হতে ৬৫ বছরের এর উপর করতে হবে, যা লেবেল ক্লেইম এ উল্লেখ করতে হবে। ২. ভ্যাক্লিটির ক্লিনিক্যাল ট্রায়ালের ডাটা লিভার ডিজিজ, ফ্যাটি লিভার, হেপাটাইটিস রোগী, প্রেগনেন্ট মহিলাদের উপর নেই বিধায় লেবেল ক্লেইম এ বিষয়টি উল্লেখ করতে হবে এবং উল্লিখিত ক্ষেত্রে ভ্যাক্সিনটি প্রয়োগে সতর্ক হতে হবে। ৩. ভ্যাক্সিনটি অত্যন্ত ৎধৎব ভ্যাক্সিন এবং বিভিন্ন রিজিওনে ভ্যাক্সিনের রেসপন্স াধ ু করে বিধায় বাংলাদেশে ভ্যাক্সিনটি উৎপাদনের পর ২ বছর পর্যন্ত চ যধংব ওঁ ঈষ রহরূাধষ এঃঙ্কাধষ/ অপ্তরব চ যধৎসধ পড়ারম রক্ষাধহপ্প করতে হবে।								
ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ		**নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদন করা হয়ঃ** ১. ভ্যাক্সিনটির ক্লিনিক্যাল ট্রায়াল যেহেতু ১৬ হতে ৬৫ বছরের সাবজেক্ট এর উপর করা হয়েছে সেহেতু ভ্যাক্সিনটির প্রয়োগও শুধুমাত্র ১৬ হতে ৬৫ বছরের এর উপর করতে হবে, যা লেবেল ক্লেইম এ উল্লেখ করতে হবে। ২. ভ্যাক্লিটির ক্লিনিক্যাল ট্রায়ালের ডাটা লিভার ডিজিজ, ফ্যাটি লিভার, হেপাটাইটিস রোগী, প্রেগনেন্ট মহিলাদের উপর নেই বিধায় লেবেল ক্লেইম এ বিষয়টি উল্লেখ করতে হবে এবং উল্লিখিত ক্ষেত্রে ভ্যাক্সিনটি প্রয়োগে সতর্ক হতে হবে। ৩. ভ্যাক্সিনটি অত্যন্ত ৎধৎব ভ্যাক্সিন এবং বিভিন্ন রিজিওনে ভ্যাক্সিনের রেসপন্স াধ ু করে বিধায় বাংলাদেশে ভ্যাক্সিনটি উৎপাদনের পর ৫ বছর পর্যন্ত চ যধংব ওঁ ঈষ রহরূাধষ এঃঙ্কাধষ/ অপ্তরব চ যধৎসধ পড়ারম রক্ষাধহপ্প করতে হবে।								
৪	ওহ্পবঢ়ঃধ ঠ ধপপরহব খঃফ. ; তরুংধনড়, ঝাধা ধৎ, উয ধশধ	জড়ঃধা রৎঁ ং ঠ ধপপরহব (খরা ব, ঙৎধ ষ)	ঠ বৎড় ঈব ষষ ফবৎরা বফ জড়ঃধা রৎঁ ং ১১৬উ ইঁ যশ্ খরা ব অঃঃবহঁ ধঃবফ ইচ হড়ঃ ষবংং ঃযধহ [ঘখ এঃ ১০৫.০ ঋখট [ঋড়পঁ ং ঋড়ৎস রহম টহ রঃ ঢ়বৎ ০.৫ স খ া রধষ.	ঠ ধপপরহবং, এঞ্ড়ী রহং, এঞ্ড়ী ড়রফং ধহফ ঝাবৎধ এঃ্রবৎধঢ়বঁ ঃরূা ঈড়ফব: ০৬৯	এঃ্রারং া ধপপরহব রং রহফরূপধ্ববফ ভ্ড়ৎ ধপঃর ব রসস ঁ হুরধ ঃরূড়হ ড়ভরহভ্রহংং ঙড়স ঃযব ধমব ড়ভ৬ ি ববশং ভ্ড়ৎ ঃযব ঢ়ৎবা বহঃরূড়হ ড়ভমধংঃৎড়বহঃবৎরাঃঃ ফঁ ব ঃড় ৎড়ঃধা রৎঁ ং রূহভ্রপঃরূড়হ ি যবহ ধফস রহরাংঃবৎবফ ধং ধ ৩-ফড়ংব ৎবমরসবহ.	ইয ধৎধঃ ইরড়ঃরপঋ ওহ্ফবৎহধঃরূড়হ ধষ খরূস রঃরূফ., ওহফরধ	ণব ং	ণব ং	ণব ং	ণব ং	ড ঐঙ চ ৎবয়ঁ ধষরূরূবফ া ধপপরহব	ঐঁ স ধহ জড়ঃধা রৎঁ ং, খরা ব অঃঃবহঁ ধঃবফ জরী ৪৪১৪ ঝাঃৎধরহ হড়ঃ ষবংং ঃযবহ ১০৬.০ঈঈওউ ৫০ **(DCC 238)**	
বিশেষজ্ঞ কমিটির সভার সিদ্ধান্ত ঃ		**ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়।**											
টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত ঃ		**ভ্যাক্সিনটি অনুমোদনের জন্য সুপারিশ করা হয়।**											
ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ		**ভ্যাক্সিনটি অনুমোদন করা হয়।**											

অহহবী -ঈ: ঐঁসধহ ঠ ধপপরহব ভড়ৎঙ্গঢ়ড়ৎঃ

Sl No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Source Name	Therapeutic Class and code	Indication	Status (New Molecule/ Existing)	GMP Certificate	Drug Approval (CFDA/NMPA)/ FSC/CPP	Manufacturing License	Lot release certificate	WHO prequalification
1.	গ ধহঁ ভাপশুঁ ৎবৎ: ইয ধৎধঃ ইরড়ঃবপষ ওহ্ববৎহধঃরড়হধষ খরুস রপ্লফ, এ বহড়স ব ঠ ধষহ্ম , ঝযধস ববৎঢ়বঃ গ ধহফধষ, গ বফপযধষ উরংঃৎরপ-৫০০০০৭৮, এপ্লযধহমধহধ ঝঃধঃব, ওহফরধ **Local Agent:** জবহধঃধ খরুস রপ্লফ গ রৎঢ়ঁ ৎ, উয ধশধ	জঙঞঅ ঠ অ ঈ ঠ ধপপরহব (খরা ব, ঙৎধ ষ)	০.৫ স খ পড়হঃধরহহম জড়ঃধা রহঁ ং ঘখঞ ১০৫০ঋখট (ভড়পঁ ং ভড়ৎস রহম ঁ হরঃ) ডভষয়র ব ৎড়ঃধা রহঁ ং ১১৬উ.	ইয ধৎধঃ ইরড়ঃবপষ ওহ্ববৎহধঃরড়হধষ খরুস রপ্লফ	ঠ ধপপরহবং, এঞ্জী রহং, এঞ্জী ড়রফং ধহফ ঝবৎধ এঞ্জাবৎধঢ়বঁ ঃরপ ঈড়ফব: ০৬৯	**ROTAVAC** রং রহফরপধ্বফ ভড়ৎ ধপঃর ব রসস ঁু ধঃরড়হ ড়ভ রহপ্রহঃং ঙড়স ঃযব ধমব ড়ভ৬ ি বিবশং ভড়ৎ ঃযব ঢ়ৎবা বহঃরড়হ ড়ভ মধংঃৎড়বহঃবৎরঃরূ ফঁ ব ঃড় ৎড়ঃধা রহঁ ং রহপ্তঃরড়হ ি যবহ ধফস রহরাংঃবৎক্ষ ধং ধ ৩-ফড়ংব ংবৎরবং,	ঐঁ স ধহ জড়ঃধ ঠ রহঁ ং, যরা ব ধঃঃবহঁ ধঃবফ জরী ৪৪১৪ ঝঃৎধরু ওঘঘ ঘড় ঃ যবংং ঃযধহ ১০৬.০ ঈঈওউ৫ ০ **DCC-234** জড়ঃধএপ্লয় • ঝড়ষঁ ঃরড়হ ভড়ৎ ঙৎধ ষ অ ফস রহরাংঃৎধঃরত্ম জড়ঃধা রহঁ ং ৷ ধপপরহব, যরা ব, ড়ৎধষ, ঢ়বহঃধা ধষবহঃ অ পঃর ব ওহ্মৎবফরবহঃং: এ ১ জবধংং ড়ৎঃধহঃ: ≥2.২ ঢ১ ০৬ ওট/ফড়ংব এ ২ জবধংং ড়ৎঃধহঃ: ≥2.৮ ঢ১ ০৬ ওট/ফড়ংব এ ৩ জবধংং ড়ৎঃধহঃ: ≥2.২ ঢ১ ০৬ ওট/ফড়ংব এ ৪ জবধংং ড়ৎঃধহঃ: ≥2.০ ঢ১ ০৬ ওট/ফড়ংব চ ১ জবধংং ড়ৎঃধহঃ: ≥২.৩ ঢ ১০৬ ওট/ফড়ংব **DCC-248**	আ ধরষ্কানষব ঈবৎঃরড়্রাবফনু উৎঁ ম ঈড়হঃৎড়ষ অ ফস রহরাংঃৎধঃরত্ম , এড়া বৎহস বহঃ ড়ভ এপ্লাযবহ্মধহধ, ওহফরধ	আ ধরষ্কানষব **Certified by :** ১. ওহফরধ. ঝঝঈ ২. ড ঐঙ কর্তৃক চ ৎবয়ঁ ধষরড়্রাবফ গ বফরপরষ্কান ৩. ঈড়ষড়া নরধ, গ রহরাংঃু ড়ভ ঐব ধষয় ৪.গ ড়ু ধস নরপয়ঁ ব, গ রহরাংঃু ড়ভ ঐব ধষয় .	আ ধরষ্কানষব ঈবৎঃরড়্রাবফনু : উৎঁ ম ঈড়হঃৎড়ষ অ ফস রহরাংঃৎধঃরত্ম, এড়া বৎহস বহঃ ড়ভ এপ্লাযবহ্মধহধ, ওহফরধ	আ ধরষ্কানষব	আ ধরষ্কানষব ড ঐঙ কর্তৃক চ ৎবয়ঁ ধষরড়্রাবফ গ বফরপরষ্কান
বিশেষজ্ঞ কমিটির সভার সিদ্ধান্তঃ	১. ভ্যাক্সিনটি WHO কর্তৃক চ ৎবয়ঁধ ষ্কাড়্রাবফ বিধায় আমদানির নিমিত্তে অনুমোদনের জন্য সুপারিশ করা হয়। ২. সভায় উপস্থিত সদস্যগণ বলেন, ড ঐঙ এর ঢ়ৎবয়ঁ ধষরড়্রাপধঃরড়হ ু ংঃবস (চছ) ংঃৎরহমবহঃ ৎবমঁষ ধঃড়ৎু ধঁঃ যড়ৎরু এর পদ্ধতির সমতুল্য এবং ভ্যাক্সিনের ংঃধহফধৎফ সমূহ ডঐঙ তৈরী করে । এমতাবস্থায়, আমদানীকৃত ভ্যাক্সিনের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে ড্রাগ কন্ট্রোল কমিটি কর্তৃক ডঐঙ চছ ৷ ধপপরহব কে ০৭ টি ংঃৎরহমবহঃ ৎবমঁষ ধঃড়ৎু ধঁ ঃযড়ৎরু (যুক্তরাষ্ট, যুক্তরাজ্য, সুইজারল্যান্ড, জার্মানী, ফ্রান্স, জাপান ও অস্ট্রেলিয়া) এবং উগঅ এর সমতুল্য হিসেবে বিবেচনা করা যেতে পারে এবং ডঐঙ এর ঢ়ৎবয়ঁধষ রড়্রাপধঃরড়হ ু ংঃবস (চছ) ভ্যাক্সিনকে রেজিস্ট্রেশন প্রদান করা যেতে পারে। ৩. ঔষধ প্রশাসন অধিদপ্তর কর্তৃক ভ্যাক্সিন রেজিস্ট্রেশন এবং ভ্যাক্সিনের ফার্মাকোভিজিল্যান্স এর জন্য গাইড লাইন প্রণয়নের সুপারিশ করা হয়।							
টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত ঃ	১. ভ্যাক্সিনটি স্থানীয়ভাবে উৎপাদনের জন্য অনুমোদনের সুপারিশ করা হয়েছে বিধায় আমদানির জন্য নামঞ্জুরের সুপারিশ করা হয়। ২. আমদানীকৃত ভ্যাক্সিনের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে ডঐঙ চছ ৷ ধপপরহব কে ০৭ টি ংঃৎরহমবহঃ ৎবমঁষ ধঃড়ৎু ধঁঃ যড়ৎরু (যুক্তরাষ্ট, যুক্তরাজ্য, সুইজারল্যান্ড, জার্মানী, ফ্রান্স, জাপান ও অস্ট্রেলিয়া) এবং উগঅ এর সমতুল্য হিসেবে বিবেচনা করা করার বিষয়ে টেকনিক্যাল সাব কমিটির সদস্যগণ দ্বিমত পোষণ করেন। ঔষধ শিল্প সমিতির প্রতিনিধি জনাব মোঃ আবদুল মুক্তাদির বলেন, ড্রাগ পলিসি মোতাবেক আমদানিকৃত ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে যুক্তরাষ্ট্র, যুক্তরাজ্য, সুইজারল্যান্ড, জার্মানী, ফ্রান্স, জাপান ও অস্ট্রেলিয়া - কমপক্ষে একটি উন্নত দেশে বাজারজাতকরণের জন্য নিবন্ধিত হতে হবে। যা অনুসরণ করা হয়ে থাকে। এক্ষেত্রে নতুন করে শুধুমাত্র ডঐঙ চছ ভ্যাক্সিনকে আমদানির ক্ষেত্রে বিবেচনা করার প্রয়োজন নেই। এ বিষয়ে উপস্থিত অন্যান্য সদস্যগণ একমত পোষণ করেন। সদস্যগণ এ বিষয়ে ড্রাগ কন্ট্রোল কমিটির ২৫০ তম সভার সিদ্ধান্তকে বলবৎ রাখার বিষয়ে মতামত দেন। ড্রাগ কন্ট্রোল কমিটির ২৫০ তম সভার সিদ্ধান্ত ঃ দেশে পর্যাপ্ত পরিমানে উৎপাদন না হলে, দেশের প্রয়োজনে ডঐ ঙ কর্তৃক চ ৎবয়ঁধ ষ্কাড়্রাবফ গ বফরপরহব আমদানির রেজিস্ট্রেশন পধৎব ঃড় পধৎব বিবেচনা পূর্বক অনুমোদন দেওয়া যেতে পারে।							

Sl No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Source Name	Therapeutic Class and code	Indication	Status (New Molecule/ Existing)	GMP Certificate	Drug Approval (CFDA/NMPA)/ FSC/CPP	Manufacturing License	Lot release certificate	WHO prequalification
ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ	১. ভ্যাক্সিনটি স্থানীয়ভাবে উৎপাদনের জন্য অনুমোদনের সুপারিশ করা হয়েছে বিধায় আমদানির জন্য নামঞ্জুর করা হয়। ২. ড্রাগ কন্ট্রোল কমিটির ২৫০ তম সভার নিম্ন সিদ্ধান্তটি বলবৎ রাখার সিদ্ধান্ত গৃহীত হয় ঃ “দেশে পর্যাপ্ত পরিমানে উৎপাদন না হলে, দেশের প্রয়োজনে ডঐঙ কর্তৃক চৎবয়ঁ ধষ্বভ্রবফ গব ফরপরুব আমদানির রেজিস্ট্রেশন পধংব ঃড় পধংব বিবেচনা পূর্বক অনুমোদন দেওয়া যেতে পারে।”										

অহহবী -উ: অহরসধষ ঠধ পপরহব ভড়ৎষড়ঃধষ ঢ়ৎড়ফঁপ ঃরড়হ

Sl No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Incepta Vaccine Ltd. (Animal Vaccine Division), Dhamrai, Dhaka.	Phosphate Buffered Saline	Sodium Chloride BP 0.00771 gm + Di Sodium Hydrogen Phosphate Anhydrous BP 0.00175 gm + Potassium di Hydrogen Phosphate Anhydrous BP 0.00088 gm + Food Grade Indigo Carmine In-house 0.000166 gm + Hydrochloric acid or Sodium Hydroxide BP q.s to pH adjustment + Water for Injection (WFI) BP q.s to 1 ml/1ml Phosphate Buffered Saline for HenPox Vaccine (Fowl Pox); 3ml, 5ml, 10ml volume	Water for Injection, Electrolytes, Blood Volume Restorers and Caloric Agents. Therapeutic Code: 079	Phosphate Buffered Saline is recommended to be used as a diluent for reconstituting the freeze-dried HenPox Vaccine, live.	**Contraindication** HenPox Diluent is isotonic and non-toxic to most cells. No contraindications. **Side-effects:** None	New	উরষঁ বহঃ টি অনুমোদনের সুপারিশ করা হয়।	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
2.	FNF Pharmaceuticals Ltd. Rautail, Nagarbathan, Jhenidah	Inactivated Avian Influenza Virus Subtype H9N2	Inactivated Avian Influenza Virus Subtype H9N2 500 Dose & 1000 Dose	Inactivated poultry Vaccine Therapeutic Code: 077	Protection against Avian Influenza Virus Subtype H9N2 (Bird flu) in Chicken	Contraindication: None Side-effects: None	New	ভ্যাক্সিনটি নিম্নোক্ত শর্তে রেজিস্ট্রেশন প্রদানের সুপারিশ করা হয়ঃ ১.ভ্যাক্সিনটির রেজিস্ট্রেশনের সময় মাস্টার সিড সম্পর্কিত সকল ডকুমেন্টস ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে। ২. ভ্যাক্সিনটি রেজিস্ট্রেশনের পর ০২ (দুই) বছর পর্যন্ত ১০০০ (এক হাজার) প্রাণির উপর ধপঃরাব ঢ়যধৎস ধপড়া রূমরষহুপব ংঃঁ ফু করতঃ ফধঃধ ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে।	ভ্যাক্সিনটির রেজিস্ট্রেশনের সময় মাস্টার সিড সম্পর্কিত সকল ডকুমেন্টস ঔষধ প্রশাসন অধিদপ্তরে দাখিল করেছে বিধায় নিম্নোক্ত শর্তে ভ্যাক্সিনটির রেজিস্ট্রেশন প্রদানের সুপারিশ করা হয়ঃ ১. ভ্যাক্সিনটি রেজিস্ট্রেশনের পর ০২ (দুই) বছর পর্যন্ত ১০০০ (এক হাজার) প্রাণির উপর ধপঃরাব ঢ়যধৎস ধপড়া রূমরষহুপব ংঃঁ ফু করতঃ ফধঃধ ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে।	নিম্নোক্ত শর্তে ভ্যাক্সিনটি অনুমোদন করা হয়ঃ ১. ভ্যাক্সিনটি রেজিস্ট্রেশনের পর ০২ (দুই) বছর পর্যন্ত ১০০০ (এক হাজার) প্রাণির উপর ধপঃরাব ঢ়যধৎস ধপড়া রূমরষহুপব ংঃঁ ফু করতঃ ফধঃধ ঔষধ প্রশাসন অধিদপ্তরে দাখিল করতে হবে।

Annex-E: Product list for Locally Manufacture (Veterinary)

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	Popular Pharmaceuticals Limited	Sodium Chloride BP 0.90gm/100ml IV Infusion **(For Veterinary Use)**	Sodium Chloride BP 0.90gm / 100ml **(For Veterinary Use)**	Fluid and Electrolyte Replenisher	For use in replacement therapy of sodium chloride and water which may become depleted in many diseases like Dehydration, Excessive Sweating, Water & Electrolyte imbalance etc. Sodium Chloride Infusions are also indicated as pharmaceuticals aids and diluents for the infusion of compatible drug additives and for washing mucous membranes and other tissue surfaces.	**Contraindication:** This solution is contraindicated where the administration of sodium or chloride could be clinically detrimental. **Adverse Reaction:** Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.	Sodium Chloride BP 0.90gm / 100ml (0.9%) IV Infusion **Human** **Approved By DCC 161**	**UKMHRA** **(UK Veterinary Medicines Directorate)**	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
2.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Danofloxacin 5gm/100ml Solution (For Veterinary Use)	Danofloxacin Mesylate INN 6.345gm (eq. to Danofloxacin 5gm)/100ml	Anti-biotic	Danofloxacin is indicated for the treatment of respiratory and digestive tract infections caused by gram positive, gram negative bacteria and Mycoplasma. **WITHDRAWAL PERIOD:** Meat: 5 days	**CONTRAINDICATIONS:** Danofloxacin is not recommended for use in the case of resistant bacteria to other fluoroquinolones. **SIDE-EFFECT:** Hypersensitivity reaction causing lameness.	**New** Danofloxacin 2.5% & 5.0% Injection Danofloxacin 180 mg/mL (USFDA)	**EMA** (এ্রাব উঁ ৎড়ঢ়বধহ অমবহপু ভ্ড়ৎ ঃযব ঊা ধষঁ ধঃরড়হ ড়ভগ বফরপরষ্ণষ চৎড়ফঁ পঃং ঠ বঃবৎরহধ্ণু গ বফরপরষ্ণং ঊা ধষঁ ধঃরড়হ টহ রঃ)	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
3.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Magnesium Hydroxide 6gm/100mL Oral Emulsion. (For Veterinary Use)	Magnesium Hydroxide USP 6gm/100 mL	Laxative	Magnesium Hydroxide is used for a short time to treat occasional constipation. It is a laxative (osmotic- type) that is thought to work by drawing water into the intestines, an effect that helps to cause movement of the intestines, liquid paraffin used as a stool lubricant.	**CONTRAINDICATIONS:** ➢ Metabolic Alkalosis ➢ Hyper Magnesimia **SIDE-EFFECT:** In some cases irritation, diarrhea may occur.	**New** Liquid Paraffin 25ml + Magnesium Hydroxide 6mg/100ml Oral Emulsion	Liquid Paraffin BP 25ml + Light Magnesium Oxide BP 4.147gm (eq. 6mg Magnesium Hydroxide/100ml Oral Emulsion) **Acme Laboratories Ltd. (DCC-244)**	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
4.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Propionic Acid 10% & Formic Acid 8% (For Veterinary Use)	Propionic Acid INN 10gm + Formic Acid INN 8.0gm/100ml	Nutritional Product	• To control water pH and intestinal pH • To suppress growth of Salmonella, E. coli and Clostridium perfringens in gut • Helps to grow beneficial organisms • To improve FCR and increase egg & meat production • To reduce negative effects of heat	**CONTRAINDICATIONS:** Danofloxacin is not recommended for use in the case of resistant bacteria to other fluoroquinolones. **SIDE-EFFECT:** Hypersensitivity reaction causing lameness.	**New** Formic acid, Propionic acid & HMTBa (**Navana**) Citric acid, sorbic	ঘড়াঁ ং ওহ্ভবৎহধঃরড়হধষ, ওহ্প., ইব যমর্ঁ স	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					stress • Acts as biological antagonist against fungus & Mytoxins • To reduce prolapsed in breeder and layer • Acts as antioxidant. **WITHDRAWAL PERIOD:** Meat 0 day; Egg 0 day		acid, Yeast extract, Formic acid, lactic acid, Propionic acid, Ammonium formate, Propylene glycol **(Square)**			
5.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Vitamin A 100000 IU, Vitamin D3 40000 IU, Vitamin E 40 mg & Vitamin K 10 mg/gm Powder (For Veterinary Use)	Vitamin A Acetate 0.5 MIU/gm (water dispersible) Feed Grade 18.823gm (eq. Vitamin A 10000000 IU) + Vitamin D3 Feed Grade 7.049gm (eq. Vitamin D3 4000000 IU) + Vitamin E 50 (water dispersible) Feed Grade 7.536gm (eq. Vitamin E 4.0gm) + Vitamin K3 MSB Feed Grade 1.918gm (eq. Vitamin K 1.0gm)	Nutritional Product	• Meets the needs of vitamins A, D3, E and K in poultry • Increases milk, meat and egg production • Increases fertility and hatchability • Increases the effectiveness and immunity of the vaccine • Helps in bone and muscle formation • Helps reduce stress caused by vaccines, deworming and antibiotics • Helps to stop any kind of bleeding **WITHDRAWAL PERIOD:** Meat 0 day; Egg 0 day	**CONTRAINDICATIONS:** Danofloxacin is not recommended for use in the case of resistant bacteria to other fluoroquinolones. **SIDE-EFFECT:** Hypersensitivity reaction causing lameness.	**New** Eskavit ADE (Vitamin A, D3 & E Oral Solution) 100ml, 500ml & 1 Lit. (**SK+F**)	ঐবনবরঘব ি ঈবহঃঃ ৎু চ যধৎস ধপবঁ ঃরুধ ষং খএঃউ., ঐবনবর,ঈয রুহধ.	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
6.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tildipirosin 180 mg/ml Injection, 10 ml (For Veterinary Use Only)	Tildipirosin INN 180 mg/ml	Antibiotic	For the treatment and control of Bovine Respiratory Disease (BRD) associated with Mannheimia haemolytica, Pasteurella maltucida, Hisphilus somni in animals. It is also indicated for the reduction of morbidity associated with BRD in feedlot calves.	**Contraindications:** It is contraindicated in animals hypersensitive to macrolide antibiotic. **Side effects:** Discomfort, transient pain and local swellings after injection may occur. **Withdrawal Period:** Cattle: Meat- 21 days and milk- Not known Pig: Meat & offal- 09 days, Milk- Not known.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
7.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tildipirosin 180 mg/ml Injection, 30 ml (For Veterinary Use Only)	Tildipirosin INN 180 mg/ml	Antibiotic	For the treatment and control of Bovine Respiratory Disease (BRD) associated with Mannheimia haemolytica, Pasteurella maltucida, Hisphilus somni in animals. It is also indicated for the reduction of morbidity associated with BRD in feedlot calves.	**Contraindications:** It is contraindicated in animals hypersensitive to macrolide antibiotic. **Side effects:** Discomfort, transient pain and local swellings after injection may occur. **Withdrawal Period:** Cattle: Meat- 21 days and milk- Not known Pig: Meat & offal- 09 days, Milk- Not known.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
8.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tildipirosin 180 mg/ml Injection, 100 ml (For Veterinary Use Only)	Tildipirosin INN 180 mg/ml	Antibiotic	For the treatment and control of Bovine Respiratory Disease (BRD) associated with Mannheimia haemolytica, Pasteurella maltucida, Hisphilus somni in animals. It is also indicated for the reduction of morbidity associated with BRD in feedlot calves.	**Contraindications:** It is contraindicated in animals hypersensitive to macrolide antibiotic. **Side effects:** Discomfort, transient pain and local swellings after injection may occur. **Withdrawal Period:** Cattle: Meat- 21 days and milk- Not known Pig: Meat & offal- 09 days, Milk- Not known.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
9.	The ACME	Florfenicol 300 mg +	Florfenicol INN 300	Antibiotic &	It is indicated for the treatment and control of	**Contraindications:** Do not use in animals that have	Florfenicol 20%	টঝঋ উঅ	আবেদন অনুমোদন	অনুমোদন করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Flunixin 16.5 mg/ml Injection, 5 ml (For Veterinary Use Only)	mg + Flunixin Meglumine BP eqv. to Flunixin 16.5 mg/ml	Anti-inflammatory	BRD associated with *Mannheimia haemolytica*, *Pasteurella maltucida*, *Hisphilus somni*, foot rot and acute interdigital necrobacillosis.	shown hypersensitivity to Florfenicol and/or Flunixin. **Side effects:** Anorexia, decreased water consumption, diarrhea, injection site reactions (may result in trim loss); IM injection may be painful in small animals. **Withdrawal Period:** Cattle: Meat- 38 days & Milk- Not known	Oral Solution		করা যেতে পারে।	
10.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Florfenicol 300 mg + Flunixin 16.5 mg/ml Injection, 10 ml (For Veterinary Use Only)	Florfenicol INN 300 mg + Flunixin Meglumine BP eqv. to Flunixin 16.5 mg/ml	Antibiotic & Anti-inflammatory	It is indicated for the treatment and control of BRD associated with *Mannheimia haemolytica*, *Pasteurella maltucida*, *Hisphilus somni*, foot rot and acute interdigital necrobacillosis.	**Contraindications:** Do not use in animals that have shown hypersensitivity to Florfenicol and/or Flunixin. **Side effects:** Anorexia, decreased water consumption, diarrhea, injection site reactions (may result in trim loss); IM injection may be painful in small animals. **Withdrawal Period:** Cattle: Meat- 38 days & Milk- Not known	Florfenicol 20% Oral Solution	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
11.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Florfenicol 300 mg + Flunixin 16.5 mg/ml Injection, 30 ml (For Veterinary Use Only)	Florfenicol INN 300 mg + Flunixin Meglumine BP eqv. to Flunixin 16.5 mg/ml	Antibiotic & Anti-inflammatory	It is indicated for the treatment and control of BRD associated with *Mannheimia haemolytica*, *Pasteurella maltucida*, *Hisphilus somni*, foot rot and acute interdigital necrobacillosis.	**Contraindications:** Do not use in animals that have shown hypersensitivity to Florfenicol and/or Flunixin. **Side effects:** Anorexia, decreased water consumption, diarrhea, injection site reactions (may result in trim loss); IM injection may be painful in small animals. **Withdrawal Period:** Cattle: Meat- 38 days & Milk- Not known	Florfenicol 20% Oral Solution	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
12.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Florfenicol 300 mg + Flunixin 16.5 mg/ml Injection, 50 ml (For Veterinary Use Only)	Florfenicol INN 300 mg + Flunixin Meglumine BP eqv. to Flunixin 16.5 mg/ml	Antibiotic & Anti-inflammatory	It is indicated for the treatment and control of BRD associated with *Mannheimia haemolytica*, *Pasteurella maltucida*, *Hisphilus somni*, foot rot and acute interdigital necrobacillosis.	**Contraindications:** Do not use in animals that have shown hypersensitivity to Florfenicol and/or Flunixin. **Side effects:** Anorexia, decreased water consumption, diarrhea, injection site reactions (may result in trim loss); IM injection may be painful in small animals. **Withdrawal Period:** Cattle: Meat- 38 days & Milk- Not known	Florfenicol 20% Oral Solution	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
13.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Florfenicol 300 mg/ml Injection, 10 ml (For Veterinary Use Only)	Florfenicol INN 300 mg/ml	Antibiotic	It is indicated for the treatment and control of BRD associated with *Mannheimia haemolytica*, *Pasteurella maltucida*, *Hisphilus somni*, foot rot and acute interdigital necrobacillosis.	**Contraindications:** Do not use in animals that have shown hypersensitivity to Florfenicol. **Side effects:** Anorexia, decreased water consumption, diarrhea, injection site reactions (may result in trim loss); IM injection may be painful in small animals. **Withdrawal Period:** Cattle: Meat- 28 days for IM injection & 38 days for SC injection, Milk- Not Known.	Florfenicol 20% Oral Solution	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
14.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Florfenicol 300 mg/ml Injection, 30 ml (For Veterinary Use Only)	Florfenicol INN 300 mg/ml	Antibiotic	It is indicated for the treatment and control of BRD associated with *Mannheimia haemolytica*, *Pasteurella maltucida*, *Hisphilus somni*, foot rot and acute interdigital necrobacillosis.	**Contraindications:** Do not use in animals that have shown hypersensitivity to Florfenicol. **Side effects:** Anorexia, decreased water consumption, diarrhea, injection site reactions (may result in trim loss); IM injection may be painful in small animals. **Withdrawal Period:**	Florfenicol 20% Oral Solution	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Cattle: Meat- 28 days for IM injection & 38 days for SC injection, Milk- Not Known.				
15.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tulathromycin 100 mg/ml Injection, 5 ml (For Veterinary Use Only)	Tulathromycin INN 100 mg/ml	Macrolide Antibiotic	**Treatment and metaphylaxis of bovine respiratory diseases:** Tulathromycin 100 mg is indicated for the treatment and metaphylaxis of bovine respiratory diseases caused by *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis*. **atment of infectious bovine atoconjunctivitis:** athromycin 100 mg is indicated the treatment of infectious bovine atoconjunctivitis caused by *raxella bovis*. **Treatment and metaphylaxis of swine respiratory diseases:** Tulathromycin 100 mg is indicated for the treatment and metaphylaxis of swine respiratory diseases caused by *Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis* and *Bordetella bronchiseptica*. **Treatment of foot rot:** Tulathromycin 100 mg is indicated for the treatment of bovine foot rot caused by *Dichelobacter nodosus*.	**Contraindications:** Tulathromycin is contraindicated with other macrolides antibiotic or lincosamides. It is contraindicated in animals hypersensitive to macrolide antibiotic. **Side effects:** **Common Side effects**: Discomfort, transient pain and local swellings after subcutaneous injection. **Rare Side effects:** Congestion, fibrosis and hemorrhage at injection site **Withdrawal Period:** Cattle: meat- 22 days & milk- Not known. **Pigs: meat- 13 days & milk- Not known.** Sheep: meat- 16 days & milk- Not known	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
16.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tulathromycin 100 mg/ml Injection, 10 ml (For Veterinary Use Only)	Tulathromycin INN 100 mg/ml	Macrolide Antibiotic	**Treatment and metaphylaxis of bovine respiratory diseases:** Tulathromycin 100 mg is indicated for the treatment and metaphylaxis of bovine respiratory diseases caused by *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis*. **atment of infectious bovine atoconjunctivitis:** athromycin 100 mg is indicated the treatment of infectious bovine atoconjunctivitis caused by *raxella bovis*. **Treatment and metaphylaxis of swine respiratory diseases:** Tulathromycin 100 mg is indicated for the treatment and metaphylaxis of swine respiratory diseases	**Contraindications:** Tulathromycin is contraindicated with other macrolides antibiotic or lincosamides. It is contraindicated in animals hypersensitive to macrolide antibiotic. **Side effects:** **Common Side effects**: Discomfort, transient pain and local swellings after subcutaneous injection. **Rare Side effects:** Congestion, fibrosis and hemorrhage at injection site **Withdrawal Period:** Cattle: meat- 22 days & milk- Not known. **Pigs: meat- 13 days & milk- Not known.** Sheep: meat- 16 days & milk- Not known	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					caused by *Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis* and *Bordetella bronchiseptica*. **Treatment of foot rot:** Tulathromycin 100 mg is indicated for the treatment of bovine foot rot caused by *Dichelobacter nodosus*.					
17.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tulathromycin 100 mg + Tolfenamic Acid 80 mg/ml Injection, 5 ml (For Veterinary Use Only)	Tulathromycin INN 100 mg + Tolfenamic Acid BP 80 mg/ml	Antibiotic-Anti-inflammatory	**Treatment of bovine respiratory diseases:** Tulathromycin 100 mg and Tolfenamic Acid 80 mg are indicated for the treatment of bovine respiratory diseases caused by *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* associated with fever and pain. **Treatment of acute mastitis, foot rot and musculoskeletal disorders:** Tulathromycin 100 mg and Tolfenamic Acid 80 mg are indicated for the treatment of acute mastitis, foot rot and musculoskeletal disorders such as lameness, inflammatory & painful conditions in animal body and reduction of post-operative pain. **Treatment of mastitis-metritis-agalactia (MMA) syndrome:** Tulathromycin 100 mg and Tolfenamic Acid 80 mg are indicated for the treatment of mastitis-metritis-agalactia (MMA) syndrome in pigs.	**Contraindications:** Tulathromycin and Tolfenamic Acid combination is contraindicated in animals hypersensitivity to it or to other drugs in it class. This combination is not used in animals with active GI ulceration and renal insufficiency. **Side effects:** **Common Side Effects:** Discomfort, Voimiting, diarrhoea, transient pain and local swellings after subcutaneous injection. **Rare Side Effects:** Kidney failure, gastro-intestinal intolerance and hemorrhage at the injection site. **Withdrawal Period:** meat & milk- Not known	Tolfenamic Acid 1 gm/25 ml Injection	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
18.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tulathromycin 100 mg + Tolfenamic Acid 80 mg/ml Injection, 10 ml (For Veterinary Use Only)	Tulathromycin INN 100 mg + Tolfenamic Acid BP 80 mg/ml	Antibiotic-Anti-inflammatory	**Treatment of bovine respiratory diseases:** Tulathromycin 100 mg and Tolfenamic Acid 80 mg are indicated for the treatment of bovine respiratory diseases caused by *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* associated with fever and pain. **Treatment of acute mastitis, foot rot and musculoskeletal disorders:** Tulathromycin 100 mg and Tolfenamic Acid 80 mg are indicated for the treatment of acute mastitis, foot rot and musculoskeletal disorders such as lameness, inflammatory & painful conditions in animal body and reduction of post-operative pain.	**Contraindications:** Tulathromycin and Tolfenamic Acid combination is contraindicated in animals hypersensitivity to it or to other drugs in it class. This combination is not used in animals with active GI ulceration and renal insufficiency. **Side effects:** **Common Side Effects:** Discomfort, Voimiting, diarrhoea, transient pain and local swellings after subcutaneous injection. **Rare Side Effects:** Kidney failure, gastro-intestinal intolerance and hemorrhage at the injection site. **Withdrawal Period:** meat & milk- Not known	Tolfenamic Acid 1 gm/25 ml Injection	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					Treatment of mastitis-metritis-agalactia (MMA) syndrome: Tulathromycin 100 mg and Tolfenamic Acid 80 mg are indicated for the treatment of mastitis-metritis-agalactia (MMA) syndrome in pigs.					
19.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Deltamethrin 12.5 mg/ml Oral Solution, 100 ml (For Veterinary Use Only)	Deltamethrin BP 12.5 mg/ml	Ectoparasiticide	As spot-on for the prevention and controlling of ectoparasitic infestations in animals as well as reduces flies from farm house.	**Contraindications:** None **Side effects:** No side effects are found at recommended dose. **Withdrawal Period:** Meat-20 days & Milk- 0 (Zero) day.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
20.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Deltamethrin 12.5 mg/ml Oral Solution, 200 ml (For Veterinary Use Only)	Deltamethrin BP 12.5 mg/ml	Ectoparasiticide	As spot-on for the prevention and controlling of ectoparasitic infestations in animals as well as reduces flies from farm house.	**Contraindications:** None **Side effects:** No side effects are found at recommended dose. **Withdrawal Period:** Meat-20 days & Milk- 0 (Zero) day.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
21.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Attapulgite 3270 mg + Kaolin 130 mg + Carob 440 mg + Pectin 290 mg + Magnesium Trisillicate 150 mg Bolus (For Veterinary Use Only)	Attapulgite USP 3270 mg + Kaolin USP 130 mg + Carob INN 440 mg + Pectin USP 290 mg + Magnesium Trisillicate USP 150 mg	Adsorbent Anti-Diarrheal OTC drug	Activated attapulgite is a specially treated mineral clay that adsorbs toxins, toxic substances, acids, bacteria & water in the gut of animals with symptoms of diarrhea. This adsorbent action helps to relieve the irritation, discomfort, and cramping associated with diarrhea. Acts as absorbent anti-diarrheal demulcent.	**Contraindications:** Contraindicated in animal hypersensitive to Attapulgite/Kaolin/Carob/Pectin/Magnesium Trisilicate. **Side effects:** Mild Constipation, bloating, flatulence, stomach upset and nausea. **Withdrawal Period:** Milk and Meat: Not known	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
22.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Chloramphenicol 50 mg + Cetrimide 10 mg + Dimethyl Phthalate 10 mg + Crystal Violet 5 mg + Dimethyl Ether 0.67 ml + Isopropyl Alcohol q.s. to 1 ml/ml Spray (For Veterinary Use Only)	Chloramphenicol BP 50 mg + Cetrimide BP 10 mg + Dimethyl Phthalate BP 10 mg + Crystal Violet BP 5 mg + Dimethyl Ether BP 0.67 ml + Isopropyl Alcohol BP q.s. to 1 ml/ml	Topical	Any type of topical infection, wound, Abrassion of skin, Burn and clinical condition associated with skin.	**Contraindications:** This combination is contraindication animals hypersensitive to Chloramphenicol, Cetrimide, Dimethyl phthalate, Crystal violet, Dimethyl ether, Isopropyl alcohol. **Side effects:** Adverse effects are rarely seen; such as tissue toxicity, delayed healing. **Withdrawal Period:** Meat & milk : 0 day	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
23.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Amoxicillin Trihydrate 12 g + Metronidazole 20 g/100 g Sachet Water Soluble Powder (WSP) (For Veterinary Use Only)	Amoxicillin Trihydrate BP 12 g + Metronidazole BP 20 g/100 g	Antimicrobial	Poultry: Necrotic Enteritis, Infectious Coryza, Fowl cholera; Horses: Anaerobic infections; Dogs and Cats: Giardiasis, Trichomoniasis, Entamoeba histolytica (trophozoite form). It has also antiprotozoal properties.	**Contraindications:** Do not administer to animals hypersensitive to penicillin and/or Metronidazole. Do not administer to laying hens with age over 16 weeks. Metronidazole should be used with caution in animals with hepatic dysfunction. **Side effects:** In some cases hypersensitivity reactions may occur. Adverse effects reported in dogs include neurologic disorders, lethargy, weakness, neutropenias, hepatotoxicity, hematuria, anorexia, nausea, vomiting, and diarrhea. Cats infrequently develop GI effects.	Amoxicillin 500 mg, 1 gm Bolus Amoxicillin 1.5 gm/10 ml Injection Amoxicillin 10%, 15%, 20%, 30%, 100% Powder	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Withdrawal Period: Meat & egg: Not known				
24.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Zilpaterol Hydrochloride 75 mg + Melengestrol Acetate 0.38 mg Bolus (For Veterinary Use Only)	Zilpaterol Hydrochloride INN 75 mg + Melengestrol Acetate USP 0.38 mg	Supplement	Fattening (body weight gain). Improved feed efficiency. Quality meat production. Suppression of estrus (heat) in heifers fed in confinement for slaughter	**Contraindications:** Contraindicated in animals hypersensitive to Zilpaterol Hydrochloride and/or Melengestrol Acetate or any of the components of the product.**Side effects:** No undesirable effects have been found at recommended doses. **Withdrawal Period:** Meat: 3 days	Melengestrol Acetate 110 mg + Zilpaterol Hydrochloride 4.8 gm/100 gm Water Soluble Powder	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
25.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Tolfenamic Acid 500 mg Bolus (For Veterinary Use Only)	Tolfenamic Acid BP 500 mg	Anti-inflammatory	It is indicated as anti-inflammatory, antitoxic, analgesic & antipyretic associated with respiratory diseases, acute mastitis, mastitis-metritis-agalactia (MMA) syndrome, musculoskeletal disorders etc. in animals. It is always indicated as supportive therapy with antibiotic. Specifying the target species, Tolfenamic acid is indicated for: 01. Name and address of the manufacturer (c) Dosage and administration In Cattle : As an adjunct in the treatment of bovine respiratory disease, acute mastitls in conjunction with antibacterial therapy & in musculoskeletal disorders In Doo : Chronic locomotor disease In Cat : Febrile syndrome In Piq:As an adjunct in the treatment of Mastitis Metritis Agalactia (MMA) syndrome.	**Contraindications:** Animals suffering from a chronic renal insufficiency, the use of Tolfenamic acid is contra-indicated in acute cases of renal insufficiency. Contraindicated for dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. **Side effects:** Tolfenamic acid is well tolerated at the recommended dosage. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur; Nausea, vomiting, dianhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported. **Withdrawal Period:** Milk and Meat: Not known	Tolfenamic Acid 1 gm/25 ml Injection	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
26.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Calcium Chloride 3000 mg + Sodium Chloride 1000 mg + Chondroitin Sulfate 50 mg + Glucosamine 50 mg + Vitamin D3 20000 IU + Orthophosphoric Acid 3000 mg + Choline Chloride 5000 mg + Hydroxy Analogue of Methionine 1000 mg + Manganese (As Manganese Chelate of Glycine, Hydrate) 250 mg + Zinc (As	Calcium Chloride BP 3000 mg + Sodium Chloride BP 1000 mg + Chondroitin Sulfate BP 50 mg + Glucosamine BP 50 mg + Vitamin D3 BP 20000 IU + Orthophosphoric Acid BP 3000 mg + Choline Chloride BP 5000 mg + Hydroxy Analogue of Methionine BP 1000 mg + Manganese (As Manganese Chelate of Glycine, Hydrate) BP	Vitamin & Mineral	For the prevention of skeletal and joint problems, to improve & support the development and maintenance of bones, cartilages and eggshells, to promote good eggshell formation in layers and breeders.	**Contraindications:** This combination is contraindicated in animals hypersensitivity to it or to other drugs in it class. **Side effects:** Overdose may cause diarrhea. **Withdrawal Period:** Meat & egg: 0 day	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
		Zinc Chelate of Glycine, Hydrate) 250 mg + Copper (As Coper II Chelate of Glycine, Hydrate) 10 mg + Biotin 1.5 mg/100 ml Liquid	250 mg + Zinc (As Zinc Chelate of Glycine, Hydrate) BP 250 mg + Copper (As Coper II Chelate of Glycine, Hydrate) BP 10 mg + Biotin BP 1.5 mg/100 ml							
27.	SHINIL Phamra Ltd., BK Bari, Gazipur	Tolfenamic Acid 200 mg/g (Veterinary)	Tolfenamic Acid 200 mg/g , Bolus	NSAID	Inflamatory disease Pain and High Fever, Pneumonia, Mastitis, Metritis, Mascular fatigue and Lameness	**Contraindication:** Hypersensitivity **Side-effects:** Vomiting & Diarrhoea **Warnings**: Should not used in animals with GI bleeding or Ulceration. NSAID should be avoidedin animals with liver or Kidney disease. **Precautions**: Should not consume meat untill 12 days after use the drug.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
28.	SHINIL Phamra Ltd., BK Bari, Gazipur	Fenbendazole 250 mg/g (Veterinary)	Fenbendazole 250 mg/g, Bolus	Anthelmintic	Round worm, lung worm & tape worm	**Contraindication:** Fenbendazole should not be used within 14 days of liver fluke treatment and animal less than 3 month of age. **Side-effects:** Allergic reaction may be seen in cattle with heavy lung worm infection. **Warnings:** Fenbendazole not embryo toxic. However, risk benefit ratio should be considered durimg administration in pregnant animal. **Precautions:** Should not consume meat 12 days and milk 3 days after use the drug.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
29.	SHINIL Phamra Ltd., BK Bari, Gazipur	Sodium Bicarbonate 75 mg/ml (Veterinary)	Sodium Bicarbonate 75 mg /ml, Injection	Antacid	Acidosis, Acute carbohydrate engorgement, Severe primary lactic acidosis, Severe primary lactic acidosis, Barbiturate toxicity, Severe diarrhea	**Contraindication**: Sodium Bicarbonate is contraindicated in animal that are losing chloride ion from body by vomiting and receiving diuretics. **Side-effects**: Sometimes overdose may cause alkalosis. **Warnings:** Use of Sodium Bicarbonate during pregnancy & lactation has not been yet established. P**recautions:** In compatible with calcium containing solution.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
30.	SHINIL Phamra Ltd., BK Bari, Gazipur	Albendazole 600 mg/g (Veterinary)	Albendazole 600 mg/g , Bolus	Anthelmintic	Round worm, lung worm,tape worm & Liver Fluke	**Contraindication**: Administration in the first 45 days of gestation. **Side-effects**: Hypersensitivity reaction **Warnings:** Risk may be considered durimg administration in pregnant animal. **Precautions:** Should not consume meat 14 days and milk 4 days after use the drug.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
31.	Navana Pharmaceuticals Limited	Florfenicol 300 mg/ml, 10 ml (Veterinary)	Florfenicol 300 mg/ml, Injection	Antibiotic	Respiratory tract infections	Contraindication: Hypersensitivity Side-effects: Diarrhoea, inappetence, reduced water intake may occur. Warnings: Avoid direct contact with eye, skin and	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						clothing. Precautions: Not for use in animals intended for breeding purpose.				
32.	Navana Pharmaceuticals Limited	Florfenicol 300 mg/ml, 30 ml (Veterinary)	Florfenicol 300 mg/ml, Injection	Antibiotic	Respiratory tract infections	Contraindication: Hypersensitivity Side-effects: Diarrhoea, inappetence, reduced water intake may occur. Warnings: Avoid direct contact with eye, skin and clothing. Precautions: Not for use in animals intended for breeding purpose.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
33.	Navana Pharmaceuticals Limited	Florfenicol 300 mg & flunixin (as flunixin meglumine) 16.5 mg per ml, 5 ml (Veterinary)	Florfenicol 300 mg & flunixin (as flunixin meglumine) 16.5 mg per ml, Injection	Antibiotic + Anti-Inflammatory	Respiratory tract infections	Contraindication: Hypersensitivity Side-effects: Diarrhoea, inappetence, reduced water intake may occur. Warnings: Avoid direct contact with eye, skin and clothing. Precautions: Not for use in animals intended for breeding purpose.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
34.	Navana Pharmaceuticals Limited	Florfenicol 300 mg & flunixin (flunixin meglumine) 16.5 mg per ml, 10 ml (Veterinary)	Florfenicol 300 mg & flunixin (flunixin meglumine) 16.5 mg per ml, Injection	Antibiotic + Anti-Inflammatory	Respiratory tract infections	Contraindication: HypersensitivitySide-effects: Diarrhoea, inappetence, reduced water intake may occur.Warnings: Avoid direct contact with eye, skin and clothing.Precautions: Not for use in animals intended for breeding purpose.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
35.	Navana Pharmaceuticals Limited	Florfenicol 300 mg & flunixin (as flunixin meglumine) 16.5 mg per ml, 30 ml (Veterinary)	Florfenicol 300 mg & flunixin (as flunixin meglumine) 16.5 mg per ml, Injection	Antibiotic + Anti-Inflammatory	Respiratory tract infections	Contraindication: Hypersensitivity Side-effects: Diarrhoea, inappetence, reduced water intake may occur. Warnings: Avoid direct contact with eye, skin and clothing. Precautions: Not for use in animals intended for breeding purpose.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
36.	Navana Pharmaceuticals Limited	Florfenicol 300 mg & flunixin (as flunixin meglumine) 16.5 mg per ml, 100 ml (Veterinary)	Florfenicol 300 mg & flunixin (as flunixin meglumine) 16.5 mg per ml, Injection	Antibiotic + Anti-Inflammatory	Respiratory tract infections	Contraindication: Hypersensitivity Side-effects: Diarrhoea, inappetence, reduced water intake may occur. Warnings: Avoid direct contact with eye, skin and clothing. Precautions: Not for use in animals intended for breeding purpose.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
37.	Navana Pharmaceuticals Limited	Tildipirosin 180 mg/ml, 10 ml (Veterinary)	Tildipirosin 180 mg/ml, Injection	Antibiotic	Bovine respiratory diseases	Contraindication: Hypersensitivity Side-effects: Swelling and inflammation may be seen at injection site. Warnings: Avoid direct contact in skin & eyes.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Precautions: Effect in pregnancy and lactation have not been studied.				
38.	Navana Pharmaceuticals Limited	Tildipirosin 180 mg/ml, 30 ml (Veterinary)	Tildipirosin 180 mg/ml, Injection	Antibiotic	Bovine respiratory diseases	Contraindication: HypersensitivitySide-effects: Swelling and inflammation may be seen at injection site.Warnings: Avoid direct contact in skin & eyes.Precautions: Effect in pregnancy and lactation have not been studied.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
39.	Navana Pharmaceuticals Limited	Tildipirosin 180 mg/ml, 5 ml (Veterinary)	Tildipirosin 180 mg/ml, Injection	Antibiotic	Bovine respiratory diseases	Contraindication: Hypersensitivity Side-effects: Swelling and inflammation may be seen at injection site. Warnings: Avoid direct contact in skin & eyes. Precautions: Effect in pregnancy and lactation have not been studied.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
40.	Navana Pharmaceuticals Limited	Tulathromycin 100 mg/ml, 5 ml (Veterinary)	Tulathromycin 100 mg/ml, Injection	Antibiotic	Bovine respiratory diseases, keratoconjunctivitis, foot rot etc.	Contraindication: Hypersensitivity Side-effects: Local pain and swelling may be seen at injection site. Warnings: Efficacy in foot rot may be reduced due to wet environment condition. Precautions: Avoid direct contact in skin & eyes.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
41.	Navana Pharmaceuticals Limited	Tulathromycin 100 mg/ml, 10 ml (Veterinary)	Tulathromycin 100 mg/ml, Injection	Antibiotic	Bovine respiratory diseases, keratoconjunctivitis, foot rot etc.	Contraindication: Hypersensitivity Side-effects: Local pain and swelling may be seen at injection site. Warnings: Efficacy in foot rot may be reduced due to wet environment condition. Precautions: Avoid direct contact in skin & eyes.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
42.	Navana Pharmaceuticals Limited	Tulathromycin 100 mg/ml, 30 ml (Veterinary)	Tulathromycin 100 mg/ml, Injection	Antibiotic	Bovine respiratory diseases, keratoconjunctivitis, foot rot etc.	Contraindication: Hypersensitivity Side-effects: Local pain and swelling may be seen at injection site. Warnings: Efficacy in foot rot may be reduced due to wet environment condition. Precautions: Avoid direct contact in skin & eyes.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
43.	Navana Pharmaceuticals Limited	Tulathromycin 100 mg and Tolfenamic Acld 80 mg per ml, 5 ml (Veterinary)	Tulathromycin 100 mg and Tolfenamic Acld 80 mg per ml, Injection	Antibiotic + Anti-Inflammatory	Bovine respiratory diseases, keratoconjunctivitis, foot rot etc.	Contraindication: Hypersensitivity Side-effects: No side-effects have been seen after administration. Warnings: Water consumption may be increased. Precautions: Do not combine with other bacteriostatic drugs.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
44.	Navana Pharmaceuticals Limited	Phenoxymethyl penicillin 293 mg/g, 100 g, (Veterinary)	Phenoxymethyl penicillin 293 mg/g, WSP	Antibiotic	Necrotic enteritis	Contraindication: Hypersensitivity Side-effects: Sometime GIT disturbance may occur. Warnings and precautions: Should not use in patient having GIT problem.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
45.	Navana	Ambroxol HCl 3	Ambroxol HCl 3	Expectaurant	Respiratory tract disorder, cough	Contraindication:	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায়	প্রয়োজনীয় রেফারেন্স নাই

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Pharmaceuticals Limited	mg/ml, 100 ml, (Veterinary)	mg/ml, Solution			Hypersensitivity Side-effects: Administer 3 times the recommended dose having no side effects. Warnings: Skin contact should be avoided. Precautions: Topical administration only. Do not administer orally or parenterally.			আবেদন নামঞ্জুর করা যেতে পারে।	বিধায় নামঞ্জুর করা হয়।
46.	Navana Pharmaceuticals Limited	Eprinomectin 5 mg/ml, 15 ml, (Veterinary)	Eprinomectin 5 mg/ml, Pour on	Anthelmintic	Infestations caused by external and internal parasites	Contraindication: Hypersensitivity Side-effects: Administer 3 times the recommended dose having no side effects. Warnings: Skin contact should be avoided. Precautions: Topical administration only. Do not administer orally or parenterally.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
47.	Navana Pharmaceuticals Limited	Eprinomectin 5 mg/ml, 30 ml, (Veterinary)	Eprinomectin 5 mg/ml, Pour on	Anthelmintic	Infestations caused by external and internal parasites	Contraindication: Hypersensitivity Side-effects: Administer 3 times the recommended dose having no side effects. Warnings: Skin contact should be avoided. Precautions: Subcutaneous administration only.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
48.	Navana Pharmaceuticals Limited	Eprinomectin 50 mg/ml, 5 ml, (Veterinary)	Eprinomectin 50 mg/ml, Injection	Anthelmintic	Infestations caused by external and internal parasites	Contraindication: Hypersensitivity Side-effects: Administer 3 times the recommended dose having no side effects. Warnings: Skin contact should be avoided. Precautions: Subcutaneous administration only.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
49.	Navana Pharmaceuticals Limited	Eprinomectin 50 mg/ml, 10 ml, (Veterinary)	Eprinomectin 50 mg/ml, Injection	Anthelmintic	Infestations caused by external and internal parasites	Contraindication: Hypersensitivity Side-effects: Risk of bleedings, blood dyscrasias. Renal papillary necrosis. Warnings: Care should be taken concurrent use of other anticholinergic drugs. Precautions: Use in pregnancy has not been established.	New	টঝঋ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
50.	Navana Pharmaceuticals Limited	Metamizole 500 mg and hyoscine butylbromide 4 mg per ml, 10 ml, (Veterinary)	Metamizole 500 mg and hyoscine butylbromide 4 mg per ml, Injection	Antispasmolytic	Gastrointestinal and urogenital spasm	Contraindication: Hypersensitivity Side-effects: Risk of bleedings, blood dyscrasias. Renal papillary necrosis. Warnings: Care should be taken concurrent use of other anticholinergic drugs. Precautions: Use in pregnancy has not been established.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
51.	Navana Pharmaceuticals Limited	Metamizole 500 mg and hyoscine butylbromide 4 mg per	Metamizole 500 mg and hyoscine butylbromide 4 mg per	Antispasmolytic	Gastrointestinal and urogenital spasm	Contraindication: Hypersensitivity Side-effects: Restlessness and swelling at injection	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
		ml, 30 ml, (Veterinary)	ml, Injection			site. Warnings & Precaution: Before use this drug, ensure there is no mechanical obstruction.				
52.	Navana Pharmaceuticals Limited	Denaverine HCl 40 mg/ml, 10 ml, (Veterinary)	Denaverine HCl 40 mg/ml, Injection	Relaxant	Dystocia/facilitating parturition	**Contraindication:** Do not administer in cases of mechanical obstetrical disorders. Do not use in cases of hypersensitivity to the active substance or to any of the excipients **Side-effects**: No side effects have been observed at recommended dose. Warnings & Precaution: Should not consume meat untill 14 days after use the drug.	New	উগ উঅ	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
53.	Navana Pharmaceuticals Limited	Sulfadiazine 750 mg, sulfadimidine 750 mg, neomycin sulfate 250 mg, riboflavine 3 mg, thiamine hydrochloride 2 mg, hyoscine 1.52 mg per bolus, (Veterinary)	Sulfadiazine 750 mg, sulfadimidine 750 mg, neomycin sulfate 250 mg, riboflavine 3 mg, thiamine hydrochloride 2 mg, hyoscine 1.52 mg per bolus, Bolus	Antibiotic	Diarrhoea, Enteric disease	Contraindication: Hypersensitivity Side-effects: Local pain and swelling may be seen at injection site. Warnings: Efficacy in foot rot may be reduced due to wet environment condition. Precautions: Avoid direct contact in skin & eyes.	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
54.	Navana Pharmaceuticals Limited	Tulathromycin 100 mg and Ketoprofen 120 mg per ml, 10 ml (Veterinary)	Tulathromycin 100 mg and Ketoprofen 120 mg per ml, Injection	Antibiotic + Anti-Inflammatory 077	Bovine respiratory diseases, keratoconjunctivitis, foot rot etc.	Contraindication: Hypersensitivity to Tolathromycin &/or Ketoprofen. Side-effects: Transient pain reactions and local swellings at the injection site that can persist for up to 32 days. Warnings: Other macrolides or lincosamides should not be used simultaneously with this drug. Precautions: Intra-arterial and intra-venous injection should be avoided.		রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
55.	Navana Pharmaceuticals Limited	Paracetamol 400 mg/ml (Veterinary)	Paracetamol 1400 mg/ml, Solution	Antipyretic 077	Fever & pain	Contraindication: Hypersensitivity to paracetamol Side-effects: Transient soft faces may occur, but will resolve without any treatment. Warnings: In case of bacterial or viral infections, use anti-infective drug concomitantly. Precautions: Avoid direct contact in skin & eyes.	Existing molecule	টঝঋ উঅ	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
56.	Navana Pharmaceuticals Limited	Toltrazuril 36.4 mg and Iron gleptoferron 484.7 mg (equivalent to 182 mg iron) per ml (Veterinary)	Toltrazuril 36.4 mg and Iron gleptoferron 484.7 mg (equivalent to 182 mg iron) per ml, Solution	Anticoccidial 077	Coccidiosis	Contraindication: Hypersensitivity to Toltrazuril &/or Iron.Side-effects: Not known at recommended dose.Warnings: It is recommended to treat all animals/birds. For best results, treatment should be initiatedbefore the clinical signs of disease have spread throughout the whole groupPrecautions: Frequent and repeated use of active substances and under dosing can lead to the development of resistance.	Existing molecule	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।
57.	Eskayef Pharmaceutical	Neomycin Sulfate 5mg and Bacitracin	Neomycin Sulfate USP 5mg and	Antibiotic	Neomycin sulfate is a broad spectrum antibiotic effective against many Gram-	**CONTRAINDICATIONS:** It should not be used in animals with known	New	রেফারেন্স নাই	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা	প্রয়োজনীয় রেফারেন্স নাই বিধায় নামঞ্জুর করা হয়।

Sl. No	Name of the Manufacturer	Name of the Medicine	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	s Limited, Tongi, Gazipur.	Zinc 500 I.U/gm Ointment.	Bacitracin Zinc USP 500 I.U/gm .		positive and Gram-negative organisms, including *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Strep. pyogenes*, *E. coli* and some strains of *Proteus vulgaris*, *Pseudomonas aeruginosa* and certain *Actinomycetes*. Neomycin sulfate is not inactivated by bacteria or pus. Bacitracin (as the stable zinc salt) is active against many Gram-positive bacteria including *Staphylococci*, haemolytic and non-haemolytic *Streptococci*, *Clostridia* of the gas gangrene group and certain Gram-negative cocci. Unlike penicillin, bacitracin is not destroyed by Gram-negative bacteria and so can be used in certain mixed infections where penicillin would be inactivated. **WITHDRAWAL PERIOD:** Meat: 28 days after last administration Milk: 7 days after last administration	hypersensitivity. **SIDE EFFECTS:** Generally this preparation is well tolerated.			যেতে পারে।	
58.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Marbofloxacin 100mg Bolus	Marbofloxacin BP 100mg	Antibiotic	Bactericidal drug, actively killing bacteria by inhibiting bacterial DNA gyrase and the topoisomerase IV enzyme, thereby inhibiting DNA replication and transcription. Indicated for the treatment of following diseases caused by both gram positive, gram negative bacteria and mycoplasma. -Diarrhoea and gastro-enteritis - Severe respiratory infections - Neonatal gastro-enteritis caused by *Escherichia coli* **WITHDRAWAL PERIOD:** Meat: 6 days, Milk: 36 hours.	**CONTRAINDICATIONS:** Marbofloxacin is not recommended for use in the case of resistant bacteria to other Fluoroquinolones and in animals with known hypersensitivity to Marbofloxacin. **SIDE EFFECTS:** A greenish retroceding colouring of faeces at the end of treatment has sometimes been shown.	New	টঝখ উঅ	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Annex-F: Products List for Import (Veterinary)

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	Manufacturer: Sung-won Co. Ltd., Korea Local Agent: Fahat Trade International, 12/2 Purana Paltan Line, Dhaka	Danapen plus Powder	Florfenicol 50gm/Kg.	Antibacterial	Poultry For the treatment of Salmonellosis and Collibacillosis.	Contra indications Not to be used in boars intended for breeding purposes, or in animals producing eggs or milk for human consumption. Do not administer in cases of previous hypersensitivity to florfenicol. The use of Introflor-100 Oral during pregnancy and lactation is not recommended. The product should not be used or stored in galvanized metal watering systems or containers. Side effects A decrease in food and water consumption and transient softening of the faeces or diarrhoea may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment. In swine, commonly observed adverse effects are diarrhoea, peri-anal and rectal erythema/ oedema and prolapse of the rectum. These effects are transient.	New	Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
2.	Manufacturer: Daeho Co. Ltd., Korea Local Agent: Rafique Medicine, College Road, Ishurdi, Pabna	Aqua-Puri	Sodium Percarbonate (USP) 950 gm	**Antiinfectives and antiseptics**	Percarbonate in a gallon of warm or hot water. (2 oz per quart) Soaks: Mix 2 to 8 oz Percarbonate in a gallon of hot water. Paste: Mix 1 to 2 ounces of Percarbonate with just enough water to make a paste. To de-stain and deodorize carpet, start by mixing a general cleaning solution	The information in this database is intended to supplement, not substitute for, the expertise and judgment of healthcare professionals. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for you or anyone else. A healthcare professional should be consulted before taking any drug, changing any diet or commencing or discontinuing any course of treatment. Side effects Skin Diseases, Bacterial	New	Korea	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
3.	Manufacturer: Daeho Co. Ltd., Korea Local Agent: Rafique Medicine, College Road, Ishurdi, Pabna	W-puri	Bacillus Subtilis		In summary, many strains of **Bacillus subtilis** exhibit the ability to act as biocontrol agents against pathogenic fungi and thus can be used to suppress disease. Several mechanisms,	Contraindication can be described as a special circumstance or a disease or a condition wherein you are not supposed to use the drug or undergo particular treatment as it can harm the patient; at times, it can be dangerous and life threatening as well. When a procedure should not be combined with other procedure or when a medicine cannot be taken with another medicine, it is called Relative contraindication. Contraindications should be taken seriously as they are based on the relative clinical experience of health care providers or from proven	New	Korea	প্রয়োজন নাই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					both direct and indirect, are responsible for their ability to control pathogenic fungi.	research findings. More: https://www.ndrugs.com/?s=bacillus%20subtilis&t=side%20effects Side effects No side effects				
4.	Manufacturer: Atomes F.D. INC, Canada Local Agent: Bio Care Agro limited	Bioxy Enviro Liquid	Liquid polyquat Disinfectant 10% + Neutralized per acid 20%	**disinfectant**	Remove all litter and manure from floor, wall and other surfaces for barns and equipment.	Contra indications : No Contra indications Side effects : No side effects	New	Canada	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
5.	Manufacturer: Samu Median Co. Ltd. 235-15 Chusa-ro Sinam- myeon, Yegan-gum Chungcheongnam-do 340-861 South Korea Local Agent: (VnF Agra Limited House No. 306/26 Amirabad , Mashkanda, Mymensingh)	CEFABEE Ointment	Cefuroxime Sodium 250 mg (base) /3g Ointment	Antibiotic	Prevention and treatment of bovine mastitis for milking period.	**Contraindication** Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. This medication may interfere with certain lab tests (including certain urine glucose tests), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug. **Side Effects** Swelling, redness, or pain at the injection site may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: easy bruising/bleeding, unusual tiredness, uncontrollable movements, mental/mood changes (such as confusion), seizures, signs of kidney problems (such as change in the amount of urine), signs of liver problems (such as nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine).	**Existing** Cefuroxime Sodium Ointment-Form-G bvB|	**South Korea**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Tell your doctor right away if you develop: diarrhea that doesn't stop, abdominal or stomach pain/cramping, blood/mucus in your stool.				
6.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis MS Live (Vet)**	Live Mycoplasma synoviae strain MS1: ($10^{6.5}$- $10^{8.0}$ CFU/dose)	Vaccine	For active immunisation of chickens to reduce clinical signs and egg production loss by M. synoviae infection.	**Contraindication:** None **Side-effect:** None Known **Drug Interaction :** Administration of anti *Mycoplasma* drug within five days prior to or two weeks after vaccination, may be detrimental to the vaccine strains. Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered from six weeks of age with Nobilis MG 6/85. This product literature of Nobilis MG 6/85 should be consulted before administration of the mixed product. The mixed product is not to be used within four weeks of onset of egg production or during lay. The Nobilis MS Live vaccine strain may spread from vaccinated to unvaccinated chickens in case it is used mixed with Nobilis MG 6/85. Withdrawal Period: Zero **Days**	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
7.	Manufacturer: Intervet Inc 411 West Delaware Avenue, Millsboro, DE 19966, USA Distribution Center: Intervet Inc. Omaha, NE 68103, USA Local Agent: Bengal Overseas Ltd.;	**Coccivac-D2 (Vet)**	Coccidiosis Vaccine, Live Oocysts/ dose of the following species of coccidian : Eimeria Acervulina 600, Eimeria Brunetti 200, Eimeria Maxima 200, Eimeria Mivati 400, Eimeria Necatrix 400, Eimeria Tenella 200	Vaccine	For vaccination of healthy chickens at one day of age by spray administration or at 4 days of age on the feed as an aid in the prevention of coccidiosis.	**Contraindication:** None **Side-effect:** None Known **Withdrawal Period:** 21 days **Drug Interaction:** This product is not ordinarily recommended for use with pre starter or starter feeds containing coccidiostats.	New	USA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.									
8.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis Rhino CV (Vet)**	Live attenuated avian rhinotracheitis virus strain TRT 11/94: At least $10^{1.5}$ $TCID_{50}$ per dose	Vaccine	For active immunisation of chickens to reduce infection with avian rhinotracheitis virus (avian pneumovirus) and to reduce clinical signs and effects of the disease caused by the virus. **Broiler chickens** Studies in chickens with and without high levels of maternally derived immunity have shown that vaccination with the product from one day of age results in a strong reduction of virus excretion and of the respiratory signs caused by infection with virulent avian rhinotracheitis virus of various antigenic categories. Protective immunity is maintained for the lifetime of the broiler birds. **Laying chickens (breeders, layers):** Studies in laying birds have shown that the product effectively primes for subsequent vaccination with inactivated avian rhinotracheitis virus vaccine, e.g. -Nobilis RT inac" or any other of Intervet's inactivated	**Contraindication:** None **Side-effect:** Vaccination with Nobilis Rhino CV may occasionally cause slight nasal discharge in some chicken. **Withdrawal Period: Zero Days** **Drug Interaction :** Nobilis Rhino CV can be given simultaneously with Itervet's live vaccines against infectious bronchitis containing the H120 or Ma5 strain, and with Intervet's live vaccines against Newcastle disease containing the Clone 30 or C2 strain. Intervet's vaccine against Gumboro disease (infectious bursal disease) containing strain D78 can be administered 7 days after Nobilis Rhino CV and Intervet's Infectious Bronchitis vaccine containing strain 4/91 can be administered 14 days after Nobilis Rhino CV.	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					poultry vaccines containing the avian rhinotracheitis component. The combination of priming at younger age with live Nobilis Rhino CV vaccine and booster vaccination with inactivated avian rhinotracheitis vaccine shortly before onset of lay results in complete protection against the negative effects on egg production and egg quality exerted by infection with virulent avian rhinotracheitis virus during lay. Protective immunity is maintained for the whole normal laying period					
9.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis Influenza H9N2 (Vet)**	Inactivated Avian Influenza Virus H9N2, strain AG415: inducing per dose ≥ 7.0 $\log_2$ HI units.	Vaccine	Nobilis Influenza H9N2 is meant to be used for active immunisation of healthy poultry as an aid in the control of Avian Influenza type A subtype H9.	**Contraindication:** None **Side-effect:** In healthy animals no clinical reactions. Slight transient reactions at the site of injection may occur. **Withdrawal Period: Zero Days** **]Drug Interaction :**This product is not ordinarily recommended for use with prestarter or starter feeds containing coccidiostats.	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
10.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent:	**Nobilis Influenza H9N2+ND (Vet)**	Inactivated Avian Influenza Virus H9N2, strain AG415: inducing per dose ≥ 7.0 $\log_2$ HI units and Inactivated Newcastle Disease Virus, strain Clone 30: inducing ≥ 4.0 $\log_2$ HI units per 1/50 dose or containing ≥ 50 PD_{50} units per dose.	Vaccine	Nobilis Influenza H9N2+ND is meant to be used for active immunisation of healthy poultry as an aid in the prevention of Avian Influenza type A subtype H9 and Newcastle	**Contraindication:** None **Side-effect:** In healthy animals no clinical reactions. Slight transient reactions at the site of injection may occur. **Withdrawal Period: Zero Days** **Drug Interaction :**This product is not ordinarily recommended for use with prestarter or starter feeds containing coccidiostats.	New	The Netherlands	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.				Disease.					
11.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis AE + POX (Vet)**	Each vial contains per dose at least 1.8 log_{10} EID_{50} of live avian encephalomyelitis virus, strain Calnek and at least 1.8 log_{10} EID_{50} of live avian fowl pox virus strain Gibbs	Vaccine	For the vaccination of chickens and turkeys against AE and foul pox.	**Contraindication:** None **Side-effect:** None **Withdrawal Period:** None **Drug Interaction :** None **Use in Pregnancy and Lay:** Do not vaccinate within 28 days of the onset of lay and during the laying period.	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
12.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis Salenvac ETC (Vet)**	Each dose of per ml contains: Inactivated Salmonella Enteritidis, strain PT 4 ≥1.0RP Inactivated Salmonella Typhimurium, strain DT104 ≥1.0RP Inactivated Salmonella Infantis, strain A, S03499-06 ≥1.0RP	Vaccine	For the active immunisation of chickens to reduce colonisation and faecal excretion of S. Enteritidis (serogroup D) , S. Typhimurium and S. Heidelberg (serogroup B), S. Infantis, S. Hadar and S. Virchow (serogroup C). Onset of immunity: 4 weeks after the second administration. Duration of immunity: 90 weeks after the second administration.	**Contraindication:** None **Side-effect:** Vaccination may very commonly result in small (up to 8 mm in size) and transient palpable nodules at the injection site. These nodules completely disappear within 2 weeks after the second vaccination. **Withdrawal Period:** None **Drug Interaction:** No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis. **Use in Pregnancy and Lay:** Do not use in birds in lay.	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
13.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th	**Nobilis Influenza H5N2 (Vet)**	Inactivated Avian Influenza Type A; Subtype H5N2 Inducing HI titre at least 6.0 log_2/ dose	Emulsion for SC or IM injection	Nobilis Influenza H5N2 is meant to be used for active immunisation of healthy poultry as an aid in the control of Avian Influenza type A subtype H5.	**Contraindication:** None **Side-effect:** None **Withdrawal Period:** None **Caution:** Use the content within 8 hours after opened. This is a water-in-oil emulsion vaccine. In case of self injection please follow the instruction given in the leaflet	New	The Netherlands	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Floor) 5, Mohakhali C/A, Dhaka-1212.									
14.	Manufacturer: Intervet International GmbH Feldstraβe 1a D-85716 Unterschleiβheim, Germany Marketing Authorization/ Supplier: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Cobactan LC (Vet)**	Cefquinome-75mg (as Cefquinome Sulphate 88.8-96.8mg) per 8gm Injector (Ointment)	Antibiotic	For the treatment of clinical mastitis in the lactating dairy cow caused by the following cefquinome sensitive organisms: *Streptococcus uberis, Streptococcus dysgalactiae*, *Staphylococcus aureus* and *Escherichia coli*.	**Contraindication:** Not to be administrated to the animals which are known to be hypersensitive to cephalosporin antibiotics and other β-lactam antibiotics. **Side-effect:** In very rare case anaphylactic reactions have been noted in animal after administration of the products. **Withdrawal Period:** Meat and offal :2 days Milk : 84 Hours **Pharmaceutical Form:** Intramammary Ointment (Oily Suspension)	New	Germany	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
15.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis IB multi + ND + EDS (Vet)**	Inactivated Infectious Bronchitis Virus (Serotype Massachusetts) strain M41:Inducing ≥4.0 log_2 VN units/dose + Inactivated Infectious Bronchitis Virus strain 249G (Serotype D274) : Inducing ≥4.0 log_2 VN units/dose + Inactivated Newcastle Disease Virus, Strain clone 30: Inducing ≥ 4.0 log_2 HI units per 1/50 dose or containing ≥50 PD_{50} units/dose + Inactivated EDS' 76 strain BC 14 : Inducing at least 6.5 log_2 HI units/ dose	Vaccine	Vaccination of breeder and layer for protection against the Massachusetts and D207/D274 serotypes of Infectious Bronchitis Virus, Newcastle Disease virus and Egg Drop Syndrome virus.	**Contraindication:** Vaccinate only healthy animals **Side-effect:** A slight transient swelling may be felt at the site of vaccination. **Withdrawal Period:** Zero Days	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
16.	Manufacturer: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands	**Nobilis IB multi + ND (Vet)**	Inactivated Infectious Bronchitis Virus (Serotype Massachusetts) strain M41:Inducing ≥4.0 log_2 VN units/dose + Inactivated Infectious Bronchitis Virus strain 249G (Serotype D274) : Inducing ≥4.0 log_2 VN units/dose + Inactivated Newcastle Disease Virus,	Vaccine	Vaccination of chickens against disease caused by infectious Bronchitis viruses of types covered by the vaccine strains and Newcastle Disease virus.	**Contraindication:** None **Side-effect:** In healthy animals no clinical reactions. Slight swelling at the sight of injection for some weeks after vaccination is occasionally observed. **Withdrawal Period:** Zero Days	New	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.		Strain clone 30: Inducing ≥ 4.0 log_2 HI units per 1/50 dose or containing ≥50 PD_{50} units/dose							
17.	Manufacturer: Intervet Productions S.A; Rue de Lyons, 27460, Igoville, France Marketing authorization: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands Local Agent: Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**EXZOLT (Vet)**	Fluralaner10mg per ml Oral Solution	Systemic Insecticide	Treatment and control of poultry Red Mite (Dermanyssusgallinae) or Northern Fowl Mite (Ornithonyssussylviarum) infestation in pullets, breeders and layer hens.	**Contraindication:** None **Side-effect:** None Known **Withdrawal Period:** Meat and offal- 14 days Eggs- Zero days.	New	France/ EMA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
18.	Manufacturer:Ewhapharmtek Corp. 80, Donyu3-Ro, Munsan-Eup, Paju-Si, Gyeonggi-Do Korea. Local Agent: Fahat Trade International,12/2 Purana Platon Line,Dhaka-1000	Levocin 20 Oral Solution	Each Liter Contains Levofloxacin hydrate-200.0g	Antibiotics	For the treatment against the following diseases by susceptible bacteria (E.coli,Salmonella, Mycoplasma, Pasteurella, Staphylococcus, Haemophilus).Chicken: Chronic Respiratory Disease, Complex Chronic Respiratory Disease, Colibacillosis, Salmonellosis, Fowl Cholera, Infectious Coryza, Staphylococcosis.	Hypersensitivity to the active substance, any other quinolone.Patients with epilepsy, patients with history of tendon disordersrelated to fluoroquinolone administration, young and growing animals, During pregnancy, period of lactation and withdraw period 28 days.	New	South Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
19.	Manufacturer:ADBIOTECH CO., LTD. 39, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24398, South Korea Local Agent: Novivo Healthcare Ltd. 68/5, Green Road, Dhanmondi, Dhaka-1205	AD-LincoSpec W.S.P. Water Soluble Powder **(Vet)**	Each Kg Contains Lincomycin Hydrochloride USP 222g Spectinomycin Sulfate EP 445g	Antibiotics	To prevent and treat CRD, CCRD, colibacillosis and staphylococcosis diseases in poultry. To prevent and treat swine dysentery, colibacillosis, vibrio gastroenteritis, pneumoniae, arthritis, bacterial diarrhea, salmonellosis, atrophic rhinitis, swine erysipelas, septic enteritis and septic arthritis	Never use it on animals showing sensitivity or shock against Lincomycin HCL and or Specinomycin Sulfate May cause watery feces or skin-flare after administration. However this is cured spontaneously.	New	South Korea	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
20.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road, Lane 13, New DOHS, Mohakhali, Dhaka - 1206	MEDIVAC ND LA SOTA Injection **(Vet)**	Each dose contains at least $10^{7.0}$ EID_{50} Newcastle disease Live vaccine, La Sota strain.	Poultry Vaccine	Medivac ND La Sota is indicated against Newcastle Disease in broilers, native chickens, layers and breeders	Do not vaccinate sick chickens because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
21.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road,	MEDIVAC GUMBORO B Oral drop or drinking water **(Vet)**	Each dose contains at least $10^{3.5}$ $TCID_{50}$ of Infectious Bursal Disease Virus of D22 Strain (Infectious bursal disease / Gumboro disease Live vaccine, D22 strain)	Poultry Vaccine	Medivac Gumboro B is indicated for protection against IBD/ Gumboro disease in broilers, native chickens, layers and breeders 10 days of age or older	Do not vaccinate sick chickens because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Lane 13, New DOHS, Mohakhali, Dhaka - 1206									
22.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road, Lane 13, New DOHS, Mohakhali, Dhaka - 1206	MEDIVAC ND-IB Eye/Nose drop or drinking water **(Vet)**	Each dose contains at least $10^{7.0}$ EID_{50} Newcastle Disease virus of Clone 45 strain and $10^{3.5}$ EID_{50} Infectious Bronchitis virus of H-120 Massachusetts strain (Newcastle disease Clone 45 strain and Infectious Bronchitis Massachusetts 120 strain, live vaccine.)	Poultry Vaccine	Medivac ND-IB is indicated for first vaccination and revaccination against ND and IB in broilers, native chickens, layers and breeders	Do not vaccinate sick chickens because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
23.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road, Lane 13, New DOHS, Mohakhali, Dhaka - 1206	MEDIVAC ND EMULSION Injection vaccine **(Vet)**	Each dose contains at least $10^{7.0}$ EID_{50} Newcastle Disease (ND) virus of La Sota strain (Newcastle disease La Sota strain, inactivated water-in-oil emulsion vaccine.)	Poultry Vaccine	Medivac ND Emulsion is indicated for prevention against Newcastle disease (ND) in broilers, native chickens, layers and breeders	Do not vaccinate sick chickens because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
24.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd.	MEDIVAC CORYZA B Injection vaccine **(Vet)**	Each dose contains at least 3×10^{8} CFU of each Avibacterium Paragallinarum of W and Modesto strain (Inactivated Avibacterium paragallinarum of W and Modesto strain)	Poultry Vaccine	Medivac Coryza B is indicated for protection against infectious coryza in broilers, layers, breeders and native chickens	Do not vaccinate sick chickens because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	H212, Lake Road, Lane 13, New DOHS, Mohakhali, Dhaka - 1206									
25.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road, Lane 13, New DOHS, Mohakhali, Dhaka - 1206	MEDIVAC GUMBORO A oral drop or drinking water **(Vet)**	Each dose contains at least $10^{2.0}$ EID_{50} of IBD virus Cheville (1/68) strain (Infectious bursal disease / Gumboro disease live vaccine, Cheville (1/68) strain)	Poultry Vaccine	Medivac Gumboro A is indicated for protection against IBD / Gumboro disease in broilers, native chickens, layers and breeders. Medivac Gumboro A may be given to chicks at 7 days old that have high maternal antibody level	Do not vaccinate sick chicken because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
26.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road, Lane 13, New DOHS, Mohakhali, Dhaka - 1206	MEDIVAC ND-IB-GUMBORO EMULSION Inactivated water-in-oil emulsion vaccine I/M; S/C **(Vet)**	Each dose contains at least $10^{7.0}$ EID_{50} of ND virus of LA SOTA Strain , $10^{4.5}$ EID_{50} IB virus of Massachusetts 41 Strain and $10^{4.5}$ EID_{50} IBD / Gumboro disease virus of Winterfield 2512 Strain (Newcastle disease (ND) La Sota strain, infectious bronchitis (IB) Massachusets 41 strain & infectious bursal disease (IBD) / Gumboro disease Winterfield 2512 strain, inactivated water-in-oil emulsion vaccine)	Poultry Vaccine	Medivac ND-IB-Gumboro Emulsion is indicated for prevention against ND, IB and IBD/Gumboro disease in broilers, native chickens, layers and breeders.	Do not vaccinate sick chicken because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
27.	Manufacturer:PT Medion Farma Jaya, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Local Agent: Novivo Healthcare Ltd. H212, Lake Road,	MEDIVAC ND CLONE 45 Freeze-dried live vaccine May be administered through eye/ nose drop, drinking	Each dose contains at least $10^{7.0}$ EID_{50} ND virus of Clone 45 strain (Newcastle disease live vaccine, Clone 45 strain)	Poultry Vaccine	Medivac ND Clone 45 is indicated for against ND in broilers, native chickens, layers and breeders	Do not vaccinate sick chickens because it cannot achieve optimum antibody level	New	Singapore	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Lane 13, New DOHS, Mohakhali, Dhaka - 1206	water or injection I/M on thigh or breast or S/C (under the skin) at the lower back of the neck) **(Vet)**								
28.	Manufacturer : M/s. Interchemie werken "De Adelaar" Eesti AS, Estonia Local Agent : M/s. BIOLAB, House No. 10, Road No. 3/A, Sector-09, Uttara, Dhaka, Bangladesh	Imochem Solution for injection	Imidocard (as dipropionate) 85mg/ml	Antiprotozoals – carbanilides.	Imochem contains imidocarb, a diamidine of the carbanalide series of antiprotozoal compounds, and is indicated for treatment and prophylaxis of babesiosis in cattle, for treatment of babesiosis and anaplasmosis in sheep, for treatment of babesiosis in horses and dogs and for treatment of anaplasmosis in cattle	Contraindications Administration to animals with known hypersensitivity to the active ingredient. Administration to animals exposed to cholinesterase-inhibiting drugs or pesticides. Administration via the intravenous route. Administration to ewes producing milk for human consumption. Administration to animals with impaired renal and/or hepatic functions.	Existing Imidocard 120mg/ml (DCC-238) Imidocard 9.35mg/ml (DCC-238)	Estonia	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
29.	Manufacturer : M/s. Interchemie werken "De Adelaar" Eesti AS, Estonia Local Agent : M/s. BIOLAB, House No. 10, Road No. 3/A, Sector-09, Uttara, Dhaka, Bangladesh	Doxy 200 WS Powder for Oral Solution	Doxycycline Hyclate Ph. Eur. 200mg/gm	Antibiotic	Gastrointestinal and respiratory infections caused by doxycycline sensitive micro-organisms, like Bordetella, Campylobacter, Chlamydia, E. coli, Haemophilus, Mycoplasma, Pasteurella, Rickettsia, Salmonella, Staphylococcus and Streptococcus spp., in calves, goats, poultry, sheep and swine.	Contraindication Hypersensitivity to tetracyclines. Administration to animals with a seriously impaired liver function. Concurrent administration with penicillines, cephalosporines, quinolones and cycloserine. Administration to animals with an active microbial digestion. Side-effect : Discoloration of teeth in young animals. Hypersensitivity reactions.	Doxycycline 100 mg/gm Powder-DCC-238 Doxycycline 5% Powder for Solution -DCC-206	Estonia	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
30.	Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston, Lancashire, PR58AH, England Local Agent: Renata Limited Mirpur, Dhaka	Masocare 1:4 Teat Dip & Teat Spray Solution	Iodine Ph. Eur 2.72 w/v	Disinfectants	To be applied diluted by dipping or spraying to dairy cows' teats immediately after milking, as an aid in the control of mastitis in lactating dairy cows, and as an aid in the prevention and healing of cracked and chapped teats	Contraindication : None identified. Side-effect : None known	Existing 2.75% w/w as Disinfectants	UK	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
31.	Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston, Lancashire, PR58AH, England Local Agent: Renata Limited Mirpur, Dhaka	Masofilm Teat Dip & Spray Solution	Iodine Ph. Eur 0.282 w/v	Disinfectants	DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking. Manual dipping - Post-milking application Apply after each milking every day (1-3 times a day).For manual application ensure full teat is covered and the animal stands for 5 minutes. Manual dipping •cows and buffaloes: 10 ml/animal per treatment •sheep: 5 ml/animal per treatment •goats: 6 ml/animal per treatment	Contraindication : None identified. Side-effect : None known	Existing 2.75% w/w as Disinfectants	UK	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
32.	Evans Vanodine International Plc. Brierley Road, Walton	Masocare RTU (Ready to Use) Teat Dip & Spray	Iodine Ph. Eur 0.535 w/v	Disinfectants	To be applied undiluted, by dipping or spraying to dairy cows' teats	Contraindication : None identified. Side-effect : None known	Existing 2.75% w/w as Disinfectants	UK	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Summit, Preston, Lancashire, PR58AH, England Local Agent: Renata Limited Mirpur, Dhaka	Solution			immediately after milking as an aid in the control of mastitis in lactating dairy cows,and as an aid in the prevention and healing of cracked and chapped teats.					
33.	Manufacturer: V.M.D. nv, Belgium Local Agent: Inter Agro BD Ltd. 718/A, 1st Floor, West Nakalpara Tejgoan, Dhaka	Doxyvet$_{D}$-Citrix Oral powder	Doxycycline hyclate 500 mg, equivalent to 433 mg doxycycline/gm	Antibiotic	Treatment of below mentioned infections of therespiratoryand gastrointestinal tractcaused bymicro-organismssensitive todoxycycline. Pre-ruminant calves: - Bronchopneumoniaandpleuropneumoniacaused by Pasteurellaspp, Streptococcusspp,Truperellapyogenes,HistophilussomniandMycoplasmaspp.. Pigs: -Atrophicrhinitis causedby Pasteurella multocidaandBordetellabronchiseptica; - Bronchopneumoniacaused by Pasteurellamultocida,StreptococcussuisandMycoplasmahyorhinisPleuropneumoniacaused by Actinobacillusspleuropneumoniae. Chickens:	**Contraindications** Do not use in cases of hypersensitivity to tetracyclines or to any of the excipients. Do not use in animals with serious liver or kidney deficiency. Do not use in ruminating cattle Special warnings for each target species None. **Withdrawal period(s)** Calves Meat and offal: 7 days Not authorised for use in animals producing milk for human consumption. Pigs Meat and offal: 8 days Chicken Meat and offal: 5 days Not for use in birds producing or intended to produce eggs for human consumption	Existing Doxycycline 100 mg/gm Powder DCC-238 Doxycycline Hydrochloride 25% + Tylosin Tartrate 20% Powder DCC-232	Belgium	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					-Respiratory infectionscaused by Mycoplasmaspp, Escherichiacoli,Haemophilusparagallinarumand Bordetellaavium; -Enteritis caused byClostridiumperfringens andClostridiumcolinum.					
34.	Manufacturer: Lohmann Animal Health International, 375 China Road, Winslow, Maine 04901 USA Importer: Elanco Bangladesh Limited Praasad Trade Center, 11th Floor),6 Kemal Ataturk Avenue, Banani Dhaka-1213 Bangladesh	AviPro ND Visota Vaccine	Quantity/vial (2500 Dose) Newcastle Disease Vaccine (NDV), B1 type, LaSota Strain Live Virus ≥ $10^{8.9}$ EID_{50} /Vial	Vaccine	**Indications:** Recommended for the vaccination of chickens as an aid in the prevention of Newcastle disease. This product is for initial vaccination of chickens at 2 weeks of age or older by the drinking water route, or at 5 weeks of age or older by the coarse spray (aerosol) route. This product can be used in replacement birds before 16 weeks of age that were previously vaccinated. Onset of immunity: 21 days following drinking water vaccination and 26 days following coarse spray (aerosol) vaccination	**Contraindication:** Do not use in clinically ill or weakened animals. **Side Effects:** None known **Withdrawal Period:** Do not vaccinate within 21 days before slaughter. **Target Species:** Chickens	New	USA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
35.	Manufacturer: Lohmann Animal Health International,	AviPro ND-IB-Polybanco Vaccine	**Quantity/vial(2500 Dose)** Newcastle Disease Virus (NDV), BI	Vaccine	Recommended for the vaccination of chickens as an aid in the	**Contraindication:** Do not use in clinically ill or weakened animals.	New	USA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	375 China Road, Winslow, Maine 04901 USA Importer: Elanco Bangladesh Limited Praasad Trade Center, 11th Floor),6 Kemal Ataturk Avenue, Banani Dhaka-1213 Bangladesh		type, Bl Strain $\geq 10^{8.9}$ EID_{50} + Infectious bronchitis virus(IBV), Mass. type, M-48 Strain $\geq 10^{6.5}$ EID_{50} + Infectious bronchitis virus(IBV), Conn. Type $\geq 10^{6.5}$ EID_{50}		prevention of Newcastle disease and infectious bronchitis, Mass. and Conn. types. This product is for initial vaccination of chickens at 5 weeks of age or older. Onset of immunity for Newcastle disease: 4 weeks following vaccination Onset of immunity for infectious bronchitis: 3 weeks following vaccination.	**Side Effects:** None known **Withdrawal Period:** Do not vaccinate within 21 days before slaughter. . **Target Species**: Chickens				
36.	Manufacturer: Lohmann Animal Health GmbH Heinz-Lohmann-Str. 4, 27472 Cuxhaven Germany Importer: Elanco Bangladesh Limited Praasad Trade Center, 11th Floor),6 Kemal Ataturk Avenue, Banani Dhaka-1213 Bangladesh	AviPro Precise Vaccine	**Each dose contains:** Live Infectious Bursal Disease (IBD) Virus, Strain LC 75 $\geq 10^{3.0}$ EID_{50}		**Indications:** For active immunization of susceptible chickens against infectious bursal disease (IBD/Gumboro). The vaccine reduces clinical signs of IBD, severe bursal lesions and mortality. Onset of immunity: within 2 weeks. Duration of immunity in broilers: at least 4 weeks Duration of immunity in layers. at least 15 weeks	**Contraindication:** Do not use in clinically ill or weakened animals. **Side Effects:** On day 7 post vaccination moderate generalized lymphocyte depletion is seen in the majority of birds. Lymphocyte repopulation occurs after day 7 post vaccination and by day 28 post vaccination only mild necrosis remains in some birds.. **Withdrawal Period:** Zero Days **Target Species**: Chickens	New	Germany	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
37.	CEVA-PHYLEXIA Veterinary Biologicals Co. Ltd. 1107 Budapest, Szallas u. 5 Hungary (ACI Ltd.)	Novamune Live, Frozen, Immune Complex Vaccine 500 ds, 1000 ds & 2000 ds/Vial	Avian Infectious Bursal Virus Strain SYZA26……min 2.65 log10 CID_{50}/Dose	Vaccine	Live viral vaccine in immune complex to stimulate active immunity against infectious bursal disease (IBD) viruses.	**Contraindication:** Do not vaccinate chickens from non-vaccinated parent flocks or having no MDA against IBD virus. **Side effects:** Mild or moderate lymphocyte depletion can be observed after the vaccine take, which is maximal at around 7 days. This depletion decreases and is followed by lymphocyte repopulation and regeneration of the bursa of fabricius.	New	HUNGARY	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
38.	CEVA-PHYLEXIA Veterinary Biologicals Co. Ltd. 1107	Cevac New Flu H9 K Inactivated	(Inactivated Newcastle disease virus (strain LaSota)….min. 32HI.U + Inactivated Avian Influenza virus	Vaccine	Cevac New Flu H9 K is recommended for the vaccination of chickens	**Contraindication:** No Contraindications are known. **Side effects:**	New	HUNGARY	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Budapest, Szallas u. 5 Hungary (ACI Ltd.)	Vaccine, 500ml/Vial	(strain H9N2)….min. 256 HI.U)/Dose		against H9N2 sub-type-A Avian Influenza and against Newcastle Disease (ND)	No undesirable effects are known.				
39.	Manufacturer: Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI "ARRIAH"), Russia. 600901 Yur'evets Vladimir, Russia Importer: One Pharma Ltd. House: 09 & 11, Road: 6/A, Block: B, Nobodoy Housing, Adabor, Dhaka, Bangladesh; Factory: Plot No.: C23-24, BSCIC Industrial Area, Fulbari, Bogura, Bangladesh	ARRIAH PPR (Vet)	Virus vaccine against peste des petits ruminants (PPR) cultural dry. Injectable Vaccine (Subcutaneous)	Vaccine	The vaccine is intended for prevention of peste des petits ruminants in affected farms and farms under threat	**Contraindications:**It is prohibited to inoculate animals with other immunobiologicals and medicinal preparations within 5 days before and after the use of virus vaccine. It is prohibited to use chemotherapeutical means (antibiotics, sulfanilamides, nitrofuran and other preparations) 1-2 days before the vaccination and in 5-7 days after its carrying out. **Side Effects:** 4-6 days after vaccination indurations 1-5 cm in diameter may occur at the injection sites of some animals. They disappear 3-14 days after the formation. Temperature rise up to 40.6-41.5˚C 4-6 days after vaccination is acceptable. It does not considerably influence on their general state. **Withdrawal Period:** None	New	Russia / Italy	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
40.	Manufacturer: Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI "ARRIAH"), Russia. 600901 Yur'evets Vladimir, Russia Importer: One Pharma Ltd. House: 09 & 11, Road: 6/A, Block: B, Nobodoy Housing, Adabor, Dhaka,	ARRIAH SHIPPOX-LSD VAC (Vet)	Culture dry virus vaccine against sheep pox and lumpy skin disease SheepPox-LSD Injectable Vaccine (Subcutaneous)	Vaccine	The vaccine is used for prophylaxis of sheep pox and cattle infectious nodular dermatitis (lumpy skin disease) in unfavorable and threatening farms on these diseases	**Contraindications:**Contra-indication not observed **Side Effects:** No major side effect observed. Sometime the site of injection may swell. **Withdrawal Period:** None	New	Russia / Italy	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Bangladesh; Factory: Plot No.: C23-24, BSCIC Industrial Area, Fulbari, Bogura, Bangladesh									
41.	Manufacturer: Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI "ARRIAH"), Russia. 600901 Yur'evets Vladimir, Russia Importer: One Pharma Ltd. House: 09 & 11, Road: 6/A, Block: B, Nobodoy Housing, Adabor, Dhaka, Bangladesh; Factory: Plot No.: C23-24, BSCIC Industrial Area, Fulbari, Bogura, Bangladesh	GUMBOROMIX (Vet)	Virus vaccine against infectious bursal disease live, dry (IBD) Oral, dry homogenous porous mass	Vaccine	Gumboroix vaccine is intended for infectious bursal disease prevention in chickens of different types kept on IBD- free infected poultry farms as well as kept on farms located in zones at IBD risk	**Contraindications:**The birds shall not be vaccinated with vaccines against other infectious avian diseases within 5 days before and after vaccination against IBD. The virus vaccine shall not be used in combination with any drugs. **Side Effects:**The vaccine is safe and induce no adverse effects providing that it is administered at prescribed doses to clinically healthy poultry.No IBD-characteristic signs or other pathological signs were detected after the virus vaccine administration. The vaccine overdosing does not induce any signs of infectious bursal disease or other pathological signs. It is recommended to strictly observe zoo hygienic standards for poultry management and feeding, increase water intake as well as A, C and E vitamin contents in the poultry diet. **Withdrawal Period:** None	New	Russia / Italy	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
42.	Manufacturer: Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI "ARRIAH"), Russia. 600901 Yur'evets Vladimir, Russia Importer: One Pharma Ltd. House: 09 & 11, Road: 6/A, Block: B,	ARRIAH H5N1+ND (Vet)	Combined Inactivated emulsion vaccine against avian influenza (H5N1) and Newcastle disease Injectable Vaccine (Intramuscular)	Vaccine	The vaccine is intended for the prevention of H5 avian influenza and Newcastle disease in chicken kept on backyards or in zones at high	**Contraindications:**Contra-indication not observed **Side effects:** No major side effect observed. Sometime the site of injection may swell. **Withdrawal Period:** None	New	Russia / Italy	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Nobodoy Housing, Adabor, Dhaka, Bangladesh; Factory: Plot No.: C23-24, BSCIC Industrial Area, Fulbari, Bogura, Bangladesh									
43.	Manufacturer: Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI "ARRIAH"), Russia. 600901 Yur'evets Vladimir, Russia Importer: One Pharma Ltd. House: 09 & 11, Road: 6/A, Block: B, Nobodoy Housing, Adabor, Dhaka, Bangladesh; Factory: Plot No.: C23-24, BSCIC Industrial Area, Fulbari, Bogura, Bangladesh	ARRIAH H9N2+ND (Vet)	Combined Inactivated emulsiion vaccine against H9N2 avian influenza and Newcastle disease Injectable Vaccine (Intramuscular)	Vaccine	The vaccine is intended for the prevention of H9N2 avian influenza and Newcastle disease in chicken kept on backyards or in zones at high	**Contraindications:**Contra-indication not observed **Side effects:** No major side effect observed. Sometime the site of injection may swell. **Withdrawal Period:** None	New	Russia / Italy	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।
44.	Laboratorios Hipra S.A., Spain Local Agent: Nasco Agro Product Every Scale Building (2nd floor), SK. Mujib Road, Agrabad, Chittagong	HIPRAVIAR-ND BROILERS 2500 dose/bottle	Inactivated Newcastle Disease Virus, strain La Sota……IHA≥ 1/16 per dose	Vaccine	To prevent Newcastle Disease In Broiler Chicken.	**Contraindications**: No contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
45.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	HIPRAVIAR-SHS 1000 dose/vial 5000 dose/vial	Rhinotracheitis virus of turkey, live attenuated, strain 1062…..... $10^{2.4}$ – $10^{4.4}$ $CCID_{50}$ per dose	Vaccine	To prevent Turkey Rhinotracheitis (TRT) and Swollen head syndrome (SHS) in chickens, layers and breeders, and turkeys.	**Contraindications**: No contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
46.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	GUMBOHATCH 1000 dose/vial 2000 dose/vial 2500 dose/vial 4000 dose/vial 5000 dose/vial with Solvent for Gumbohatch	Live attenuated Infectious Bursal Disease Virus, strain 1052…… Between 10exp. 1.48 and 10exp. 2.63 PU per dose	Vaccine	Immunocomplex vaccine to prevent Avian infectious bursal disease virus (IBDV) in chickens.	**Contraindications**: No contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
47.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	EVANT 1000 dose/vial 5000 dose/vial 10000 dose/vial With HIPRAMUNE T (solvent)	Each dose (0.007 ml) of undiluted vaccine contains: Eimeria acervulina, strain 003, 332 – 450* Eimeria maxima, strain 013, 196 – 265* Eimeria mitis, strain 006, 293 – 397* Eimeria praecox, strain 007, 293 – 397* Eimeria tenella, strain 004, 276 – 374* per dose * Number of sporulated oocysts derived from precocious attenuated lines of coccidia, according to in vitro procedures of the manufacturer at the time of blending.	Vaccine	For the active immunization of **broiler** chicks from 1 day of age against coccidiosis caused by Eimeria acervulina, Eimeria maxima, Eimeria mitis, Eimeria praecox and Eimeria tenella to reduce typical signs of disease, intestinal lesions and oocysts output.	**Contraindications**: No contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
48.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	EVALON 1000 dose/vial 5000 dose/vial 10000 dose/vial With HIPRAMUNE T (solvent)	Each dose (0.007 ml) of undiluted vaccine contains: Eimeria acervuline, strain 003, 332-450 sporulated oocysts Eimeria brunetti, strain 034, 213-288 sporulated occysts Eimeria maxima, strain 013, 196-265 sporulated oocysts Eimeria necatrix, strain 033, 340-460 sporulated oocysts Eimeria tenella, strain 004, 276-374 sporulated oocysts per dose	Vaccine	For active immunization of **GP, PS, Layer** chick to reduce clinical signs, intestinal lesions and oocysts output of Coccidiosis caused by Eimeria acervuline, Eimeria brunetti, Eimeria maxima, Eimeria necatrix and Eimeria tenella.	**Contraindications**: No contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
49.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	BRONIPRA ND 1000 dose/bottle	Inactivated Newcastle disease virus, strain La Sota…….IHA: 1/16 – 1/1024 Inactivated Infectious Bronchitis virus, Strain H52……SN: 2.4 – 16 per dose	Vaccine	To prevent Avian Infectious Bronchitis and Avian Newcastle Disease in Breeders and Layers.	**Contraindications**: No Contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
50.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	TOXIPRA PLUS 100ml/bottle 250ml/bottle 500ml/bottle	β toxoid of type B, C and D Clostridium perfringens……..≥ 10 IU ε toxoid of type B, C and D Clostridium perfringens……..≥ 5 IU α toxoid of type B Clostridium novyi……..≥ 3.5 IU Toxoid α of Clostridium septicum……≥ 2.5 IU Anaculture of Clostridium chauvoei…100% protection Clostridium tetani toxoid……≥ 2.5 IU per dose	Vaccine	To prevent Enterotoxaemia, Necrotic hepatitis, Blackleg, Tetanus, Dysentery, Haemorrhagic enteritis, Pulpy Kidney Disease in Cattle, Sheep and Goats.	**Contraindications**: No Contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
51.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	HIPRAVIAR TRT 1000 dose/bottle	Inactivated Turkey Rhinotracheitis Virus, strain 1062……ELISA≥ 196 /dose	Vaccine	To prevent Turkey Rhinotracheitis (TRT) and Swollen head syndrome (SHS) in chickens, layers and breeders, and turkeys.	**Contraindications**: No Contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
52.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	BRONIPRA 1 1000 dose/vial 2500 dose/vial 5000 dose/vial	Live attenuated Infectious Bronchitis virus, strain H120……10^{3}-$10^{5.4}$ EID_{50} per dose	Vaccine	To prevent Avian Infectious Bronchitis Breeders and Layers.	**Contraindications**: No Contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
53.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	AVISAN CLON/H120 1000 dose/vial 2500 dose/vial 5000 dose/vial	Live Infectious Bronchitis, strain H120…….>/=10exp. 3 EID50 Live Newcastle Disease Virus, strain Clone CL/79……>/= 10exp. 6.5 EID50 per dose	Vaccine	To prevent Avian Infectious Bronchitis and Avian Newcastle Disease in GP, Parents and Layers.	**Contraindications**: No Contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
54.	Laboratorio Avi-Mex, S.A. de C.V., Spain (Nasco Agro Product)	COLERA-MEX 1000 dose/bottle	Pure culture* of *Pasteurella multocida* group A serotype 1, elaborated in microbiologic medium (inactivated with formaldehyde), no less than 0.250 mL with a minimum bacterial contribution of 2.5 X $10^{6.0}$ CFU/mL. per dose Pure culture* of *Pasteurella multocida* group A serotype 3, elaborated in microbiologic medium (inactivated with formaldehyde), no less than 0.250 mL with a minimum bacterial contribution of 2.5 X $10^{6.0}$ CFU/mL. Pure culture* of *Pasteurella multocida* group A serotype 4, elaborated in microbiologic medium	Vaccine	To prevent Fowl Cholera in poultry Layers and breeders.	**Contraindications**: No Contraindications are known **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Sl No	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			(inactivated with formaldehyde), no less than 0.250 mL with a minimum bacterial contribution of 2.5 X $10^{6.0}$ CFU/mL. Adjuvant and excipients no more than: Sterile water, 0.220 mL (as required); Aluminum hydroxide gel, 0.030 mL.							
55.	KEPRO B.V. Maagdenburg-Straat 17, 7421 ZA - Deventer P.O. Box 2081 7420 AB Deventer THE Netherlands Impoter : Nutech animal Health	PROCILLINE L/A Inj.	(Procaine penicillin G 100,000 IU + Benzathine Penicillin G 100,000 IU + Dihydro streptomycin sulphate 200 mg)/ml	Long acting Antibiotic	Indicated for the treatment of infections caused by bacteria sensitive to the antibiotics combination; like respiratory, uterine, and elementary infections , mastitis, metritis, septicemia etc.	Do not administer to animals hyper sensitive to penicillin or procaine.	Existing Combicillin LA (Korea) Procaine penicillin G 150,000 IU Benzathine Penicillin G 100,000 IU Dihydro streptomycin sulphate 200 mg	The Netherlands	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

Annex-: G Proposed Products for Locally Manufacture (Herbal)

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Fennel Extract + Fenugreek Extract + Cumin Powder + Cumin Extract + Dill Powder + Aniseed Extract Capsule Fennel Extract 83.33mg + Fenugreek Extract 83.33mg + Cumin Powder 83.33mg + Cumin Extract 83.33mg + Dill Powder 16.67mg + Aniseed Extract 16.67mg	Increase milk production of nursing mothers (galactogogue)	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** PDR for herbal medicine, 4th edition (Page no: 244, 256, 319 & 787). WHO monographs on selected medicinal plants. **Reference product:** Fembona mothers milk, Germany	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
2.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Melissa Leaf Powder + Red Clover Extract + Fenugreek Seed Extract + Lady's Mantle Extract + Monk's Peppers Powder Capsule Melissa Leaf Powder 93.33mg + Red Clover Extract 83.33mg + Fenugreek Seed Extract 41.67mg + Lady's Mantle Extract 41.67mg + Monk's Peppers Powder 20mg	Reduce menopausal symptoms like hot flashes etc.	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose..	New	**Reference Pharmacopeia:** PDR for herbal medicine, 4th edition (Page: 319, 509, 514 & 693) The American Botanical Council **Reference product:** Fembona cycle harmony, Germany	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
3.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Allium Cepa + Heparin + Allantoin gel Allium Cepa 100mg + Heparin 50IU + Allantoin 10mg/gm gel	Wounds, light burns and bruises.	**Contra-indication:** Should not be used in patients with known hypersensitivity to any of its Ingredients or Alkyl -4 hydroxybenzoates (parabens). **Side-effect:** This Gel is generally well tolerated even on long-term use. In rare cases some local	New	**Reference Pharmacopeia:** The Complete German Commission E Monographs, Page: 176-177 b) PDR for Herbal medicine, Page: 619-620 c) Mosby's Drug consult, Page: 1356-1358 **Ref.Product:** Contractubex Gel Merz Pharmaceuticals	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				irritations are reported such as slight erythema and itching. These side effects do not require discontinuation of the treatment. IN CASE UNDESIRABLE EFFECTS, PLEASE CONSULT YOUR DOCTOR		GmbH, Germany			
4.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Cranberry Fruit Extract (Vaccinium macrocarpon) + Saw Palmetto Extract (Serenoa repens) + Pygeum Bark Extract (Pygeum africanum) + Tomato Extract (Lycopersicon esculentum) + Uva Ursi Extract (Arctostaphylos uva-ursi) Capsule Cranberry Fruit Extract (Vaccinium macrocarpon) 125mg + Saw Palmetto Extract (Serenoa repens) 125mg + Pygeum Bark Extract (Pygeum africanum) 50mg + Tomato Extract (Lycopersicon esculentum) 75mg + Uva Ursi Extract (Arctostaphylos uva-ursi) 75mg Capsule	Diuresis, Widely used to prevent urinary tract infection.	**Contra-indication:** This product is contraindicated in those who are hypersensitive to any component of the product. **Side effects:** Generally well tolerated.	New	**Reference Pharmacopeia:** PDR for Herbal Medicine, 4th Edition, Page-238,679,725,849, 868 **Ref. Product:** UT-Ease, Vitahealth, Malaysia	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
5.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Horny Goat Weed Extract (10% Icariins) + Maca Root + Tribulus Terrestris Extract + Tongkat Ali Root Extract + L-Arginine (as HCl) + Muira Puama Root + Polypodium Vulgare + Panax Ginseng Extract + Black Pepper Extract (95% Piperine) Capsule Horny Goat Weed Extract (10% Icariins) 500mg + Maca Root 125mg + Tribulus Terrestris Extract 37.5mg + Tongkat Ali Root Extract 50mg + L-Arginine (as HCl) 50mg + Muira Puama Root 10mg + Polypodium Vulgare 10mg + Panax Ginseng Extract 10mg + Black Pepper Extract (95% Piperine) 2.5mg Capsule	Increases libido and supports sexual health, Boosts energy and stamina, Improves energy, performance and vigor.	**Contra-indication:** Generally well tolerated **Side effects:** Anxiety states, elevated blood pressure, exanthema, nausea, insomnia, tachycardia, tremor,mania and vomiting.	New	**Reference Pharmacopeia:** PDR for Herbal Medicine, P:107, 384, 592 American Botanical Council USP DSC 2015: Page: 876 **Ref. Product:** Nutrachamps Horny Goat Weed	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
6.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Bifidobacterium lactis Blend (Eqv. to Bifidobacterium lactis (HN019) Capsule Bifidobacterium lactis Blend 265mg (Eqv. to Bifidobacterium lactis (HN019) 10 billion CFU) Capsule	Ant- Diarrheal, Relieving occasional constipation	Contraindications: Probiotics are contraindicated in those who are hypersensitive to any component of a probiotic-containing product. Side effects: Probiotics are generally well tolerated.	New	**Reference Pharmacopeia:** PDR for Herbal Medicine. Page: 996- 1001 **Ref. Product:** Howaru Transit, Dupont, USA	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
7.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Vitis Vinifera Extract + Natural Vitamin E + Shea Butter + Telmesteine + Isohexadecane + Allantoin+ Bisabolol + Piroctone Olamine + Alglycera cream Vitis Vinifera Extract 1mg + Natural Vitamin E 10mg + Shea Butter 60mg + Telmesteine 0.10mg + Isohexadecane 80mg + Allantoin 3.50mg + Bisabolol 12mg + Piroctone Olamine 10mg + Alglycera 10mg / gm cream	It is used for the treatment of dermatitis, wound healing and tissue damage.	Contraindications: This cream is contraindicated in those who are hypersensitive to any component of the product. Side effects: This cream is generally well tolerated, as it does not cause any rebound effects, which are commonly associated with topical corticosteroids.	New	**Reference Pharmacopeia:** PDR for Herbal Medicine, 4th Edition.Page: 219, 405, 1013 American Botanical Council. **Ref. Product:** Sebclair Cream (Alliance Pharma PLC, UK)	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।
8.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Malic acid + Cayenne Pepper Fruit Powder + Ginger Root Powder + Garcinia cambogia Fruit Extract Capsule Malic acid 300mg + Cayenne Pepper Fruit Powder 50mg + Ginger Root Powder 50mg + Garcinia cambogia Fruit Extract 50mg Capsule	Weight management, support for healthy digestive tract function.	Contraindications: Contraindicated in patients with known hypersensitivity to any of the ingredients. Side effects: Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** PDR for herbal medicine, 4th edition (Page: 365) **Reference product:** GNC Superfoods Apple Cider Vinegar, GNC, Pittsburgh, Pennsylvania, United States	No referance for All the ingredients	সকল ingredients এর রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	সকল ingredients এর রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হয়।
9.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Soya lecithin+ Citicholine Sodium + European Bilberry Extract + Lutein 10mg + Saffron Extract + , Zeazanthin + Astaxanthin Capsule Soya lecithin 125mg + Citicholine Sodium 125mg + European Bilberry Extract 40mg + Lutein 10mg +	Improves all eyesight performance, Enhances night vision, Improves memory, mental alertness and focus Reduces eye fatigue and ensures better	Contraindications : Generally well tolerated Side effects: No side effects	New	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th Ed, P: 78,980 Herbal Drugs and Phytopharmaceuticals, 3rd Ed: P: 159	Document not submitted as per requirement	প্রয়োজনীয় ডকুমেন্টস দাখিল করেনি বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় ডকুমেন্টস দাখিল করেনি বিধায় আবেদন নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Saffron Extract 10mg + , Zeazanthin 2mg + Astaxanthin 0.5mg Capsule	sleep, Protects against digital eye strain			**Ref. Product:** Optimeyes (Eyetamins, USA)			
10.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Ishobgul (Plantago ovata) + Sonapata/Sonamukhi (Cassia angustifolia/senna) + Haritaki (Terminalia Chebula)+ Banorhati/Sonali (Cassia fistula) + Josthimodhu (Glycyrrhiza glabra) + Mouri (Foeniculum vulgare) powder Ishobgul (Plantago ovata) 2gm + Sonapata/Sonamukhi (Cassia angustifolia/senna) 0.75gm + Haritaki (Terminalia Chebula) 0.50gm + Banorhati/Sonali (Cassia fistula) 0.50gm + Josthimodhu (Glycyrrhiza glabra) 0.25gm + Mouri (Foeniculum vulgare) 0.05gm / 5gm powder	Constipation, Irregular bowel habits, Supportive treatment in hemorrhoids	**Contra-indication:** No known contraindications found. **Side-effect**: Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** The Complete German Commission E Monographs (Page: 191-192, 204-206) **Reference Pharmacopeia:** The clinical guide to herbs (Page-273-283) PDR for herbal medicine 4th edition (Page-743-746) **Ref. product:** Softovac, Lupin limited, Mumbai, India	Document not submitted as per requirement	প্রয়োজনীয় ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়।
11.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Bacopa Monnieri Extract (as bacosides-A) + Ginkgo Biloba Extract (as ginkgo flavonglycosides) + Lecithin 50mg Capsule Bacopa Monnieri Extract (as bacosides-A)135mg + Ginkgo Biloba Extract (as ginkgo flavonglycosides) 5.70mg + Lecithin 50mg Capsule	Supports mental alertness and cognitive Performance.	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients **Side-effect:** Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** The ABC clinical guide to herbs (Page-187-192) b. The complete German commission E monographs (Page-136-138, 210-211) c. PDR for herbal medicine (Page-371-379).**Ref. Product**: Bio Organics, Ultrasorb Brahmi, India	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
12.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Glucosamine Hydrochloride + Chondroitin Sulfate + Undenatured Type ll Collagen capsule Glucosamine Hydrochloride 150mg + Chondroitin Sulfate 120mg + Undenatured Type ll Collagen 40mg capsule	Osteoarthritis Rheumatoid arthritis Joint pain & inflammation	Contraindications: Undenatured Type ll Collagen with Glucosamine and Chondroitin is contraindicated in those who are hypersensitive to any components of the product. Side effects:	Existing as Glucosamine HCl 150 mg,Chondroitin sulfate 120	**Reference Pharmacopeia:** PDR For Herbal Medicines (4th Edition) (Page 955-958, 967-970) 2. USP Dietary Supplement Compendium 2015, Page:2437 **Ref. Product:** Glucosamine and Chondroin Plus UC-II,	Document submitted as per requirement but Glucosamine Hydrochloride + Chondroitin Sulfate is a	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				Undenatured collagen ll is generally well tolerated in recommended dose. Over dose may cause Constipation and headache. Glucosamine and chondroitin are considered safe, with no serious side effects reported in studies. They might affect blood sugar levels, and one small study found they raise eye pressure, which could increase the risk for glaucoma.	mg,Undenatured type 2 collagen 40 mg tablet	CVS Health, USA	regstard in Pharmacutical Product		
13.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Sea Buckthorn Oil (Extract of Hippophae rhamnoides) + Tea Tree Oil (Extract of Melaleuca Alternifolia) + Lactic Acid liquid Sea Buckthorn Oil (Extract of Hippophae rhamnoides) 0.250gm + Tea Tree Oil (Extract of Melaleuca Alternifolia) 0.050gm + Lactic Acid 1.20gm/100ml Topical liquid	It has Anti-microbial, Ant-Fungal And Wound Healing Effect.	Contraindications: Contraindicated in patients with known hypersensitivity to any of the ingredients side effects: Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** PDR for herbal medicine, 4th edition (Page: 740-741, 839-843) **Reference product**: Vwash Plus, Glenmark Pharmaceuticals Ltd., India	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
14.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Collagen peptide + Inulin 90% Soluble fiber + Fish Collagen Tri Peptide + Malic acid + Mix Berry Powder + Garcinia Extract 100mg + Sodium Ascorbate (Vitamin C) + d-alpha Tocopherol (Vitamin E) Sachet Collagen peptide 9gm + Inulin 90% Soluble fiber 4gm + Fish Collagen Tri Peptide 1gm + Malic acid 300mg + Mix Berry Powder 200mg + Garcinia Extract 100mg + Sodium Ascorbate (Vitamin C) 60mg + d-alpha Tocopherol (Vitamin E) 20mg / 15gm Sachet	It has Strong Laxative effect. Use as Laxative and antioxident	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** PDR for herbal medicine, 4th edition (Page: 1008,1013) USP Dietary Supplement Compendium 2015; (Page: 2437) **Ref. Product:** Donuttbrand Collagen Peptide 10000mg Inulin Plus , Thailand	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
15.	Square Pharmaceuticals Ltd., (Herbal Division),	Undenatured Type-II Collagen + Hyaluronic acid + MSM (methylsulfonyl-methane) + Turmeric Extract	It has Anti- Inflammatory effect, use in Rheumatoid	**Contra-indication:** Undenatured Type ll Collagen	New	**Reference Pharmacopeia:** PDR For Herbal Medicines	Document submitted as	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
	BSCIC, Pabna	+ Boswellia Serrata Extract Capsule Undenatured Type-II Collagen 20mg + Hyaluronic acid 35mg + MSM (methylsulfonyl-methane) 200mg + Turmeric Extract 50mg + Boswellia Serrata Extract 50mg Capsule	arthritis Joint pain & inflammation	with Glucosamine and Chondroitin is contraindicated in those who are hypersensitive to any components of the product. **Side effects:** Undenatured collagen ll is generally well tolerated in recommended dose. Over dose may cause constipation and headache. Glucosamine and chondroitin are considered safe, with no serious side effects reported in studies. They might affect blood sugar levels, and one small study found they raise eye pressure, which could increase the risk for glaucoma.		(4th Edition) (Page 955-958, 967-970) USP Dietary Supplement Compendium 2015, Page:2437 The complete German commission E monographs **Ref. Product:** Joint Complex (single dose) Pure Encapsulation (USA)	per requirement		
16.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Vitamin C + Zinc Capsule Vitamin C 600mg + Zinc 20mg Capsule	Increases immune system, reduces risk of age related eye diseases, helps wounds healing and aiding the body to absorb iron.	Contraindications : Generally well tolerated. Side effects: Well tolerated in recommended dose.	New	**Reference Pharmacopeia:** PDR for Herbal Medicine Page-1008, 1021 **Ref. Product:** Q Blend Vitamin C and Zinc (NutraVita, UK)	Document submitted as per requirement but these are pharmacituciul ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
17.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Extract of Mentha Piperita (as Menthol) + Extract of Cinnamomum Camphora (as Camphor) + Extract of Wintergreen oil (as Methyl salicylate) Nasal stick Extract of Mentha Piperita (as Menthol) 415.40mg + Extract of Cinnamomum Camphora (as Camphor) 415.40mg + Extract of Wintergreen oil (as Methyl	Clears stuffy noses due to colds. (Catarrhs of the respiratory tract)	Contraindications Contraindicated in patients with known hypersensitivity to any of the ingredients . Side effects: Well tolerated in recommended	New	**Reference Pharmacopeia:** The complete German commision E monographs (Page: 180-182, 260-261) b. The ABC clinical guides to herbs (Page no: 300-303) c. PDR for herbal medicine	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		salicylate) 122.70mg / gm Nasal stick		dose.		4th edition (Page: 905). **Ref. Product:** Vics Inhaler, India			
18.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Carica Papaya Leaf (as Extract) Syrup Carica Papaya Leaf (as Extract) 275mg/5ml Syrup	Viral infections and upper respiratory tract infection.	**Contra-indication:** No known contraindications found **Side effects:** Well tolerated in recommended dose.	Existing as Carica papaya leaf extract 250 mg Capsule	**Reference Pharmacopeia:** PDR for herbal medicine 4th edition (Page: 627-628) The complete German commision E monographs (page no- 360) **Reference product:** Caripill syrup, Micro Labs Limited, Bangalore, India	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
19.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Omega 7 Oil soft gel Capsule Omega 7 Oil 900mg soft gel Capsule	• Improves insulin sensitivity	Contraindications: Generally well tolerated Side effects: Consuming too much may deplete potassium, cause muscle weakness and irregular heartbeat, Urine color change & Laxative effect.	New	**Reference Pharmacopeia:** PDR for Herbal Medicine (4th edition), Page: 740-741 **Ref. Product:** NusaPure Omega 7 Fatty Acids Buckthorn Oil 900 mg, Nusapure, USA	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
20.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Melon Extract (Cucumis melo L) + Vitamin C + Vitamin E + Vitamin B9 + Vitamin B12 + Selenium 40µg + Copper Gluconate + Zinc soft gel Capsule Melon Extract (Cucumis melo L) 10mg + Vitamin C 40mg + Vitamin E 10mg + Vitamin B9 100µg + Vitamin B12 1µg + Selenium 40µg + Copper Gluconate 1mg + Zinc 5mg soft gel Capsule	Used in Vitiligo and as antioxidant	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	Existing as Melon Extract (Cucumis melo L) 10.00 mg Vitamin C (L-ascorbic acid) 40.00 mg Vitamin E (DL- alpha	**Reference Pharmacopeia:** PDR for herbal medicine, 4th edition (Page: 962, 1008, 1013, 1021) ABC clinical guide to herb **Reference product:** Vitix tablet, ACM laboratories, dermatological, France	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
					– tocopheryl acetate) 10.00 mg Vitamin B9(Folic acid) 100.00 µg Vitamin B12 (Cynocobalamine) 1.00 µg Selenium 40.00 µg Copper Gluconate 1000.00 µg Zinc Gluconate 5.00 mg Tablet				
21.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	L-Glutathione (Reduced) Softgel Capsule L-Glutathione (Reduced) 500 mg Softgel Capsule	a) Anti-Aging .	**Contra-indication:** Contraindicated in patients with Asthma **Side-effect:** No known side effects.	Existing as L-Glutathione 500 mg Capsule	**Reference Pharmacopeia:** 1) USP-38 NF-33, Volume-4, Page-6080-6081. 2) USP –Dietary Supplement Compendium, Page: 1174-1175 **Refrence product:** Reduced L-Glutathione, Vedhealthcare	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
22.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Citronella (Cymbopogon citratus) Extract (oil) topical spray	Topical spray used to prevent insect repellent.	**Contra-indication:** Contraindicated in patients	New	**Reference Pharmacopeia:** The complete German commision E monographs	Document submitted as per	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Citronella (Cymbopogon citratus) Extract (oil) 250mg/ml topical spray		with known hypersensitivity of the ingredient. **Side-effect:** No known side effects.		Page 341 **Refrence product:** Sketolene, Thailand	requirement		
23.	Drug International Ltd (Herbal Division) Monipur Bazar,Bokran, Gazipur	Coconut Oil (Organic Extra Virgin) Coconut Oil (Organic Extra Virgin) 1000mg capsule	Coconut Oil supports healthy digestion, thyroid function, healthy hair and skin, weight management, brain health and healthy cholesterol. It is also used for colds and inflammation of the throat & tooth decay, dysuria, coughs, bronchitis and to stop hair from turning gray.	**Contraindication:** It is contraindicated in those patients who are hypersensitive to any component of this product. **Precaution:** There is no data available. **Warning:** There is no data available. **Side effects:** There is no data available.	New	**Reference Pharmacopeia:** a) Physician Desk Reference-for Herbal Medicines, 4th edition, Page: 209-210 b)https://www.amazon.com/Coconut-Oil-Capsules-Softgels-Management/dp/B00T6UTILC?th=1 c) USP-41 NF 36, Pages 5299 **Reference Product:** Coconut Oil Country Name: USA	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
24.	Drug International Ltd (Herbal Division) Monipur Bazar,Bokran, Gazipur	Olive Oil D-Alpha Tocopheryl Acetate Provides Vitamin E Olive Oil 1000 mg & D-Alpha Tocopheryl Acetate (Provides Vitamin E 700 IU/g)	This capsule helps to support Cardiovascular Health and aid in the reduction of Bad LDL Cholesterol. It can be reduced the risk of coronary heart disease due to the monounsaturated fat in olive oil. This capsule also used in cholangitis, inflammation of the gallbladder, flatulence, constipation, gastrointestinal ulcers and kidney stones. We get antioxidant effect naturally olive oil with vitamin E.	**Contraindication:** This capsule is contraindicated in those patients who are hypersensitive to any component of this product. There is no data available. **Precaution:** There is no data available. **Warning:** There is no data available. **Side effects:** This capsule generally well tolerated. No significant side effects have been observed in therapeutic	New	**Reference Pharmacopeia:** a) Physician Desk Reference-for Herbal Medicines, 4th edition, Page: 617-619 **Reference Product:** AL SHIFFA (OLIVE OIL) Country Name: Turkey	Document submitted as per requirement but No referance for Vitimin E	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				dosage.					
25.	Drug International Ltd (Herbal Division) Monipur Bazar,Bokran, Gazipur	Cranberry Extract, Vitamin C (Ascorbic Acid, Vitamin E Acetate Cranberry Extract 140mg, Vitamin C (Ascorbic Acid 100mg, Vitamin E Acetate 3.00mg	It is indicated for the treatment and prevention of urinary tract infection, kidney stones. Cranberry has also been investigated for numerous other medicinal uses including prevention of *H. pylori* infection and dental plaque. Vitamin C & E Supports body's immune function and their antioxidant property helps to fight free radicals.	**Contraindication:** It is contraindicated in those patients who are hypersensitive to any component of this product. It is also contraindicated for the patient with aspirin allergy, atrophic gastritis, hypochlorhydria. **Precaution:** There is no data available. **Warning:** There is no data available. **Side effects:** Generally well tolerated. Occasionally diarrhea or mild gastrointestinal upset may occur at high dose.	New	**Reference Pharmacopeia:** a) Physician Desk Reference-for Herbal Medicines, 4th edition, Page no: 238-241 b)www.webmd.com/vitamins/ai/ingredientmono-958/cranberry C)British Pharmacopoeia **Reference Product:** Cranberry with Vitamin C & E Country Name: USA	Document submitted as per requirement but Vitamin C and E are used as Pharmacutical products	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
26.	Drug International Ltd (Herbal Division) Monipur Bazar,Bokran, Gazipur	Mustard Seed Oil soft gel Capsule Mustard Seed Oil 450mg soft gel Capsule	Mustard seeds are considered effective in stimulating the circulation and digestive system. Mustard oil is traditionally applied to the skin as counter-irritant to help support rheumatic pain.	**Contraindication:** It is contraindicated in patients with hypersensitivity to any component of this capsule. **Precaution:** There is no data available. **Warning:** There is no data available. **Side effects:** This capsule generally well tolerated. No significant side effects have been observed in therapeutic dosage.	New	**Reference Pharmacopeia:** a) PDR for Herbal medicine 4th edition. Page No: 105-106 b)www.amazon.com/Mustard-Seed-450-capsules-511652/dp/B008X8P5OC **Reference Product:** Mustard Seed Country Name: Poland	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
27.	Drug International Ltd (Herbal Division) Monipur Bazar,Bokran, Gazipur	Collagen (Marine Fish Collagen Tripeptide), L-Arginine , dl-Alpha-Tocopheryl Acetate (Vitamin E), Coenzyme Q10, Vitamin C, Glycine Collagen (Marine Fish Collagen Tripeptide) 600mg, L-Arginine BP 10mg, dl-Alpha-Tocopheryl Acetate (Vitamin E) USP 6mg, Coenzyme Q10 BP 12.50mg, Vitamin C BP 20mg, Glycine BP 10mg	Usefull in Degenerative join diseases and used as antioxidant.	**Contraindication:** It is contraindicated in patients with hypersensitivity to any component of this capsule. **Side effects:** This capsule generally well tolerated. No significant side effects have been observed in therapeutic dosage.	New	**Reference Pharmacopeia:** a) BP-British Pharmacopoeia. b)PDR-: PDR for Nutritional Supplements 2nd Edition, Page No. 300-301. **Reference Product:** Collagen Tripeptide-600 Plus Coenzyme Q10 Country Name: Thailand	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
28.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Cordyceps + Picrorhiza Kurroa Cordyceps 6mg + Picrorhiza Kurroa 294mg Capsule	**INDICATIONS:** • Kidney diseases e.g.chronic nephritis, chronic pyelonephritis, nephritic syndrome Impotence and seminal essence	**Contra-indication** : None **Side effect :** It might cause mild side effects such as diarrhea, constipation, and abdominal discomfort. When taken by mouth, cordyceps might increase the risk of bleeding during surgery. Stop taking cordyceps 2 weeks before surgery.	New	**Reference Pharmacopeia:** Pharmacopoeia of the people's republic of China 2015 (P115) + Indian Herbal Pharmacopoeia Revised New Edition 2019 (P289-296) **Reference Product :** Bhutan Cordycep & Picrorhiza **Manufacturer : Bhutan Wild Cordyceps, Bhutan**	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
29.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Raspberry leaves and Fruit Extract Capsule Raspberry leaves and Fruit Extract 100mg Capsule	Raspberry is use for disorders of the gastrointestinal traxt.	**Contra-indication** : None **Side effect/ Undesirable effects :** Bad taste in the mouth	New	**Reference Pharmacopeia:** PDR for Herbal Medicine. (Page- 690) **Reference Product :** Holland & Barrett Raspberry Manufacturer : Holland & Barrett, UK	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
30.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Gelatin (as Hydrolysed Collagen) Gelatin (as Hydrolysed Collagen) 500mg/gm Powder	Gelatin (as Hydrolysed Collagen) is use for degnerative joint disease.	**Contra-indication** : None **Side effect/ Undesirable effects :** Bad taste in the mouth	New	**Reference Pharmacopeia:** PDR for Herbal Medicine. (Page- 300) Japanese Pharmacopoeia; 15th Edition (Page 696) **Reference Product :** Hydrolysed Collagen	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
						Manufacturer : Holland & Barrett, UK			
31.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Gelatin (as Hydrolysed Collagen) Gelatin (as Hydrolysed Collagen) 1000mg/gm Powder	Gelatin (as Hydrolysed Collagen) is use for degnerative joint disease.	**Contra-indication** : None **Side effect/ Undesirable effects :** Bad taste in the mouth	New	**Reference Pharmacopeia:** PDR for Herbal Medicine. (Page- 300) Japanese Pharmacopoeia; 15th Edition (Page 696) **Reference Product** : Hydrolysed Collagen Manufacturer : Holland & Barrett, UK:	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
32.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Gelatin (as Hydrolysed Collagen) Gelatin (as Hydrolysed Collagen) 500mg Tablet	Gelatin (as Hydrolysed Collagen) is use for degnerative joint disease.	**Contra-indication** : None **Side effect/ Undesirable effects :** Bad taste in the mouth	New	**Reference Pharmacopeia:** PDR for Herbal Medicine. (Page- 300) Japanese Pharmacopoeia; 15th Edition (Page 696) **Reference Product :** Hydrolysed Collagen Manufacturer : Holland & Barrett, UK	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
33.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Gelatin (as Hydrolysed Collagen) Gelatin (as Hydrolysed Collagen) 1000mg Tablet	Gelatin (as Hydrolysed Collagen) is use for degnerative joint disease.	**Contra-indication** : None **Side effect/ Undesirable effects :** Bad taste in the mouth	New	**Reference Pharmacopeia:** PDR for Herbal Medicine. (Page- 300) Japanese Pharmacopoeia; 15th Edition (Page 696) **Reference Product :** Hydrolysed Collagen Manufacturer : Holland & Barrett, UK:	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
34.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	L-Arginine L-Arginine 600mg/gm Powder	**ACTIONS:** L-arginine is converted in the body into a chemical called nitric oxide. Nitric oxide causes blood vessels to open wider for improved blood flow.	Contra indications : Contraindicated in people with guanidinoacetatemethyltransferase deficiency. Side Effects : It may cause abdominal pain, bloating,	New	**Reference Pharmacopeia:** The Japanese Pharmacopoeia; 15th Edition. (Page 313) **Reference Product :** L-Arginine	Document submitted as per requirement but it is included as	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
			Thus it can reduce blood pressure in pregnant women with pre-eclampsia. L-arginine also seems to keep pregnant women from developing pre-eclampsia. **INDICATIONS:** Pre eclampsia	diarrhea, gout, allergies, worsening of asthma, and low blood pressure.		Manufacturer : GNC, UK	pharmacutical products		
35.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Psyllium Husk Psyllium Husk 510mg Capsule	Used in Chronic Constipation.	Contra indications : Intestinal obstruction, Colonic atony. Side effects : Hypersensitivity reactions. Temporary increase of flatulence and abdominal distension.	Ispaghula Husk USP 3.5gm. DCC-245 Mebeverine HCl BP 135mg + Psyllium Husk BP 3.5gm/ Sachet-DCC-243 Psyllium Husk Powder + Standardize Senna Leaf Dry Extract. DCC-245	**Reference Pharmacopeia:** The German Commission E Monographs (Page: 192) **Reference Product :** Psyllium Husk Capsule Manufacturer : PipinkRock, USA	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
36.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Henbane (Hyoscyamine Extract) (*Hyoscyamus Niger*) Henbane (Hyoscyamine Extract) (*Hyoscyamus Niger*) 0.5 mg Tablet	Dyspeptic complaints & spasms	**Contra-indication:** Tachycardiac arrhythmias, prostatic adenoma, angle-closure glaucoma, acute pulmonary edema, mechanical stenosis in the area of the gastrointestinal tract and	New	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page: 438-439)	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				megacolon. It is contraindicated in Pregnancy & lactating mother. **Side-effects:** No health hazards are known in conjunction with the proper administration of designated therapeutic dosages. Skin reddening, dryness of the mouth, tachycardiac arrhythmias, mydriasis (the four early warning symptoms of a poisoning), accommodation disorders, heat builup through decline in sweat secretion, micturation disorders. **Warnings & Precautions:** • Skin reddening, dryness of the mouth, tachycardia arrhythmias, mydriasis (the four early warning symptoms of a poisoning).					
37.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Standardized Licorice (Glycyrrhizin Extract) (*Glycyrrhiza glabra*) + Ma-Huang (Ephedrine extract) (*Ephedra sinica*) Standardized Licorice (Glycyrrhizin Extract) (*Glycyrrhiza glabra*) 2 g + Ma-Huang (Ephedrine extract) (*Ephedra sinica*) 0.30 g/100 ml Syrup	Cough, bronchitis, Sore throats, dry cough, asthma, allergies & severe acute respiratory syndrome virus	**Contra-indication:** Contraindications for Licorice include chronic hepatitis, cholestatic diseases of the liver, cirrhosis of the liver, severe renal insufficiency. It is contraindicated in Pregnancy & lactating mother. **Side-effects:** Common side effects of Ma Huang including headache, dizziness, motor restlessness, sleeplessness, nausea,	New	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition Licorice (Page: 522-529) & (tradishonal chiness Pharmacopia) tcm (Pag: 543-549) **no product referance**	Document submitted as per requirement	প্রয়োজনীয় প্রডাক্ট রেফারেন্স সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় প্রডাক্ট রেফারেন্স সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				vomiting. **Warnings & Precautions:** • Licorice should not be used for a prolonged period of time except under the supervision of a qualified health practitioner. • Chronic ingestion of the herb may result in hypertension, edema, cardiac complaints, pseudo hyperaldosteronism with hypercortisolism, sodium retention or severe electrolyte imbalances such as hypernatremia and hypokalemia, resulting in hypotonia, muscular weakness.					
38.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Standardized Peppermint (I-Menthol Extract) (*Mentha piperita*) + Camphor Tree (D-Camphor Extract) (*Cinnamomum camphora*) + Eucalyptus Oil (*Eucalyptus globulus*) + Mint Oil (*Mentha arvensis)* Standardized Peppermint (I-Menthol Extract) (*Mentha piperita*) 50 mg + Camphor Tree (D-Camphor Extract) (*Cinnamomum camphora*) 45 mg + Eucalyptus Oil (*Eucalyptus globulus*) 50 mg + Mint Oil (*Mentha arvensis)* 10 mg/g Cream	Symptomatic relief of mild tension type headache, nasal congestion, cutaneous chest uses for the relief of symptoms in cold and it is also used in inhalation for the relief of symptoms in cough and sinusitis.	**Contra-indication:** Preparations containing of the oil should not be applied to the faces of infants or small children. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • The volatile oil possesses a weak potential for sensitization due to its menthol content. Hypercreativity reactions may include skin rash and perianal burning. • Do not apply topical peppermint oil to open skin areas.	Peppermint Oil Capsule	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition Peppermint oil (Page: 640-643), Cinnamomum camphora The completade German Commision E monogharph (Page: 150-151), Eucalyptus (Page: 293-296)	Document submitted as per requirement **no product referance**	প্রয়োজনীয় রেফারেন্স প্রোডাক্ট নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স প্রোডাক্ট নেই বিধায় আবেদন নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
39.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 20 mg Tablet	Stevia is used as a natural sweetener (300 times sweeter than sucrose). It has the following Pharmacological effects: a) type 2 diabetes b) hypertension.	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented with stevia.	Stevia Leave Powder	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:789-790), USFDA-GRAS	Document submitted as per requirement **no product referance**	প্রয়োজনীয় রেফারেন্স প্রোডাক্ট নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স প্রোডাক্ট নেই বিধায় নামঞ্জুর করা হয়।
40.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 30 mg Tablet	Stevia is used as a natural sweetener (300 times sweeter than sucrose).	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented with stevia.	Stevia Leave Powder	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:789-790), USFDA-GRAS	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
41.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 40 mg Tablet	Stevia is used as a natural sweetener (300 times sweeter than sucrose).	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented with stevia.	Stevia Leave Powder	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:789-790), USFDA-GRAS	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
42.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 20 mg/Sachet	Stevia is used as a natural sweetener (300 times sweeter than sucrose).	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented with	Stevia Leave Powder	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:789-790), USFDA-GRAS	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				stevia.					
43.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 30 mg/Sachet	Stevia is used as a natural sweetener (300 times sweeter than sucrose)	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented with stevia.	Stevia Leave Powder	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:789-790), USFDA-GRAS	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
44.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 98% Rebaudioside A (Leaf Extract of *Stevia rebaudiana*) 40 mg/Sachet	Stevia is used as a natural sweetener (300 times sweeter than sucrose)	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented with stevia.	Stevia Leave Powder	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:789-790), USFDA-GRAS	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
45.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Aloe Vera *(Aloe barbadensis Mill.)* Extract + Tea Tree Oil (*Melaleuca alternifolia)* Aloe Vera *(Aloe barbadensis Mill.)* Extract 100 mg + Tea Tree Oil (*Melaleuca alternifolia)* 50 mg/g Gel	Acne, Herpes, Psoriasis, Allergic skin reaction & Wound healing.	**Contra-indication:** Safe, No Interaction. **Side-effects:** Currently, no side effects. **Warnings & Precautions:** • Adverse cardiovascular and kidney/ genitourinary effects have been documented.	Aloe Vera 400 Capsule	**Reference Pharmacopeia:** Mosby's Drug Consult (2006), Part III, Aloe Vera (Page 1-2) + Tea Tree Oil (Page 108-109) **Referance Product : Alovera ESI gel, Italy**	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
46.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	*Gymnema sylvestre* (Meshashrunga) Root Extract *Gymnema sylvestre* (Meshashrunga) Root Extract 500 mg Capsule	Type I & type II diabetes	**Contra-indication:** It is contraindicated in Pregnancy & lactating mother. **Side-effects:**	Gymnema Sylvertre + Garcinai Cambogia	USP DSC 2015 VOL 2 (Page: 120-123)	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				Headache, Dizziness or lightheadedness, Shakiness & Nausea. **Warnings & Precautions:** It is contraindicated in Pregnancy & lactating mother.	Capsule				
47.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	*Ganoderma lucidum* (Reishi Mushroom) Extract *Ganoderma lucidum* (Reishi Mushroom) Extract 600 mg Capsule	High blood pressure, High cholesterol, cardiovascular disease, Viral Infections, Cancer and immune deficiency	**Contraindication:** Concurrency with other anticoagulant medications. **Side effect:** Side effects are mild and may include dizziness, GI upset, or irritated. **Warning & Precaution:** Do not take Ganoderma lucidum if you are allergic to reishi or any ingredients contained in this drug. Keep out of reach of children.	Ganoderma Lucidam Capsule	**Reference Pharmacopeia:** 1. USP DSC 2015 VOL 2 Page-95-100 2. The Review of Natural Products, page-508 **Reference Product:** Solaray Reishi Mushroom, USA	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
48.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Moringa Leaf Extract (*Moringa oleifera*) Moringa Leaf Extract (*Moringa oleifera*) 500 mg Capsule	It has Anti-microbial effect, Used for gastrointestinal complaints,.	**Contraindication:** None **Side effect:** No major side effects were noted in clinical studies that used moringa leaf powder up to 20 g/day. Moringa was safe even at very high doses, but due to its bitter taste is unpleasant in larger amounts **Warning & Precaution:** Low concentration of Moringa leaf extract is safe for hyperthyroidism. Although, slightly higher intake may increase thyroid activity. So, it is generally advised to limit the	New	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:71-72) **Reference Product:** 1. Moringa Capsules, USA 2. Moringa leaf powder Capsule, India	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				intake of Moringa or to consult your doctor before taking Moringa if are taking thyroid drugs.					
49.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Papaya Leaf Extract (*Carica papaya)* Papaya Leaf Extract (*Carica papaya)* 1100 mg Tablet	Viral infections and upper respiratory tract infection.	**Contraindication:** Not to be used during pregnancy. **Side effect:** Nausea, vomiting, abdominal pain, heartburn, dyspepsia **Warning & Precaution:** Allergic reactions, including asthma attacks are possible	New	**Reference Pharmacopeia:** PDR for Herbal Medicine 4th edition (Page:627-628) The complete German commision E monographs (page no- 360) **Reference Product:** Caripill Tablet 1100 mg, India	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
50.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Maca Root Extract (*Lepidium meyenii*) Maca Root Extract (*Lepidium meyenii*) 500 mg Capsule	Boosts Energy, Stamina, Vigor, Endurance & Improves mood	**Contra-indication:** It is contraindicated in Pregnancy & lactating mother **Side-effects:** Animal studies have reported elevated levels of luteinizing hormone, progesterone and testosterone. **Warnings & Precautions:** • It is contraindicated in Pregnancy & lactating mother	New	**Reference Pharmacopeia:** Text book of natural medicine 4th edition Page: 1597-1598,1604 **no product referance**	Mention ed Reference book is not included in reference books	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়
51.	The ACME Laboratories Ltd. (Herbal & Nutraceuticals Division) Dhamrai, Dhaka	Dong Quai (*Angelica polymorpha*) Root Extract + Carotenoids (*Dunaliellasalina cells*) eqv. to. Betacarotene + Colloidal Anhydrous Silcia NF eqv. to Silicon + Ascorbic Acid (Vitamin C)+ Calcium Pantothenate BP [eqv. to Pantothenic Acid (Vitamin B5) & Calciu + Zinc Glycinate eqv. to Zinc + Pyridoxine Hydrochloride eqv. to Pyridoxine (Vitamin B6) + Inositol + d-alpha Tocopheryl Acid	For Healthy Hair, Skin & Nails.	**Contraindication:** None **Side effect:** This product contains selenium which is toxic in high doses. **Warning & Precaution:** • Do not use during pregnancy and breastfeeding.	New	**Reference Pharmacopeia:** 1. PDR for Herbal Medicine 4th edition, Page: 260-263) 2. The Review of Natural Products, Page: 194-196 **Reference Product:** Fusion Tablet (Hair, Skin & Nails), Australia.	Mention ed Reference book is not included in reference books	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Succinate + Lycopene + Riboflavin (Vitamin B2) + Manganese Glycinate eqv. to manganese + Selenomethionine eqv. to Selenium + Potassium Iodide to Iodine + Biotin + Cupric Sulfate Pentahydrate eqv. to Copper Dong Quai (*Angelica polymorpha*) Root Extract 150 mg + Carotenoids (*Dunaliellasalina cells*) 33.330 mg eqv. to. Betacarotene 2.5 mg + Colloidal Anhydrous Silcia NF 160.93 mg eqv. to Silicon 75 mg + Ascorbic Acid (Vitamin C) BP 125 mg + Calcium Pantothenate BP 109.18 mg [eqv. to Pantothenic Acid (Vitamin B5) 100 mg & Calcium 9.17 mg] + Zinc Glycinate BP 48.98 mg eqv. to Zinc 15 mg + Pyridoxine Hydrochloride BP 30.39 mg eqv. to Pyridoxine (Vitamin B6) 25 mg + Inositol BP 50 mg + d-alpha Tocopheryl Acid Succinate BP 41.33 mg + Lycopene BP 2.50 mg + Riboflavin BP (Vitamin B2) 25 mg + Manganese Glycinate BP 92.40 mg eqv. to manganese 2.5 mg + Selenomethionine BP 124 mcg eqv. to Selenium 50 mcg + Potassium Iodide BP 65.40 mcg eqv. to Iodine 50 mcg + Biotin BP 2.50 mg + Cupric Sulfate Pentahydrate BP 196.46 mcg eqv. to Copper 50 mcg Tablet							
52.	**UniMed UniHealth Pharmaceuticals (Herbal Division)** **B.K.Bari, Gazipur**	**Aloe-Vera Moisturizing Gel 99%** Each 100 g gel contains Aloe –Vera (*Aloe* barbadensis *miller.*)Inner Leaf Gel 10X(10 times concentrate) 9.90 g equivalent to Aloe-vera inner leaf gel (Fresh) 99.00 g	Anti-inflammatory, Acne, Psoriasis, UVB light exposed skin damage or Sunburn, Wound Healing.	**Contra-indication:**It is contraindicated in case of known allergy to plant in the Liliaceae. **Side-effect:**There have been a few reports of contact dermatitis and burning skin sensations following topical applications of Aloe Vera Gel to derma braded skin. These	New	**Reference Pharmacopeia:** a) PDR for Herbal Medicine-4th edition. Page:19-26 b) WHO monographs on selected medicinal plants. Volume-I Page :43-48 **Product Name :**	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				reactions appeared to be associated with anthraquinones contaminants in this preparation. A case of disseminated dermatitis has been reported following application of Aloe Vera Gel to a patient with stasis dermatitis .An acute bullous allergic reaction and contact urticaria have also been reported to result from the use of Aloe Vera Gel		1.Pure Mind Aloe Vera Gel, Korea Hobert, IN, 46342-1751, USA			
53.	**UniMed UniHealth Pharmaceuticals (Herbal Division)** **B.K.Bari, Gazipur**	**Magnesium Drink Powder** Each 4 g drink powder contains Magnesium 325.00 mg	This is nature made magnesium that helps boost the essential nutrients your body may be lacking for stress relief, restful sleep and more relaxed muscles. Also Magnesium is used for migraine, bone restoration, diabetes, hypertension, arrhythmias, PMS, nephrolithiasis, spasm and leg cramps during pregnancy	**Contra-indication:**Magnesium is not to be used in presence of heart block, severe renal disease or toxemia in the 2 hours preceding delivery. an obstructed bowl, or are currently on medication, consult with your doctor **Side-effect :** Side effects including blurred vision , photophobia, diarrhea, hypomagnesaemia, hypotension, increased bleeding time, neuromuscular blockade (In higher dose) and vasodilation	New	**Reference Pharmacopeia:** a) PDR for Herbal Medicine-4th edition. Page:985-990 b) USP42 NF37, Volume-II Page :2660-2661 c) BNF-78 Page:71 **Product Name :** Natural CLAM Natural Vitality,USA	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
54.	Total Herbal & Nutraceuticals	Alpha Ketoanalogue **tablet** Alpha Ketoanalogue 850 mg are (Calcium-3-	Low Protein Diet for (a) Kidney dysfunction (b) Chronic Kidney Disease	Contraindications – Hypersensitivity to the active substances or to any of the	New	**Reference Pharmacopeia:** 1) United States Pharmacopeia- DSC-2015,	Document submitted as per	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		methyl-2-oxo-valerate (α-ketoanalogue to isoleucine , calcium salt) 67 mg + Calcium-4-methyl-2-oxo-valerate (α-ketoanalogue to leucine , calcium salt) 101 mg + Calcium-2-oxo-3-phenylpropionate (α-ketoanalogue to phenylalanine , calcium salt) 68 mg + Calcium-3-methyl-2-oxo-butyrate (α-ketoanalogue to valine , calcium salt) 86 mg+ Calcium-dl-2-hydroxy-4(methylthio) butyrate (α-hydroxyanalogue to methionine , calcium salt) 59 mg + Lysine acetate u.s.p.(eq to lysine 75 mg.) 105 mg + L-threonine u.s.p. 53 mg +L-tryptophan u.s.p. 23 mg + L-histidine u.s.p 38 mg + L-tyrosine u.s.p. 30 mg) **tablet**	(c) Diabetic Nephropathy	excipients − Hypercalcaemia − Disturbed amino acid metabolism		PageNo:1215-1216, 1226,1322-1323,1456-1457, 2112-2113,1244-1245,1431-1432,1439-1441,1202-1203,1445-1446 **Reference Products:** Brand: NefroGard- **Centaur Pharmaceuticals Pvt. ltd. India** Ketosteril - Fresenius Kabi, Germany	requirement but some of the ingredients are pharmacutical ingredient		
55.	Total Herbal & Nutraceuticals	Magnesium Tablet Magnesium Oxide 400mg Tablet	a) Osteoporosis, b) Leg cramps, c) Migraines, d) Fatigue, e) PMS, F) Preeclampsia, g) Pre-term labor, h) Heart attack, i) High blood pressure, j) Serum lipids, k) Diabetes	Side effects include indigestion or nausea. Possible reaction if allergic to shellfish	New	**Reference Pharmacopeia:** 1) United States Pharmacopeia- DSC-2015, Vol-1, Page No -1254. 2) Korean Pharmacopeia (Herbal & Supplement). Page-:KPX 767 **Reference Products:** Brand : Magox /Magnesium 400 mg, a) Akorn Consumer Health, USA. / b) Windmill Health Products- USA	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
56.	Total Herbal & Nutraceuticals	L-Carnitine + Maca + Grape Seed Extract +Asian Ginseng+ Coq10 + Vitamine A + Vitamin C + Vitamin D3 + Vitamin E + Vitamin K + Thiamin Hcl + Riboflavin + Vitamin B6 + Folic Acid + Vitamin B12 + Pantothenic Acid + iodine +Zinc + Selenium + Copper + Manganese + Chromium **Capsule** L-Carnitine 350.00 mg, + Maca 300.00 mg + Grape Seed Extract 100.00 mg +Asian Ginseng 100.00 Mg + Coq10 50.00 Mg+ Vitamine A 5000.00 IU +	1) Improve overall male reproductive Health 2) Sperm parameters such Increase Sperm Count 3) Increase Sperm motility (movement) and morphology (shape) 4) Infertility formulation support for men	No interactions have been reported.	New	**Reference Pharmacopeia:** United States Pharmacopeia-DSC-2015, Page No. Page No: 1226-1227,139-146, 1183-1185, 889-890, 1445-1446, 906-907, 879-880, 1497-1503, 1462-1463, 1268 ,1427-1428, 1359-1360, 1348-1349, 1643-1644, 1052-1053, 967-968, 1214, 1715-1717,	Document submitted as per requirement but some of the ingredients are pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Vitamin C 250.00 mg + Vitamin D3 400.00 IU + Vitamin E 150.00 IU + Vitamin K 80.00 mcg + Thiamin Hcl 1.50 mg + Riboflavin 1.70 mg + Vitamin B6 2.00 mg + Folic Acid 500.00 mcg + Vitamin B12 25.00 mcg + Pantothenic Acid 10.00 mg + iodine 150.00 mcg +Zinc 30.00 mg + Selenium 100.00 Mg + Copper 2.00 Mg + Manganese 2.00mg + Chromium 120.0 0 Mcg **Capsule**				1398-1399, 1038-1039,1262-1263,1031-1032. **Reference Products:** Brand: **FertilAid for Men** Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA.			
57.	Total Herbal & Nutraceuticals	Red Clover Leaf 4:1 extract+ PABA + Eleuthero Root 5:1 extract + Chaste Tree Fruit 4:1 extract + Ginkgo Leaf Extract + Vitamin A + Vitamin C + Vitamin D3 + Vitamin + Thiamin + Riboflavin + Niacin + Vitamin B6 + Folic Acid + Vitamin B12 + Pantothenic Acid + Iron +Iodine +Magnesium: as magnesium oxide + as magnesium Chloride + Zinc + Selenium + Copper **Capsule** Red Clover Leaf 4:1 extract 225 mg + PABA200 mg + Eleuthero Root 5:1 extract 125 mg + Chaste Tree Fruit 4:1 extract 40 mg + Ginkgo Leaf Extract 30 mg + Vitamin A 4000 IU + Vitamin C 85mg + Vitamin D3 400 IU + Vitamin E 100 IU + Thiamin 1.5mg + Riboflavin 1.7 mg + Niacin 20 mg + Vitamin B6 2 mg + Folic Acid 600 mg + Vitamin B12 6 mcg + Pantothenic Acid 10 mg + Iron 18 mg + Iodine 245 mg +Magnesium: as magnesium oxide 320 mg + as magnesium Chloride 75 mg + Zinc 15 mg + Selenium 70 mcg + Copper 2 mg **Capsule**	1) Help to women conceive naturally, an effective alternative to invasive /Expensive infertility treatment. 2) Provides optimal nutritional support for trying to conceive women. 3) Particularly helpful of those with irregular cycles for conditions such as PCOS	No interactions have been reported.	New	**Reference Pharmacopeia:** United States Pharmacopeia-DSC-2015, Page No: 1350-1353, 2461, 1085, 1013,1156,1460,879,1020,1462,1427,135,1305,1348,958,1052,966,1215,1214,1252,1252,1248,1715,1398,2470,1038. **Reference Products:** Brand : **FertilAid for Women** Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA.	Document submitted as per requirement but some of the ingredients are pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
58.	Total Herbal & Nutraceuticals	Maca (Root) + Withania + Sombifera (Root) + Pannax Ginseng Root + Mucuna Puriens Extract (Seed) + d-Ribose + CoQ10 + L-lutathione	1) 1) Increase sperm count for male 2) 2) Increase sperm	No interactions have been reported. Safe, non-prescription formula	New	**Reference Pharmacopeia:** United States Pharmacopeia-DSC-2015, PageNo, Vol-2-	Document submitted as per	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Reduced + Vitamin C + Riboflavin+ Niacin + Vitamin B12 **Capsule** Maca (Root) 100 mcg + Withania Sombifera (Root) 50 mg + Pannax Ginseng Root 50 mg + Mucuna Puriens Extract (Seed) 50 mg + d-Ribose 50 mg + CoQ10 50 mg + L-lutathione Reduced 50 mg + Vitamin C 500 mg + Riboflavin15 mg + Niacin 25 mg + Vitamin B12 100 mcg **Capsule**	mobility for male 3) 3) Support overall productivity for male			Page: 139-144, 19-22. USP-DSC-Vol-1 Page: 881-883, 882-806, 1445-1447, 1174, 880, 1359, 1306, 1052. **Reference Products:** Brand : **Count Boost for Men** Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA.	requirement but some of the ingredients are pharmacutical ingredients		
59.	Total Herbal & Nutraceuticals	*Lactase* ***Tablet*** *Lactase* 350 mg eqv to 9000 FCC **Tablet**	(a) Used to control Diarrhoea	This medication usually has very few side effects. If you have any unusual effects from taking this medication contact your doctor or pharmacist promptly	New	**Reference Pharmacopeia:-** United States Pharmacopeia-DSC-2015, Page No. Page No: 1225-1226. BNF 78 (Page no- 65,1575) **Reference Products:** Brand : **Lactase Complex,** Lamberts Health Care Ltd. UK,	Document submitted as per requirement but Lactase is an Enzyme	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
60.	Total Herbal & Nutraceuticals	Lactase **drop** Lactase 100 mg eqv to 3000 FCC 30ml **drop**	(a) Used to control Diarrhoea	This medication usually has very few side effects. If you have any unusual effects from taking this medication contact your doctor or pharmacist promptly	New	**Reference Pharmacopeia:-** United States Pharmacopeia-DSC-2015, Page No. Page No: 1225-1226. BNF 78 (Page no- 65,1575) **Reference Products:** Brand: **Lactase Drop** Seeking Health, Bellingham, USA.	Document submitted as per requirement but Lactase is an Enzyme	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
61.	Total Herbal & Nutraceuticals	Alpha Lipoic Acid + Chromium as Picolinate + Zinc + Selenium + Vitamin E + Vitamin B5 + Vitamin B6 + Vitamin B1 + Vitamin H Biotin **tablet** Alpha Lipoic Acid 600 mg+ Chromium as Picolinate 100 mcg + Zinc 10 mg + Selenium 50 mcg + Vitamin E 15 mg + Vitamin B5 9 mg + Vitamin B6 3	a) Neurotropic b) Anti-Inflammatory c) Antioxidant d) Altered Nervous Tropism e) Oxidative Stress.	Women who are pregnant or who could become pregnant should not use this supplement. There have been no reports of significant drug interactions	New	**Reference Pharmacopeia:-** United States Pharmacopeia-DSC-2015, Page No. Page No: 1225-1226. **Reference Products:** Brand Name: **Nevralip,**	Document submitted as per requirement but some of the ingredients are	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		mg + Vitamin B1 2 mg + Vitamin H Biotin 100 mcg **Capsule**				RIVER PHARMA s.r.l. Viale Stazione n. 6 | 26863 Orio Litta (LO) – Italy	pharmacutical ingredients		
62.	Total Herbal & Nutraceuticals	Coal Tar Oil Shampoo Coal Tar Oil 2% Shampoo	a) Seborrheic dermatitis, b) Atopic eczema.	Women who are pregnant or who could become pregnant should not use	New	**Reference Pharmacopeia:-** BNF 69 (Page no- 809-814) **Products Reference: Redwin Coal Tar Shampoo** Pharmacare Laboratories Australia. Product Name: Redwin Sensitive Skin Coal Tar Shampoo	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
63.	Total Herbal & Nutraceuticals	Propolis Capsule Propolis 500 mg Capsule	a) Wasting – thirst. b) Used in Arthritis	None reported.	New	**Reference Pharmacopeia:-** 1) Chinese Pharmacopeia Volume -1, Page no: 372-374 **PDR for Herbal Medicine- (page n0- 522-524)** **Products Reference:** (1) Propolis Capsule premium David Health International. Canada.	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
64.	Total Herbal & Nutraceuticals	Myo Inositol+ D Chiro Inositol+L Methyl Folate+ Vitamin D3 Sachet	1) Polycystic ovary syndrome (PCOS) 2) Women Infertility.	**CONTRAINDICATIONS:** The drug is contraindicated in pregnancy and in nursing	New	**Pharmacopeia Reference:** 1) USP Dietary supplements Compendium-2015, Page no-	Document submitted as per	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Myo Inositol 2000 mg + D Chiro Inositol 50mg + L Methyl Folate 1000 mcg+ Vitamin D31000IU Sachet	3) Premenstrual syndrome (PMS) 4) Menopausal complaints	mothers.		2068-2067, 958, 1118, 1020-1021. 2) PDR Herbal Medicine-Herbal Monograph, Page No: 151-152. **Products Reference:** Lactonova, #81-3, IDA Mallapur, Hyderabad, Telangana 500076, India.	requirement but some of the ingredients are pharmacutical ingredients		
65.	Total Herbal & Nutraceuticals	Salicylic Acid+ Tea Tree Oil Soap Salicylic Acid 3%+ Tea Tree Oil1% Soap	**1)** Inching, 2) Anti-Acne 3) Skin disorders. 4) Scabies,	Tea tree oil is **POSSIBLY SAFE** for most people when put on the skin, but it can cause skin irritation and swelling	New	**Pharmacopeia Reference:** 1) United States Pharmacopeia- USP-42, Page-. 6093-6094 2) Who Selected Medicinal Plant, Volume-2, Page172-179 **Products Reference:** (1) MARS Medi Soap, 54/B/2 Changodar Ind. Estate, Changodar, Ahmedabad - 382213, Gujarat, India.	Document submitted as per requirement but one of the ingredients are pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
66.	Total Herbal & Nutraceuticals	Salicylic Acid+ Coal Tar Oil Soap Salicylic Acid 3%+Coal Tar Oil 1% Soap	a) Seborrheic dermatitis, b) Dandruff. c) Pityriasisversicolor d) Itching e) Scaling f) Flaking & redness	Women who are pregnant or who could become pregnant should not use There have been no reports of significant drug interactions	New	**Reference Pharmacopeia:-** 1)USP-United States Pharmacopeia Page-1111,6093-6094 Products Reference: Brand: **SELKOLSoap** MARS Medi Soap, 54/B/2 Changodar Ind. Estate, Ahmedabad, Gujarat, India.	Document submitted as per requirement but one of the ingredients are pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
67.	Total Herbal & Nutraceuticals	Saw Palmetto Extract +Lycopane +Pumpkin Extract +Pygeum Africanum Extact +*Stinging Nettle Extract*	1) Benign Prostatic hyperplasia	No interactions have been reported		**Pharmacopeia Reference**: 1) British Herbal	Document submitted as	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		+ Vitamin D3 + Vitamin E + Folate +Vitamin B12 +Calcium +Magnesium Zinc + Selenium Saw Palmetto Extract 320mg +Lycopane 10mg +Pumpkin Extract 100mg +Pygeum Africanum Extact 100 mg +*Stinging Nettle Extract* 100 mg + Vitamin D3 400 IU + Vitamin E 50 IU + Folate 133 mcg +Vitamin B12 17 mcg +Calcium 135mg +Magnesium 40mg Zinc 9.4mg + Selenium 63mcg	2) Frequent urination 3) Support normal prostate function 4) Healthy urinary flow.			Pharmacopeia 1996, Page no: 166-167, 143-144,155-156 *1) United State Pharmacopeia-DSC-, Page no:1020-1021,1118-1119,1239-1240,1462-1463,1052-1053, 943-944, 1252-1253,1718-1719.943-944* . **Products Reference**: Brand Name: Urozonic Tablet, Manufactured by: Vitanergy,	per requirement but some of the ingredients are pharmacutical ingredients	যেতে পারে।	
68.	Total Herbal & Nutraceuticals	Cranberries Ext + D Mannose **Capsule** Cranberries Ext 400mg + D Mannose 100mg **Capsule**	1) Urinary Tract Infection (UTI), 2) Cranberries have also been used for blood disorders, 3) Prevent Liver problems, 4) Scurvy and in the preparation of wound dressings. 5) Antioxidant activity	Very rear side effect on Cranberry Stomach or abdominal upset and Diarrhea in high dosage.	New	**Pharmacopeia Reference:** 1)United States Pharmacopeia-USP-DSC-2015 - Page- 1039, **Products Reference:** GNC Herbal Plus, Cranberry +D Mannose	Document submitted as per requirement reference for D Mannose is not Supplied	প্রয়োজনীয় রেফারেন্স সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়
69.	Total Herbal & Nutraceuticals	Activated Charcoal **Capsule** Activated Charcoal 520 mg **Capsule**	a) Activated Charcoal is a gastrointestinal adsorbent. b) Reduction of absorption of poisons in the gastro- intestinal system, see also active elimination techiniques above.	This medication usually has very few side effects. If you have any unusual effects from taking this medication, contact your doctor or pharmacist promptly	New	**Pharmacopeia Reference:** **BNF 69 (Page no- 35)** **PDR for Herbal Medicines (Page no- 19-21)** **Reference Products:** **(a)** Naturs Truth, (b) Spring Valley , France	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
70.	Total Herbal &	Bifidobacterium breve+ Bifidobacterium	a) Diarrhea relief	**CONTRAINDICATIONS:** The	Existing	**Pharmacopeia Reference:**	Document	প্রয়োজন নেই বিধায়	প্রয়োজন নেই বিধায় নামঞ্জুর

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
	Nutraceuticals	lactis+Bifidobacterium longum +Bifidobacterium bifidum +Bifidobacterium infantis +Lactobacillus acidophilus +Lactobacillus paracasei +Lactobacillus plantarum +Lactobacillus reuteri +Lactobacillus rhamnosus + L-lysine+ Zinc gluconate + Vitamin B1 +Vitamin B2 Vitamin B6 **Capsule** Bifidobacterium breve 0.2 bill eqv to 1 mg + Bifidobacterium lactis 5 bill eqv to 10 mg+ Bifidobacterium longum 0.1 bill eqv to 1 mg + Bifidobacterium bifidum 0.2 bill eqv to 1 mg +Bifidobacterium infantis 0.1 bill eqv to 1 mg + actobacillus acidophilus 0.6 bill eqv to 3 mg + Lactobacillus paracasei 3.6 bill eqv to 9 mg + Lactobacillus plantarum 5 bill eqv to 10 mg + Lactobacillus reuteri 0.2 mg eqv to 1 mg + Lactobacillus rhamnosus 5 bill eqv to 10 mg + L-lysine 50 mg + Zinc gluconate 36 mg + Vitamin B1 2 mg + Vitamin B2 2 mg + Vitamin B6 2 mg **Capsule**	b) Digestion health c) Absorption boost d) Anti-picky foods	drug is contraindicated in pregnancy and in nursing mothers.		PDR for Herbal Medicines; 3rd edition. - P.996-1001. **Products Referance:** Biogrowing Inc. Shanghai, China-, Products Name: BifiGuard **country of origin China**	submitted as per requirement but some of the ingredients are pharmacutical ingredients	আবেদন নামঞ্জুর করা যেতে পারে।	করা হয়।
71.	Alien Pharma (Herbal)	L-CARNITINE (AS TARTRATE) + MACA ROOT + ASIAN GINSENG ROOT + CoQ10 + VITAMINE A (AS BETA CAROTENE) + VITAMIN C (AS ASCORBIC ACID) + VITAMIN E (AS D-ALPHA TOCOPHEROL) + FOLIC ACID (Folate) + VITAMIN B12 (AS METHYLCOBALAMINE) + ZINC (AS ZINC GLUCONATE) + DHA + SELENIUM (SELENOMETHIONINE) + CHROMIUM (POLYNICOTINATE) + L-Arginine + VITAMIN D **Capsule** **Per 3 Capsules Contain:** L-CARNITINE (AS TARTRATE) 350.00 mg + MACA ROOT 300.00 mg + ASIAN GINSENG ROOT 100.00 mg + CoQ10 50.00 mg + VITAMINE A (AS BETA CAROTENE)	a) Improve overall male reproductive Health, b) Sperm parameters such Increase Sperm Count, c) Increase Sperm motility (movement) and morphology (shape).	**Contra-indication:** No interactions have been reported. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** 1) United States Pharmacopeia DSC-2015; Pages: 1226-1228, 139-141, 889-891, 1445-1446, 906-907, 876-877, 879-880, 1462-1464, 1052-1053, 1715-1717, 1398-1399, 1031-1032, 1118, 1020-1023. **Products Reference:** a) **Product Name:** Fertilaid for men. **Company Name:** Fairhaven Health, LLC, USA.	Document submitted as per requirement but some of the ingredients are pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		5000.00 IU + VITAMIN C (AS ASCORBIC ACID) 250.00 mg + VITAMIN E (AS D-ALPHA TOCOPHEROL) 150.00 IU + FOLIC ACID (Folate) 500.00 MCG + VITAMIN B12 (AS METHYLCOBALAMINE) 25.00 MCG + ZINC (AS ZINC GLUCONATE) 30.00 mg + DHA 10.00 mg + SELENIUM (SELENOMETHIONINE) 100.00 mg + CHROMIUM (POLYNICOTINATE) 120.00 MCG + L-Arginine 25.00 mg + VITAMIN D 400.00 IU						
72.	Alien Pharma (Herbal)	Magnesium (Magnesium Oxide) Tablet Magnesium (Magnesium Oxide) 400mg Tablet	a) Osteoporosis, b) Leg cramps, c) Migraines, d) Fatigue, e) PMS, f) Preeclampsia g) Pre-term labor, h) Heart attack, i) High blood pressure, j) Serum lipids, k) Diabetes Stroke	**Contra-indication:** No reports of significant drug interactions. **Side Effect:** Possible reaction if allergic to shellfish.	New	**Reference Pharmacopeia: -** 1) USP-DSC, Volume -1 Page No-1254 **Products Reference:** a) **Product Name:** Magnesium Oxide 400 mg, **Company Name:** Windmill Health Products- USA. b) **Product Name:** MagOx 400mg, Company Name: Health Care Products, USA.	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
73.	Alien Pharma (Herbal)	Lactase **drop** Lactase 100 mg eqv to 3000 FCC 30ml **drop**	a) Used to control Diarrhoea	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** BNF 78 (Page 65,1575) **Products Reference:** (a) **Product Name:** Lactase Complex 200mg **Company Name:** Lamberts Health Care ltd, UK. (b) **Product Name:** Super Strength Lactase 9000, **Company Name:** Nature's	Document submitted as per requirement but Lactase is an Enzyme	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
						Best, England.			
74.	Alien Pharma (Herbal)	Cinnamon + Alpha lipuic acid + Chromium **Capsule** Cinnamon 500 mg + Alpha lipuic acid 150 mg + Chromium 100mcg	a) Diabetes, b) Liver disease, c) Diabetes mellitus, d) Glaucoma, e) Hypertension and f) Alzheimer's disease.	**Contra-indication:** None documented. **Side Effect:** Currently, No side effects. But, contact with cinnamon bark or oil may cause an allergic reaction. Should not be used on the skin.	New	**Reference Pharmacopeia:** a) Monographs on Selected Medicinal Plants, vol 1. Page: 95-104 b) USP DSC- 2015 Page:1233-1234. **Products Reference:** (a) **Product Name:** Mason Natural Whole Herb Cinnamon & Alpha Lipoic Acid. **Company Name:** Mason Vitamins, Inc. country of origin is not identyfed	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
75.	Alien Pharma (Herbal)	Zinc Gluconate **Tablet** Zinc Gluconate 25 mg	This mineral may enhance immune function, stabilize blood sugar levels, and help keep your skin, eyes, and heart-healthy	**Contra-indication:** None reported. **Side Effect:** His is not a complete list of side effects and others may occur.	New	**Reference Pharmacopeia:** a) USP DSC- 2015 Page: 1715-1717.	Document submitted as per requirement but ingredients are pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
76.	Alien Pharma (Herbal)	Glucosamine Hydrochloride + Chondroitin Sulfate + MSM + Collagen **Tablet** Glucosamine Hydrochloride 500 mg + Chondroitin Sulfate 250 mg + MSM (Methyl Sulfonyl Methane) 100 mg + Collagen (Collagen Type 2) 100 mg	Osteoarthritis Rheumatoid arthritis Joint pain & inflammation	**Contra-indication:** No reports of significant drug interactions. **Side Effect:** Include indigestion or nausea.	New	**Reference Pharmacopeia:** PDR For Herbal Medicines (4th Edition) (Page 955-958, 967-970) a) USP DSC- Vol- 1 - 2015, Page: 1029 - 1030, 1163 - 1165, 1279-1280. b) USP VOLUME 1-(2017)-	Document submitted as per requirement but some of the ingredients are used as pharmacuticul products	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
						USP 40 NF 35, Pages: 185-190 **Products Reference:** **Products Name:** Mega Joint 4x Glucosamine + Chondroitin + Sulfate + MSM + Collagen, **Company Name:** GreeNatr Premium. USA.			
77.	Alien Pharma (Herbal)	Coal Tar + Salicylic acid **Shampoo** Coal Tar 1.0% + Salicylic acid 3.0%	a) Eczema, b) Psoriasis, c) Seborrheic dermatitis, d) Dandruff other skin disorders.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Including staining of clothes and tar odor.	New	**Reference Pharmacopeia:** a) British Herbal Pharmacopoeia 2016- Volume-2; Page no.: 796-797, 991. **Products Reference:** a) **Product Name:** Cosalic Coaltar & Salicylic Acid Ointment Solution. **Company Name:** Salve Pharmaceuticals Pvt. Ltd, India.	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
78.	Alien Pharma (Herbal)	Coal Tar + Salicylic acid **Ointment** Coal Tar 6.0% + Salicylic acid 3.0%	a) Eczema, b) Psoriasis, c) Seborrheic dermatitis, d) Dandruff other skin disorders.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Including staining of clothes and tar odor.	New	**Reference Pharmacopeia:** a) British Herbal Pharmacopoeia 2016- Volume-2; Page no.: 796-797, 991. **Products Reference:** **Product Name:** Cosalic Coaltar & Salicylic Acid Ointment. **Company Name:** Salve Pharmaceuticals Pvt. Ltd, India.	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
79.	Alien Pharma (Herbal)	Cholecalciferol **Tablet**	a) Osteoporosis, b)	**Contra-indication:** Safe, No	New	**Reference Pharmacopeia:** a)	It is used as	প্রয়োজন নেই বিধায়	প্রয়োজন নেই বিধায় নামঞ্জুর

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Cholecalciferol (Vitamin D3) 5000 IU	Osteoarthritis, c) Vitamin D Deficiency, d) Rickets, e) Hypothyroidism, f) Hypophosphatemia, g) Hypocalcaemia.	Interaction. **Side Effect:** Currently, No side effects.		USP DSC-2015, Page no: 1020-1023.	pharmacuticul Item	আবেদন নামঞ্জুর করা যেতে পারে।	করা হয়।
80.	Alien Pharma (Herbal)	Cholecalciferol **Liquid Solution** Cholecalciferol (Vitamin D3) 5000 IU	a) Osteoporosis, b) Osteoarthritis, c) Vitamin D Deficiency, d) Rickets, e) Hypothyroidism, f) Hypophosphatemia, g) Hypocalcaemia.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** a) USP DSC-2015, Page no: 1020-1023.	It is used as pharmacuticul Item	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
81.	Alien Pharma (Herbal)	Neem + Tea Tree Oil **Shampoo** Neem (Folium Azadirachti) 0.2% + Tea Tree (Aetheroleum Melaleucae Alternifoliae) Oil 1.0%	Used for Warm infestation and as a disinfectant.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia: PDR For herbal medicinces Page 539, 540, 757** a) WHO monographs on Selected Medicinal Plants, Pages: 88-99, 172-178 **Products Reference:** **a) Product Name:** Lice-Nil, **Company Name:** Sujanil Chemo industries, India. **b) Product Name:** Neem Tea Tree Shampoo, **Company Name:** Universal Essence, India.	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
82.	Alien Pharma (Herbal)	Tea Tree Oil (Aetheroleum Melaleucae Alternifoliae) + Salicylic Acid **Foot Cream** Tea Tree Oil (Aetheroleum Melaleucae Alternifoliae) 2.0% + Salicylic Acid (Beta hydroxy acid) 3.0%	Common skin disorders such as tinea pedis (Athlete's foot), Bromidrosis (Foul smelling) Etc.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Do not get any side effect.	New	**Reference Pharmacopeia:** a) WHO monographs on Selected Medicinal Plants, Pages: 172-178. b) BP 2016- Volume-2, Page: 796-797. **Products Reference:** **(a) Product Name:** SaliSkin	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
						Acne Treatment Cream. **Company Name:** Scientific Solutions Inc. USA.			
83.	Alien Pharma (Herbal)	Zinc + Magnesium + Vitamin B6 **Tablet** Zinc Gluconate 30 mg + Magnesium Oxide 450 mg + Vitamin B6 (Pyridoxine Hydrochloride) 10.5 mg Tablet	a) Normal development, b) Growth, c) Immune system, d) Vital for every organ & heart, muscles, kidneys and bones, e) Boost energy.	**Contra-indication:** Safe, non-prescription formula. **Side Effect:** Currently, no side effects have been reported.	New	**Reference Pharmacopeia:** 1) United States Pharmacopeia DSC-2015; Pages: 1348-1349, 1715-1717 & 1252-1253. **Products Reference:** 1) **Products Name:** Sundown Natural Optimum Nutrition ZMA. **Company Name:** OPTIMUM NUTRITION, INC USA. 2) **Products Name:** Musclematic Scientific Nutrition ZMA. **Company Name:** Influx Healthcare India.	All are pharmaceutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
84.	Alien Pharma (Herbal)	Neem + Tea Tree Oil + Activated Charcoal **Soap** Neem Extract/Oil 2.0 % + Tea Tree Extract/Oil 1.0% + Activated Charcoal 0.24%	Acne and Ringworm.	**Contra-indication:** No monograph available at this time. **Side Effect:** Currently, no side effects have been reported.	New	**Reference Pharmacopeia:** 1) WHO monographs on Seleted Medicinal Plants -Vol -2 & Vol -3. Page: 172-178, 88-97. 2) USP-DSC- 2015- Vol-1; Pages: 1008-1009. **Products Reference:** 1) **Products Name:** Charcoal Neem & Tea Tree Soap. **Company Name:** Savon Art Scentsations Handcrafted Bath & Body Delights, Republic of Trinidad and Tobago.	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
85.	Alien Pharma (Herbal)	Phenol (Carbolic Acid) **Soap** Phenol (Carbolic Acid) 2.0 %	For external use in injury.	**Contra-indication:** No monograph available at this time. **Side Effect:** Its powerful properties can make it an irritant, so avoid using it if you have sensitive or dry skin.	New	**Reference Pharmacopeia:** 1) BP 2016- Volume-2; Pages: 549-550. The complete German Commission E monographs. **Products Reference:** 1) **Products Name:** Blue Power Carbolic Soap. **Company Name:** Blue Power Group Limited, Jamaica.	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
86.	Alien Pharma (Herbal)	L-Citrulline + Zinc Oxide + L-Arginine HCl + Maca Root Extract + Epimedium Aerial Part Extract **Tablet** L-Citrulline 25.00 mg + Zinc Oxide 5.00 mg + L-Arginine HCl 50.00 mg + Maca Root Extract 31.25 mg + Epimedium Aerial Part Extract 62.50 mg	Nitric Oxide (NO) Booster-Improves sexual performance, libido, and health. It's also an energy tonic with calming action, which improves the ability to cope with stress and exhaustion. Stress and exhaustion are often some of the underlying causes of low libido.	**Contra-indication:** There have been no reports of significant drug interactions. **Side Effect:** Do not get any side effect.	New	**Pharmacopeia Reference:** a) USP - DSC, Volume -1 Page No- 876-877, 1718-1719. b) USP- DSC, Volume -2 Page No- 139-141. c) USP VOLUME-4-(2017)-USP 40 NF 35, Pages: 6907-6908. **Products Reference:** a) Super Sample Supplements, USA. **Product Name:** Men's Sexual HEALTH	Document submitted as per requirement but no approved book reference for Epimedium Aerial	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়
87.	Alien Pharma (Herbal)	Myo-inositol (Inositol USP) + Co-enzyme Q10 (Ubidecarenone USP) + L-Carnitine (Levocarnitine USP) + Chromium Picolinate + Melatonin + Folate (Folic Acid) + Vitamin C (Ascorbic acid) + Vitamin E	PCOS formula: a) Polycystic ovary syndrome (PCOS) b) Women Infertility.	**Contra-indication:** The drug is contraindicated in pregnancy and in nursing mothers.	New	**Pharmacopeia Reference:** a) USP - DSC, Vol-1 - 2015, Pages- 2068-2069, 1445-1446, 1226-1228, 1031-1032,	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		+ Vitamin D3 (cholecalciferol-D3) + Vitamin B6 (Pyridoxine Hydrochloride) + Vitamin B12 (Cyanocobalamin) **Tablet** Myo-inositol (Inositol USP) 1000 mg + Co-enzyme Q10 (Ubidecarenone USP) 10 mg + L-Carnitine (Levocarnitine USP) 50 mg + Chromium Picolinate 20 mcg + Melatonin 500 mcg + Folate (Folic Acid) 200 mcg + Vitamin C (Ascorbic acid) 50 mg + Vitamin E 50 IU + Vitamin D3 (cholecalciferol-D3) 50 IU + Vitamin B6 (Pyridoxine Hydrochloride) 750 mcg + Vitamin B12 (Cyanocobalamin) 4 mcg	c) Premenstrual syndrome (PMS). d) Menopausal complaints. e) Support egg quality.	**Side Effect:** Occasionally, the administration of the drug leads to the formation of rashes.		1118, 879-880, 1462-1464, 1020-1021, 1347-1349, 1052-1053, 1266-1267. b) USP VOLUME-4-(2017)- USP 40 NF 35, Pages- 7094-7095. **Products** **Product Name:** OVA-Booster. Country of origin is not identyfide	but some of the ingredients are used as pharmacuticul products		
88.	Alien Pharma (Herbal)	Shatavari (Asparagus racemosus) + Vidharikand (Pueraria tuberosa) + Ashwagandha (Withania somnifera) + Lasun (Allium sativum) + Methi Seeds (Trigonella foenum graecum) + Jivanti (Leptadenia reticulata) + Dudhi (Traxaacum officinale) **Capsule** Shatavari (Asparagus racemosus) 525mg + Vidharikand (Pueraria tuberosa) 400mg + Ashwagandha (Withania somnifera) 100mg + Lasun (Allium sativum) 50.0 mg + Methi Seeds (Trigonella foenum graecum) 200mg + Jivanti (Leptadenia reticulata) 225mg + Dudhi (Traxaacum officinale) 50 mg	To Improve Lactation: a) Improves the quality and quantity of breast milk. b) Relieves breast pain due to improper secretions of milk. c) Improves lactogenesis and galactogenesis. d) Normalises the hormonal imbalance and nourishes the reproductive system. e) Offers patient compliance.	**Contra-indication:** There have been no reports of significant drug interactions. **Side Effect:** Do not get any side effect.	New	**Pharmacopeia Reference:** a) USP-DSC - 2015- Vol- 1. Page No: 881-883, 1138-1140. b) WHO monographs on Selected Medicinal Plants -Vol -3. Pages: 328-335, 338-346. c) Indian Pharmacopoeia-2010 – Vol- 3, Page no- 2540-2041. **Products Reference:** UNIJULES LIFE SCIENCES LTD. India, **Product Name:** Morolac Plus Capsule.	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
89.	Alien Pharma (Herbal)	Selenium Sulfide 2.5% **Lotion** Selenium Sulfide 2.5%	For the treatment of tinea versicolor, seborrheic dermatitis of the scalp, and treatment of dandruff.	**Contra-indication:** There have been no reports of significant drug interactions. **Side Effect:** Do not get any side effects. Avoid contact with eyes.	New	**Pharmacopeia Reference:** a) USP VOLUME 3-(2017)- USP 40 NF 35, Page: 6140. 11. **Products Reference:** a) Morton Grove Pharmaceuticals, USA. **Product Name:** Selenium Sulfide Lotion, USP 2.5%.	Document submitted as per requirement IT is Introduce as Pharmacutiical Product	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
90.	Alien Pharma (Herbal)	Ashwagandha Extract + L-Arginine + L-Citrulline + Mucuna Pruriens Extract + Fenugreek (Methi) Extract + Ginseng (Asian Ginseng) Extract + Tribulus Terrestris Extract + Zinc Sulfate **Tablet** Ashwagandha Extract 500.00 mg + L-Arginine 250.00 mg + L-Citrulline 250.00 mg + Mucuna Pruriens Extract 250.00 mg + Fenugreek (Methi) Extract 250.00 mg + Ginseng (Asian Ginseng) Extract 50.00 mg + Tribulus Terrestris Extract 500.00 mg + Zinc Sulfate 5.00 mg	Testosterone-Booster Improves sexual performance, libido, and health. It's also an energy tonic with calming action, which improves the ability to cope with stress and exhaustion. Stress and exhaustion are often some of the underlying causes of low libido.	**Contra-indication:** There have been no reports of significant drug interactions. **Side Effect:** Do not get any side effects.	New	**Pharmacopeia Reference:** a) USP- DSC, 2015 Vol -1 Page No- 876-877, 881-883, 889-891, 1721-1722. b) USP VOLUME-4-(2017)-USP 40 NF 35, Pages: 6907-6908. c) WHO monographs on Selected Medicinal Plants, Pages: 338-346. **Products Reference:** Influx Healthcare, India. **Product Name:** Cratus Right Nutrition Testosterone-Booster. UK	Document submitted as per requirement but some of the ingredients are Pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
91.	Alien Pharma (Herbal)	Natural Tocopherols + Vitamin B6 + Zinc + Mucuna Pruriens + American ginseng + Ashwagandha + Maca **Capsule** Natural Tocopherols (Alpha Tocopherol Standardized to 30%) 300.0 mg + Vitamin B6 (Pyridoxal-5-phosphate) 250.0 mg + Zinc 100.0 mg + Mucuna Pruriens (Standardized Extract to 15%) 200.0 mg + American ginseng (Ginseng root Extract 4:1) 250.0 mg + Ashwagandha (Standardized Root Extract to 5%) 250.0 mg + Maca (Root Extract 4:1) 300.0 mg	Galactorrhoea (abnormal production of breast milk), loss of sex drive, osteoporosis, amenorrhea (absence of periods).	**Contra-indication:** There have been no reports of significant drug interactions. **Side Effect:** You should consult a health professional before taking this product if you are pregnant, breastfeeding, or have a health problem.	New	**Pharmacopeia Reference:** a) USP- Vol-1- 2015- DSC. Page No: 1462-1464, 1347-1349, 1709-1710, 862-864, 881-882. b) USP- DSC-Volume-2-2015. Page No: 139-141. **Products Reference:** SN WORLDWIDE, UNIPESSOAL, LDA. Portugal. **Product Name:** Supersmart - Natural Anti Prolactin Support. Germany	Document submitted as per requirement but some of the ingredients are Pharmacutical ingredients	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
92.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi,	Undenatured Collagen Ⅱ + Calcium (Red Algae Extract) + Vitamin D_3 (Mushroom Extract) + Citrus Vitamin C (L-ascorbic Acid from Corn) + Zinc (Yeast) /Tablet	Osteoporosis Osteoarthritis Osteomalacia Osteopenia	**Side Effects:** Generally well tolerated in recommended dose. Flatulence, diarrhea,	Existing (Undenatured Collagen	**Pharmacopeia Regference:** PDR for nutritional supplements Page: 130;	Document submitted as per requirement	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
	Gazipur-1710, Dhaka	Undenatured Collagen Ⅱ 40.00mg + Calcium (Red Algae Extract) 600mg + Vitamin D_3 (Mushroom Extract) 25 mcg (equivalent to 1000 IU) + Citrus Vitamin C (L-ascorbic Acid from Corn) 45mg + Zinc (Yeast) 7.50mg /Tablet	Rheumatoid arthritis Rickets Bone and Joint health Parathyroid disease	constipation, upper GI discomfort nausea, vomiting, stomach cramps and dry mouth may occasionally occurred. **Contraindications:** Contraindicated in patients with known hypersensitivity to undenatured collagen Ⅱ, Algae Calcium, Vitamin D_3, Vitamin C, Zinc as well as hypocalcaemia, hyperparathyroidism, bone metastases, severe renal insufficiency, severe hypercalciuria and renal calculi.	Ⅱ)	PDR for Herbal Medicines (4th Edition; Page-948, 1008, 1021); Mosby's Drug Consult (Page 118); **Product Reference**: Caltrate Bone & Joint (Pfizer Consumer Healthcare) Canda	but some of the ingredients Pharmacutical ingredients (natural source)		
93.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Undenatured Collagen Ⅱ + Calcium (Red Algae Extract) + Vitamin D_3 (Mushroom Extract) + Citrus Vitamin C (L-ascorbic Acid from Corn) + Zinc (Yeast) + Magnesium + Copper + Manganese /Tablet Undenatured Collagen Ⅱ 40.00mg + Calcium (Red Algae Extract) 600mg + Vitamin D_3 (Mushroom Extract) 25 mcg (equivalent to 1000 IU) + Citrus Vitamin C (L-ascorbic Acid from Corn) 45mg + Zinc (Yeast) 7.50mg + Magnesium 50.00mg + Copper 0.50mg + Manganese 1.80mg /Tablet	Osteoporosis Osteoarthritis Osteomalacia Osteopenia Rheumatoid arthritis Rickets Bone and Joint health Parathyroid disease	**Side Effects:** Generally well tolerated in recommended dose. Flatulence, diarrhea, constipation, upper GI discomfort nausea, vomiting, stomach cramps and dry mouth may occasionally occurred. **Contraindications:** Contraindicated in patients with known hypersensitivity to undenatured collagen Ⅱ, Algae Calcium, Vitamin D_3, Vitamin C, Zinc as well as hypocalcaemia, hyperparathyroidism, bone metastases, severe renal insufficiency, severe	Existing (Undenatured Collagen Ⅱ)	**Pharmacopeia Regference:** PDR for nutritional supplements Page: 130; PDR for Herbal Medicines (4th Edition; Page-948, 985, 1008, 1021); Herbal Medicines Compendium – USP Dietary Supplement Monographs (USP30-NF25; Page-1833, 1526); Mosby's Drug Consult (Page 118); **Product Reference:** Caltrate Bone & Joint (Pfizer Consumer Healthcare) Canada	Document submitted as per requirement but some of the items are Pharmacutical Items (natural source)	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				hypercalciuria and renal calculi.					
94.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	*Lactobacillus rhamnosus* + *Saccharomyces boulardii* + Zinc (yeast)/Capsule *Lactobacillus rhamnosus* 1 billion + *Saccharomyces boulardii* 5 billion+ Zinc (yeast) 20mg /Capsule	Acute infectious diarrhea of infants, children	**Side Effects:** The intake of large quantities may cause gastritis. Allergic intolerance reactions are possible (itching, urticaria, exanthema, Quinck's disease). Migraine headaches can be triggered in susceptible patients. **Contra-indication :** Contraindicated to the patient with known hypersensitivity to Saccharomyces boulardii. Saccharomyces boulardii is contraindicated for use in patients with a central venous catheter placement. PREGNANCY AND LACTATION: No restrictions known	New	**Pharmacopeia Regference:** PDR for Herbal Medicines (4th Edition; Page-127, 996, 1021); **Product Reference:** Darolac Z (Aristo Pharma India)	Document submitted as per requirement but one of the item is Pharmacutical Item Zinc (from natural source)	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
95.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Pelargonium Root Extract *(Pelargonium sidoides)* Syrup Pelargonium Root Extract *(Pelargonium sidoides)* 20mg/1.5ml Syrup	Effective in children, Adolescents with Acute bronchitis.	**Side Effects:** Generally well tolerated in recommended dose. Occasionally hypersensitivity or allergic reaction may occur. **Contraindications:** Contraindicated in patient with known hypersensitivity to	Existing	**Pharmacopeia Regference:** The American Botanical Council Clinical Guide to Herbs (HerbalGram, Page-35); **Product Reference:** Kaloba (Dr. Willmar Schwabe GmbH) , Germany	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				Pelargonium. Contraindicated for those who are suffering from severe liver and kidney disease.					
96.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Lactobacillus paracasei + Lactobacillus fermentum/Capsule Lactobacillus paracasei 2 billion + Lactobacillus fermentum (GMN 090) 2 billion /Capsule	Used as Anti- Diarrhoea, in the treatment of various gastrointestinal (GI) tract pathologies.	**Side Effects:** The intake of large quantities may cause gastritis. Allergic intolerance reactions are possible (itching, urticaria, exanthema, Quinck's disease). Migraine headaches can be triggered in susceptible patients. **Contraindication:** Contraindicated to the patient with known hypersensitivity. PREGNANCY AND LACTATION: No restrictions known.	New	**Pharmacopeia Regference:** 1) PDR for Herbal Medicines (4th Edition; Page-996) Herbs PDR for herbal Medicine (4th edition: page 996-999) 2) **Product Reference:** Allerbio Capsule (Sundyota Numandis)	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
97.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	D-chiro-inositol (*Ceratonia siliqua*)+ Myo-inositol (Phytin`s corn)+ Folic acid (5-methyltetrahydrofolate) /Tablet  D-chiro-inositol ( *Ceratonia siliqua*) 150mg+ Myo-inositol (Phytin`s corn) 550mg+ Folic acid (5-methyltetrahydrofolate) 200mcg /Tablet	Polycystic ovary syndrome (PCOS) Menstrual cycle irregularity Infertility	**Side Effects:** No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. **Contraindication:** None listed PREGNANCY AND LACTATION: None listed	New	**Pharmacopeia Regference:** The American Botanical Council Clinical Guide to Herbs (HerbalGram, Page-158, 231); PDR for Herbal Medicines (4th Edition; Page-962); **Product Reference:** Rediva MA (Sundyota Numandis), Spain Inofolic Combi (Lo.Li. Pharma) India	Book referance for one ingredient (Myo-inositol) not Supplied	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	অনুমোদিত রেফারেন্স বই এর ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়।
98.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Cactus extract (*Opuntia dillenii*) + Sesame oil (*Sesamum indicum*) + Beeswax (*Cera flava*) standardized extract/ Ointment Cactus extract (*Opuntia dillenii*) 0.15g + Sesame oil	Use for removeal of scabs and crust formations. Skin and mucous membrane irritation.	**Side Effects:** No serious side effects have been reported. **Contra-indication :** Contraindicated to the patient	New	**Pharmacopeia Regference:** PDR for Herbal Medicines (4th Edition; Page-603,747); Pharmacopoeia of the people's republic of China	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		(*Sesamum indicum*) 28.5g + Beeswax (*Cera flava*) 1.35g standardized extract/30gm Ointment		with known hypersensitivity to Cactus extract, Sesame oil and Beeswax. For scar prevention, only use after wound healing or stitch removal; for wounded or ulcerous scars, do not use it until the wound heals completely. PREGNANCY AND LACTATION: Lack of sufficient clinical data for safe use during pregnancy and lactation		**Product Reference:** MEBO Scar ointment (Julphar Pharma, UAE)			
99.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Horopito Extract (*Pseudowintera colorata)* + Cranberry Extract (*Vaccinium macrocarpon*) /Tablet Horopito Extract (*Pseudowintera colorata)* 120mg + Cranberry Extract (*Vaccinium macrocarpon*) 500mg /Tablet	Urinary tract infection and Fungal infection	**Side Effects:** **G**enerally well tolerated in recommended dose. Flatulence, diarrhoea, constipation, upper GI discomfort nausea, vomiting, stomach cramps and dry mouth may occasionally occurred. **Contra-indication :** Contraindicated in patients with known hypersensitivity to Undenatured collagen II, Algae calcium, Vitamin D3, Vitamin C, Zinc as well as in hypocalcaemia, hyperparathyroidism, bone metastases, severe renal insufficiency, severe	New	**Pharmacopeia Regference:** The American Botanical Council Clinical Guide to Herbs (HerbalGram, Page-76); **Product Reference:** Kolorex Cranberry Plus Horopito (Forest Herbs Research), Newzland	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	অনুমোদন করা হয়।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
				hypercalciuria and renal calculi. PREGNANCY AND LACTATION: Lack of scientific evidence during use in pregnancy or reastfeeding.					
100.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Lactobacillus Helveticus Rosell-52 + Lactobacillus Rhamnosus Rosell-11 + Bifidobacterium Longum Rosell 175 + Saccharomyces Boulardii CNCM -1079) 5 billion (CFU) /capsule Lactobacillus Helveticus Rosell-52 + Lactobacillus Rhamnosus Rosell-11 + Bifidobacterium Longum Rosell 175 Saccharomyces Boulardii CNCM -1079 270.0000 mg	Used for Diarrhea, Antibiotic associated Diarrhea.	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported.	New	PDR for herbal Medicine (4th edition: page 996-999) Product referance : Probio'vit flore, Company : Granions Labaratoire, France	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
101.	Incepta Herbal & Nutricare Ltd.,Dhamrai. .	Lactobacillus Reuteri ATCC PTA 6475 5 billion (CFU) +Vitamin D_3 200 IU per capsule Lactobacillus Reuteri ATCC PTA 6475 5 billion (CFU) + Vitamin D_3 200 IU containing blend 265.0000 mg	Reduces bone loss in older adult.	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported.	New	PDR for herbal Medicine (4th edition: page 996-999) Mosby's Drug Consult 2006 Product referance : BioGaia, Osfortis Company : BioGia Ab, Sweden	One of the ingredients is used as Pharmacutical Product.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
102.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Lactobacillus Reuteri DSM 17938 100 million (CFU) per Sachet Lactobacillus Reuteri DSM 17938 2.0000 gm	Used for Constipation, Colitis.	**Contraindication:** No known interaction with other medicine. **Side-effects:** No serious side effects have reported	New	PDR for herbal Medicine (4th edition: page 996-999) Product referance : BioGaia, Protectis Company : BioGia Ab, Sweden	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
103.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Lactobacillus salivarius LS01 + Bifidobacterium Breve B632 2 billion (CFU) /Sachet Lactobacillus salivarius LS01 + Bifidobacterium Breve B632 Containing Blend 2.0000 gm	Used for Irritable bowel syndrome, urinary tract infection	**Contraindication:** No known interaction with other medicines. **Side-effects:** No serious side effects have been reported.	New	PDR for herbal Medicine (4th edition: page 996-999) Product referance : Biome Breathe Company : Biome, Italy	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
104.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Lactobacillus Paracasei 8700:2 + Lactobacillus Plantarum Heal 9 + Lactobacillus Plantarum Heal 19 10 billion (CFU) + Vitamin D_3 60 IU per capsule Lactobacillus Paracasei 8700:2 + Lactobacillus Plantarum Heal 9 + Lactobacillus Plantarum Heal 19 + Vitamin D3 containing blend 270.0000 mg	Reduces bone loss in older adult.	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported	New	PDR for herbal Medicine (4th edition: page 996-999) Mosby's Drug Consult 2006 Product referance : Biome Osteo Company : Biome, Sweden	One of the ingredients is used as Pharmacutical Product.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
105.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Lactobacillus Salivarius LS01 2 billion (CFU) /Sachet Lactobacillus Salivarius LS01 1.0000 gm	Used for Diarrhea, Bacterial vaginosis, Vaginal Candidiasis, Dermatitis.	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported	New	PDR for herbal Medicine (4th edition: page 996-999) Product referance : Newdirran AD Company : Probiotical SPA, Italy	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
106.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Bifidobacterium Infantis BB02 + Bifidobacterium Lactis BB12 + Streptococcus Thermophiles TH-4 1 billion (CFU) /Sachet Bifidobacterium Infantis BB02 + Bifidobacterium Lactis BB12 + Streptococcus Thermophiles TH-4 containing blend	Used for Colitis, Diarrhea, Prevention of Diarrhea, Improve intestine function.	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported	New	PDR for herbal Medicine (4th edition: page 996-999) Product referance : Similac Company : Abbott, USA	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	জবভবৎবহপব	মন্তব্য	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		1.0000 gm							
107.	Incepta Herbal & Nutricare Ltd.,Dhamrai.	Bifidobacterium Lactis B420 10 billion (CFU) per capsule Bifidobacterium Lactis B420 containing blend 150.0000 mg	Used for Diarrhea, Irritable bowel syndrome	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported	New	PDR for herbal Medicine (4th edition:page 996-999) Product referance : Ultraflora Control Company : Metagenics, USA	Document submitted as per requirement	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হয়।**
108.	S.B. Herbal & NutraceuticalsM	Maca (Lepidium meyenii) Caplsule Maca (Lepidium meyenii) Caplsule 500mg	A Variety of use are reported for Maca. These are as follows : 1. Sexual Function and Libio : Maca might use for improving sexual dysfunction and libido in men, 2. Antidepressant- Induced sexual dysfunction : maca may alleviate antidepressant-induced sexual dysfunction in women, 3. Fertility : It was reported that semen quality and hormone levels were assessed after the intake of Maca, 4. Other Indication : In the treatment of anemia, leukemia, chronic fatigue syndrom, improving memory boosting the immune system	**Contraindication:** No known interaction with other medicines **Side-effects:** No serious side effects have reported	New	Product referance : Maca Root Company : Vita bright	No book reference for Maca and Country of origin is not mention in reference	প্রয়োজনীয় ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় ডকুমেন্ট সরবরাহ না করায় আবেদন নামঞ্জুর করা হয়।

Annex-H
Medical Device & Surgical Equipment

Sl. No.	Name of the Manufacturer and Local Agent	Name of the product & Dosage form	Generic Name with strength	Class	Indication	CPP/FSC	EC/CE Certificate	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	**Mfgr :** ঈু ঃড়ঝড়ৎনবহঃ ওুপ্ ট ঝঅ **Local Agent :** জধফরধহঃ ঊী ঢ়ড়ৎঃ ওসঢ়ড়ৎঃ উহঃবৎঢ়ৎরব., খঁ নফযাড়শ, ৪য় ঋষড়ড়ৎ, ৪৭৪ চ, জড়ধফ ঘড়-৩, ঝবপঃড়ৎ-১২, ট ঃঃধৎধ, উ যধশধ-১২৩০	ঈু ঃড়ঝড়ৎন ৩০০ স ষউ বা রপব	ঈু ঃড়ংড়ৎন	ঈ	এঃরব ঈু ঃড়ঝড়ৎন উ বা রপব (ঈু ঃড়ঝড়ৎন) রু ধ হড়হ-ঢ়ু ৎড়মবহরপ্ ংঃবৎরঃধ, ংরুমষধ- ংব ফবা রপব পড়হঃধরুহরুহম ধফৎড়ৎনবহঃ ঢ়ড়য়ু সব ৎ নবধফৎ ফবংরুমহবফ ঃড়ৎবস ড়া ব পু ঃড়শরুহবং, ধং নষড়ড়ফঢ়ধংংবং ঃযৎড়ঁ ময ঃযব ফবা রপব. ঈু ঃড়ঝড়ৎন রু ঢ়ষধপবফরুহ ধ নষড়ড়ফঢ়ঁ স ঢ় পরুপঁ রু. ঈু ঃড়ঝড়ৎন রু রুহফরুপধঃবফহ ভড়ুঁ ংব রুহ পড়হফরুঃড়হং ি যবৎব বষধা ধঃবফহ ফধা বষ ড়ভপু ঃড়শরুহবং ধৎব ঢ়ৎবংবহঃ. ঈু ঃড়ঝড়ৎন এঃরবৎধঢ়ু স ধু নব ধ ঢ়ৎড়স রুরুহম ধহফ রুস ঢ়ড়ৎঃধহঃ ঃযবৎধঢ়বঁ ঃরপ ড়ঢ়ঃরড়হ ঃড় যবষ্ স ধহধমব ঃযব ংবৎরড়ঁ ং পড়স ঢ়ষধপধঃরড়হং পধঁ ংবফনু পু ঃড়শরুহব ংঃড়ৎস ধহফ যু ঢ়বৎরুহভধসস ধঃরড়হ রু পৎরুরপধষ্ু রুষ ঈঙ ঠ ঞ্জ-১৯ রুভপ্ঢ়বফ ঢ়ধংরবহংং.	ট ঝঋউ অ উসব ৎমবহপু ট ংব অঁ ঃযড়ড়ৎুধঃ রড়হ প্রদান করেছে। FSC-France		পদটি অনুমোদনের সুপারিশ করা হয়।	পদটি অনুমোদন করা হয়।
2.	**Mfgr :** এঙ ঋঅজগ ঝঢ়. ত ড়. ড়. ঝঢ়.শ., চড়ষ্ধহফ **Local Agent :** ইব ধপড়হ ইঁ ংরুহবংং ঝড়ষঁ ঃরড়হ খ ঃফ, ই বধপড়্হ ইঁ ংরুহবংং ঈবহ ঃৎব ৯/ই/ ২, এঃড়ু বহনবব ঈরৎপঁ ষ্ধৎ জড়ধফ (ই ড়ী ঈঁ ষ বৎঃ জড়ধফ), গ ড়ঃরুষ্নববষঈ/অ, উ যধশধ-১০০০.	ঙ হপড়ু ওসসঁ ভ্নহ এ বষ ঙ হ ঝশরুহ অ ভল্লৎ জধফরড়ঃযবৎধঢ়ু	ঙ হপড়ু ওসসঁ ভ্নহ এ বষ ঙ হ ঝশরুহ অ ভল্লৎ জধফরড়ঃযবৎধঢ়ু	ই	ঙ হপড়গ বফ মবষড়হ ংশরুহ ধভল্লৎ ৎধফরড়ঃযবৎধঢ়ু রু ধ সব ফরুপধষফবা রপব রু ভড়ুস ড়ভমবষঁ ংবং ভড়ৎ ঢ়ৎড়ঢ়বৎ সড় রুঃ ণ্ডুল্ল হম, ষঁ নৎরুপধঃরুহম ধহফ পৎবধঃরুহম ড়ভঢ়ৎড়ঃবপল্লর ব নধৎৎরুৎ হবধৎ ঃযব ঢ়ষধপবং ংঁ নল্লপঃবফ ঃড়ৎধফরড়ঃযবৎধঢ়ু . উঁ ব ঃড়ু পৎবধঃরড়হ ড়ভঢ়ৎড়ঢ়বৎ বহা রুড়হস বহঃ রুংঁ ঢ়ঢ়ড়ৎংং পড়ঁ ৎংব ড়ভহধঃ ধ ধষধৎবমবহবৎধঃরুহম ঢ়ৎড়পবংংবং.	ঋঝঈ-চড়ষ্ধহফ		পদটি অনুমোদনের সুপারিশ করা হয়।	পদটি অনুমোদন করা হয়।
3.	**Mfgr :** এঙ ঋঅজগ ঝঢ়. ত ড়. ড়. ঝঢ়.শ., চড়ষ্ধহফ **Local Agent :** ইব ধপড়হ ইঁ ংরুহবংং ঝড়ষঁ ঃরড়হ খ ঃফ, ই বধপড়্হ ইঁ ংরুহবংং ঈবহ ঃৎব ৯/ই/ ২, এঃড়ু বহনবব ঈরৎপঁ ষ্ধৎ জড়ধফ (ই ড়ী ঈঁ ষ বৎঃ জড়ধফ), গ ড়ঃরুষ্নববষঈ/অ, উ যধশধ-১০০০.	ওসসঁ ভ্নহ ঙ হপড়ু ঐ ধহফ-ঋড়ড়ঃ ঝু হফৎড়সব ঈৎবধস	ওসসঁ ভ্নহ ঙ হপড়ু ঐ ধহফ-ঋড়ড়ঃ ঝু হফৎড়সব ঈৎবধস	ই	ঙগ ট ঋউঘ – ঙ হপড়ু ঐ ধহফ-ঋড়ড়ঃ ঝু হফৎড়সব ঈৎবধস ঈৎব ধ্রবফ ভ্রষ্ফস , বধংবং পড়ঁ ৎংব ড়ভংরুধব বভস্নপঃ, ড়ভংড়সব পয্বসড় ঃযবৎধঢ়বঁ ঃরপং ধহফ নরড়ষড়মরপধষসবফ রপ্নহবং, ষ্ণশব ঐ ধহফ-ঋড়ড়ঃ ঝু হফৎড়সব (ঢ়ধষ্ফ ধৎ ঢ়ধহঃধৎ বু ঃযৎড়ফু ংবং ঃযবংরপ). এঃরব পৎবধস ংযড়ঁ ফনবঁ ংবফ ধং ংঁ ঢ়ঢ়ড়ভঃ ভক্ত স ধরুহ ড়হ পড়ষড়মরপধষ ঃযবৎধঢ়ু (পয্বসড় ঃযবৎধঢ়ু).	ঋঝঈ-চড়ষ্ধহফ		পদটি অনুমোদনের সুপারিশ করা হয়।	পদটি অনুমোদন করা হয়।
4.	**Mfgr :** এ বষ্ফংরু, ওধযু . **Local Agent :** উ বষ্ধ চয ধৎস ধ খ রসর ঃবফ, ঐড়ঁ ংব-৫০১, জড়ধফ-৩৪, ঘ বি উঙ ঐ ঝ, গড় যধশযধষ্ফ্ উ যধশধ-১২০৬	ঈরঃৎরপ অপরু ধহফ ঈ বষ্ষ ষড়ংব ঝঁ ঢ়বৎধনংড়ৎনবহঃ যু ফৎড়মবষ ঢ়ধৎঃরুপষ্কাং চয. এৎ. ৭৫০.০০ স ম ঈধঢ়ংঁ ষ্ধ	ঈরঃৎরপ অপরু ধহফ ঈ বষ্ষ ষড়ংব ঝঁ ঢ়বৎধনংড়ৎনবহঃ যু ফৎড়মবষ ঢ়ধৎঃরুপষ্কাং চয. এৎ. ৭৫০.০০ স ম ঈধঢ়ংঁ ষ্ধ	ঈ	Plenity™ is an oral capsule that promotes fullness and may help to increase satiety to help patients manage their weight. Plenity is nonsystemic and works directly in the gastrointestinal (GI) tract. Plenity is made from two natural ingredients, cellulose and citric acid, that form a three-dimensional matrix designed to occupy volume in the stomach and small intestine, to create a sensation of fullness.	জবমরু ঃবৎবফহ রু ঋউঅ		প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।

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5.	**Mfgr :** উর ধংধ-চয ধৎস ধা ধপ ঝ. অ, ঝঢ়ধরহ **Local Agent :** ঙ ৎরহঃধষচয ধৎস ধ অ মৎড় ঠ বঃং খ ঃফ., ণ বধৎঢ়ঁ ৎ, তরুধনড়, অযঁ ষ্ণ, উ যধশধ	অ উজঙ ঋ অজ ঝঢ়ৎধু	ঐ ফৎড়পযষড়ৎরফব ঈয ষড়ৎঃবঃৎধপু পষ্ণহব উচ ২সম /১০০মস		ঝঁ ৎমরপধষ ড়ঁ হফং, ং ঢ়বৎঙ্গপরষ ড়ঁ হফং, ধফল্লা ধহঃ রহ ঃযব ঃৎবধঃসবহ ঃ ড়ভ ভড়ঃ রহ ভপঃড়হং পঁধ ংবফ নু ংবহংরুর ব সর পঃড়ড়ৎমধহরুস ং রহ ধষ্ণং ঢ়বপরবং.	ঋবাঈ -ঝঢ়ধরহ (গ বহঃরড়হবফ রহ ধঢ়ঢ় ষ্ণপধঃরড়হ নঁঃ পড়ঢু ড়ভ ঋবাঈ যধং হড়ঃ ংঁনসর ঃঃবফ)		প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
6.	**Mfgr :** উর ধংধ-চয ধৎস ধা ধপ ঝ. অ, ঝঢ়ধরহ **Local Agent :** ঙ ৎরহঃধষচয ধৎস ধ অ মৎড় ঠ বঃং খ ঃফ., ণ বধৎঢ়ঁ ৎ, তরুধনড়, অযঁ ষ্ণ, উ যধশধ	ঈঅ খ ঈ ওঙ ঠ উএঃ ওহ্লপঃরড়হ ৫০০ সষ	ঈধষপঁর স এ ষঁ পড়হধঃব (উঁ ৎ চয) ১৮১.১ স ম		অহ রহ ফরপধঃরড়হ রু ধ ঃবৎস ঁ ংবফ ভড়ৎ ঃযব ষ্ণং ঃ ড়ভ পড়হ ফরঃরড়হ ড়ৎ ংু স ঢ় ঃড়স ড়ৎ রষ্ণহবংং ভঙ্ক িযরপয ঃযব সব ফরপহব রু ঢ়ৎবং পৎরাবফ ড়ৎঁ ংবফ নু ঃযব ঢ় ধঃরবহঃ. ঋড়ৎ বী ধস ঢ়ষ্ণ, ধপবঃধসর হড়ঢ় যবহ ড়ৎ ঢ় ধৎধপবঃধসড় যরু ঁ ংবফ ভড়ৎ ভব বৎ নু ঃযব ঢ় ধঃরবহঃ, ড়ৎ ঃযব ফড়পঃড়ৎ ঢ়ৎবং পৎরাবং রু ভড়ৎ ধ যবধফধপযাব ড়ৎ নড়ফু ঢ় ধরহং. ঘ ড়ি ভ্লা বৎ, যবধফধপযাব ধহফ নড়ফু ঢ় ধরহং ধৎব ঃযব রহ ফরপধঃরড়হং ড়ভ ঢ় ধৎধপবঃধসড় ষ অ ঢ় ধঃরবহঃ ংযড়ঁ ফ্ফ নব ধি ধৎব ড়ভ ঃযব রহ ফরপধঃরড়হং ড়ভ সব ফরপধঃরড়হং ঁ ংবফ ভড়ৎ পড়সস ড়হ পড়হ ফরঃরড়হং নবপঁধ ংব ঃযবু পধহ নব ঃধশবহ ড়া বৎ ঃযব পড়ঁ হ ঃবৎ রহ ঃযব ঢ় যধৎস ধপু স বধহরুম ি রিযড়ঁ ঃ ঢ়ৎবং পৎরঢ়ঃরড়হ নু ঃযব চযু ংরপরবহ গড় ৎব: যঃঃঢ়ং://ি ি .হফঁ মং.পড়স /?ং=পধফার ব##ফড়পঃড়ৎথরহ ফরপ ধঃরড়হংথপধফাঁর স% ২০মষ পড়হধঃব	ঋবাঈ -ঝঢ়ধরহ (গ বহঃরড়হবফ রহ ধঢ়ঢ় ষ্ণপধঃরড়হ নঁঃ পড়ঢু ড়ভ ঋবাঈ যধং হড়ঃ ংঁনসর ঃঃবফ)		প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
7.	ক ওঞ্জ তণ গ উ ঝঅ, চ ধৎপ ওফঁং ঃৎবষফবং ঐ ধঃ ং-ঝধৎঃং, তড়হব ২, জঁব ফব গ রষ্ণ ড়ৎঃ, ৬৮০ ই উ-৪০৪০ ঐ বৎঃংধষ-ই বষমর্ণ স. **Local Agent:** তধং ওফঁং ঃৎবৎ খ ঃফ., ৮০/২২ গ ু সব হংযরহম জ ড়ধফ, ঘঁৎ লষ্ণধহ এ্রড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয.	ঝষরা গ বফ ভ অফা ধহপবফ ঈ ধঢ়ংঁষ বং	ঈ যরঃড়ৎধহ অড়স অ.হরমবৎ ৫০০সম, গ ধমহবংরঁ স ঝঃবধৎধঃব ৩.০সম, ঝরষ্ণপা,ঈ ড়ষফ্ড়রফধষ অহযু ফৎড়ং ১.০ সম	ঈ	• tৎবধঃস বহঃ ড়ভবীপ বংং ড়ভ ি বরমযঃ, • wবরমযঃ পড়হঃৎড়ষ	ঋবাঈ- ই বষমর্ণ স.	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
8.	ক ওঞ্জ তণ গ উ ঝঅ, চ ধৎপ ওফঁং ঃৎবষফবং ঐ ধঃ ং-ঝধৎঃং, তড়হব ২, জঁব ফব গ রষ্ণ ড়ৎঃ, ৬৮০ ই উ-৪০৪০ ঐ বৎঃংধষ-ই বষমর্ণ স. **Local Agent**: তধং ওফঁং ঃৎবৎ খ ঃফ., ৮০/২২ গ ু সব হংযরহম জ ড়ধফ, ঘঁৎ লষ্ণধহ এ্রড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয.	ক রড়ংযরাষ এ্রনষক	এ ষঁ পড়সধ হহধহ ১০০০ সম ঈ যরঃড়ৎধহ অড়স অ.হরমবৎ ৫০০সম , গ ধষষ্ণফবী ঃৎবহ ৬২৫সম, ঈ ড়ষফ্ড়রফধষ ংরষ্ণপড়হ ফরড়ী রফব ২০সম.	ঈ	ঁং বফ রহ ঃযব ঃৎবধঃস বহঃ ধহফ ঢ়ৎবাব হঃরড়হ ড়ভ ড়াব ি বরমযঃ রহ ড়ৎফবৎ গ্রু ঢ়ৎবা বহঃ ফরংবধংবং ৎবষধৎবফ গ্রু ড়ব বীপ বংং ড়ভ ি বরমযঃ ধহফ নড়ফু ভসংং ধহফ রু রহ্ণহবহফবফ গ্রু যবষঢ়ি রিয়: • tৎবধঃস বহঃ ড়ভবীপ বংং ড়ভ ি বরমযঃ, • ি বরমযঃ পড়হঃৎড়ষ নু স বধহং ড়ভৎবফঁ প্লহম পধষড়ৎরপ রহঃধশব ভড়ৎ ৎবংঃড়ৎরহম ধ যবধষয়ু বহ বৎমবংরুপ নধষধফপব ধহফ ংঁঢ়ঢ় ড়ৎঃরুম ধ ি বরমযঃ সধ হধমবস বহঃ ঢ়ৎড়মৎধস ঃ যধহশং গ্রু ধ ফড়ঁনষ ব ধপঃরড়হ: • ৎবফঁ প্লহম ধঢ়ঢ়বঃরুব ধহফ ঢ়ৎবা বহঃরুম বীপ বংংরব ব বধঃরুম ধহফ পৎধা রহমং, ধহফ • Iড়ি বৎবহম ভসঃ রহঃধশব অড়স ফরাঃ.	ঋবাঈ ই বষমর্ণ স.	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
9.	ক ওঞ্জ তণ গ উ ঝঅ, চ ধৎপ ওফঁং ঃৎবষফবং ঐ ধঃ ং-ঝধৎঃং, তড়হব ২, জঁব ফব গ রষ্ণ ড়ৎঃ, ৬৮০ ই উ-৪০৪০ ঐ বৎঃংধষ-ই বষমর্ণ স. **Local Agent:** তধং ওফঁং ঃৎবৎ খ ঃফ., ৮০/২২ গ ু সব হংযরহম জ ড়ধফ, ঘঁৎ লষ্ণধহ এ্রড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয.	এ্রধহং নরড়ঃধ ঝধপযবঃং	চ ংু ষর্ণ স ঐঁং শ ২৫০০ সম, ঈ যরঃরু-মফপ ধহ ১৫০০ সম, গ ধষষ্ণফবী ঃৎবহ ১৫৪৯ সম, ঈ রঙ্করপধপরফ৩০০ সম	ঈ	এ্রাব এ্রধবধঃস বহঃ ঙ ভগ ড়ফবৎধঃব ঈ ড়ংং ঃরুধঃরড়হ এ্রাব চ ৎড়স ড়ঃরড়হ ঙ ভঘ ড়ৎধষ য এ্রধহং রঃ এ্রাব জবযরাভ ঙ ভ এ ধং ংড়-ওঃংবং ঃরুধষ ঝু সঢ়ঃ ড়সং জবযধ্কবফ এ্রড়ঈ ড়ংং ঃরুধঃরড়হ অ হফ/ঙ ৎ এঁঃ উ ংনরড়ংরং.	ঋবাঈ ই বষমর্ণ স. .	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
10.	ক ওঞ্জ তণ গ উ ঝঅ, চ ধৎপ ওফঁং ঃৎবষফবং ঐ ধঃ ং-ঝধৎঃং, তড়হব ২, জঁব ফব গ রষ্ণ ড়ৎঃ, ৬৮০ ই উ-৪০৪০ ঐ বৎঃংধষ-ই বষমর্ণ স.	এ ধংঃৎধঢ়ভ উ রঞ্জপঃ ঝধপযবংং	Chitin-glucan from A. Niger 500mg ,Simethicone 250mg,	**B**	এ্রাব জবযরাভ ঙ ভ এ ধং-জবযধ্কবফ ঝু সঢ়ঃ ড়সং ঝঁপ য অ ং অ ই ষড়ধঃবফ ঋবযবরুম, ঋষধ্ক ফহপব অহফ অনফড়স রহধষচ ধরহ এ্রাব জবমষ ধৎরু ধঃরড়হ ঙ ভ ওঃংবং ঃরুধষ এ্রধহং রঃ অহফ ঝঃড়ড়ষ উা ধপঁধ ঃরড়হ এ্রাব ঘ ড়ৎসধ যুর ধঃরড়হ ঙ ভ এ্রাব ওঃংবং ঃরুধষ ঋঁহপ ঃরড়হ	ঋবাঈ ই বষমর্ণ স.	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer and Local Agent	Name of the product & Dosage form	Generic Name with strength	Class	Indication	CPP/FSC	EC/CE Certificate	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Local Agent: তধং ওহফঁং ঃড়বহ খঃফ., ৮০/২২ গ ু সব হংযরহম জড়ধফ, ঘঁৎ লক্ষধহ এঢ়ড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয.		ংরস্নপড়হ ফরড়ী রফব ২৫০সম .						
11.	ক ড়ৎধ ঐবধষয়পধৎব ঐবধফ ঙ ভ্রূপব, ঝড়িড়ৎফং ইঁং রহবংং চ ধৎশ, ঝড়িড়ৎফং, ঈড় উঁনষ রহ, ওবষধহফ. **Local Agent:** তধং ওহফঁং ঃড়বহ খঃফ., ৮০/২২ গ ু সব হংযরহম জড়ধফ, ঘঁৎ লক্ষধহ এঢ়ড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয.	জবমবষস্ক এ বষ	Regelle contains purified water and polycarbophil. Polycarbophil is a bioadhesive polymer which clings to the vaginal walls and serves to hold the lubricating water in place. Regelle also contains glycerol, mineral oil, hydrogenated palm oil glycerides, carbopol 974P and sorbic acid. Regelle is paraben-free.	ঈ	ঘ ড়হ-যড়ৎস ড়হধষষড়ৎম ষধংঃরহম া ধমরহধষস ড়রংঃঁ ৎরংবৎ ভ্রুৎ া ধমরহধষ ফু হবংং ধহফ ধঃৎড়ঢ়যু	ঋবাঈ-ওবষধহফ	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
12.	ক ড়ৎধ ঐবধষয়পধৎব ঐবধফ ঙ ভ্রূপব, ঝড়িড়ৎফং ইঁং রহবংং চ ধৎশ, ঝড়িড়ৎফং, ঈড় উঁনষ রহ, ওবষধহফ. খড়পধষ অমবহঃ: তধং ওহফঁং ঃড়বহং খঃফ., ৮০/২২ গ ু সব হংযরহম জড়ধফ, ঘঁৎ লক্ষধহ এঢ়ড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয	জবষধপঃধমবষ এ বষ	lactate vaginal gel.	ঈ	ঋড়ৎ ঃবব ঃৎবধঃস বহঃ্ চ ৎবাব হঃরড়হ ড়ভ ই ধপঃবৎরধষ্ঠ ধমরহড়ংরং	ঋবাঈ-ওবষধহফ	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
13.	ই রড়ভশঃড়ৎ ঝঢ়. ত ড়.ড়.ঁষ . ঈ ু ংঃধ ৪ ৯৬-১০০ ঝশরঃৎহরব রপব , চ ড়ষধহফ. খড়পধষ অমবহঃ: তধং ওহফঁং ঃড়বহং খঃফ., ৮০/২২ গ ু সব হংযরহম জড়ধফ, ঘঁৎ লক্ষধহ এঢ়ড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয	ঐ ধষঁ ভ্রাষঝঢ়ঢ় ড়ংরড়ুৎ	Sodium hyaluronate 10mg	ই	গ বফরপধষফবা রপব রু ৎবপড়সস বহফবফ ঃড়নবঁং বফ ঃড়স ড়রংঃবহ ধহফ ঢ়ৎড়ঃবপঃ সঁ পড়ুং সব সনৎ ধহব, রহ পড়হফরুরড়হং ৎবয়ঁর ৎরহম ংঃরঁষ ধঃরড়হ ড়ভহধঃ ৎধষৎবমবহবৎধঃরব ঢ়ৎড়পবংংবং ধহফ যবধষরুম ড়ভৎবপঃধষসঁ পড়ুং সব সনৎ ধহব ধহফ ধহধষপধহধষ.	ঋবাঈ চ ড়ষধহফ	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
14.	ই রড়ভশঃড়ৎ ঝঢ়. ত ড়.ড়. ঁষ . ঈ ু ংঃধ ৪ ৯৬-১০০ ঝশরঃৎহরব রপব , চ ড়ষধহফ. খড়পধষ অমবহঃ: তধং ওহফঁং ঃড়বহং খঃফ., ৮০/২২ গ ু সব হংযরহম জ ড়ধফ, ঘঁৎ লক্ষধহ এঢ়ড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয	ঐ ধষড়ঃরপ চ বংংধৎরবহ	Sodium hyaluronate 10mg and lactic acid 5mg	ই	গ বফরপধষফবার পব রং ৎবপড়সস বহফবফ ঃড়নবঁং বফ ধং স ড়রংঃঁ ৎরু রহম ধমবহঃ ৎবমবহবৎধঃরুম া ধমরহধষ সঁ পড়ংধ ধহফ ষর্ড় বৎরহম রহঞ্জধপস ধঃরড়হ	ঋবাঈ চ ড়ষধহফ	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।
15.	ই রড়ভশঃড়ৎ ঝঢ়. ত ড়.ড়. ঁষ . ঈ ু ংঃধ ৪ ৯৬-১০০ ঝশরঃৎহরব রপব , চ ড়ষধহফ. খড়পধষ অমবহঃ: তধং ওহফঁং ঃড়বহং খঃফ., ৮০/২২ গ ু সব হংযরহম জড়ধফ, ঘঁৎ লক্ষধহ এঢ়ড়ি বৎ, ই ধহমষধসড়ঃ ড়ৎ, উ যধশধ-১০০০, ই ধহমষধফবংয	ওহঃর ধম চ বংংধৎরবহ	Lactic acid 5mg	ই	গ বফরপধষ ফবার পব রং ৎবপড়সস বহফবফ ঃড়নবঁং বফ রহ ড়ৎফবৎ ঃড়সধ রহঃধরহ ঃবব ঢ়ৎড়ঢ়বৎ ধপরাঃরুঃ ড়ভঃযব া ধমরহধষ বহা রঙড়হস বহঃ.	ঋবাঈ চ ড়ষধহফ	উঈ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।

Sl. No.	Name of the Manufacturer and Local Agent	Name of the product & Dosage form	Generic Name with strength	Class	Indication	CPP/FSC	EC/CE Certificate	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
16.	**Mfgr :** ঙ ৎধঐবধষ্ফয ঈড়ৎঢ়ড়ৎধঃরড়হ, ট ঝঅ **Local Agent :** ইব ধপড়হ ইঁ ংরুহবংং ঝড়ঁষ ঃরড়হ খঃফ, ই বধপড়ুহ ইঁ ংরুহবংং ঈবহঃৎব ৯/ই/২, এঃড়ু বহনবব ঈরৎপঁ ক্ষৎ জড়ধফ (ইড়ী ঈঁ ষ বৎঃ জড়ধফ), গ ড়ঃরুষ্মববষ ঈ/অ, উ যধশধ-১০০০.	ঢ়ু ষরূ বষঃ ঋড়ৎ উ ৎু স ড়ঁঃ য ঙ ৎধষঅ ফযবৎৎরহম উ রংপং	550mg Xylitol per Adhering Disc	অ	ঢ়ু ক্ষাব ষ্ণং ভড়ৎ উ ৎু গড়ঁ ঃয ধৎব রুহফরূপধঃবফ ভড়ৎ ঃযব ঃবস ঢ়ড়ৎধৎু ৎবষ্ণবভ ড়ভ ৎধফরড়ঃযবৎধঢ়ু ধহফ ঈযবস ড়ঃযবৎধঢ়ু রুহফঁ পবফ ফ্ণু স ড়ঁ ঃয ধং ি বক্ষ ধং মবহবৎধষফ্ণু স ড়ঁ ঃয.	ঋঝঈ- ট ঝঅ (উ বঢ়ধৎঃস বহঃ ড়ভ অমৎরঁপ্ক ঃ ৎব) গ ঐজঅ (গ বফরূপধষ উ বা রূপব) জবভ্ জবমরংৎধঃরড়হ ঘ ড়. ঈঅ ০১৪৭৩১ যঃঃঢ়ঃ//ধরপসয ৎধ.মড়ৗঁশ/ বৎধ/ঢ়ফৎহং ভঁফ বা রূপবপড়ফব?ড়ঢ়বহঢ় ধমব্জ বংঃৎরূপঃএঃড়ঈ ধঃবমড়ুু =ঝধষরূ ধঃরড়হ% ২০ংঃরূঁষ ধঃরড়হ% ২০ষড়ু বহমব্ং ঃধৎঃ=১প উঁহঃ =২০০	ঈউ	প্রয়োজন নাই বিধায় পদটি নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নাই বিধায় পদটি নামঞ্জুর করা হয়।

১. ঙ গ ঈ ঐবধষ্ফয ঈধৎব চা ঃ. খঃফ. কর্তৃক উদ্ভাবিত Real Detect COVID-১৯ RT PCR Kit এর অনুকূলে Emergency Use Authorization প্রদান সংক্রান্ত বিষয়ে গ বফরূপধষ উ বা রূপব্ ঝাঁৎম রূপধষ উয়ঁর ঢ়স বহঃ এপ্পপ্যহরূপধষ ংঁনপ ড়স স রূঃবব ভড়ৎ উ ঈঈ -২৫২ এর মতামত প্রদানের জন্য উপস্থাপন করা হয়ঃ

ঙ গ ঈ ঐবধষ্ফয ঈধৎব চা ঃ. খঃফ. কর্তৃক উদ্ভাবিত Real Detect COVID-১৯ RT PCR Kit টির পারফরমেন্স ট্রায়াল করা হয়েছে Department of Immunology, Bangladesh University of Health Science, IEDCR এবং idesHi তে। পারফরমেন্স ট্রায়াল এর ethical clearance BMRC হতে গ্রহণ করা হয়েছে। পারফরমেন্স ট্রায়াল এর রিপোর্ট মোতাবেক কীটটির Sensitivity ৯৮.৩৩% এবং Specificity ১০০% পাওয়া গিয়েছে।

স্বাস্থ্য ও পরিবার কর্যাণ মন্ত্রণালয়ের স্মারক নং-৪৫.০০.০০০০.১৮২.২৪.১০১.১৮-১২৪, তারিখঃ০৪/০৬/২০২০ মোতাবেক কোভিড-১৯ চিকিৎসার জন্য পাবলিক হেলথ ইমারজেন্সির ক্ষেত্রে ঔষধ, ইনভেস্টিগেশনাল ড্রাগ, ভ্যাক্সিন ও মেডিক্যাল ডিভাইসের মূল্যায়ণের নিমিত্তে গঠিত কমিটির সুপারিশ মোতাবেক ঔষধ প্রশাসন অধিদপ্তর কর্তৃক প্রণীত নীতিমালা অনুযায়ী COVID-১৯ এর RT-PCR test kit এর emergency use authorization প্রদানের ক্ষেত্রে RT-PCR test kit সমূহের ক্ষেত্রে নূন্যতম sensitivity ৯৫% এবং specificity ১০০% বিবেচনা করা হবে।

উক্ত নীতিমালা অনুযায়ী ঙ গ ঈ ঐবধষ্ফয ঈধৎব চা ঃ. খঃফ. কর্তৃক উদ্ভাবিত Real Detect COVID-১৯ RT PCR Kit টির Sensitivity ৯৮.৩৩% এবং Specificity ১০০%, যা সন্তোষজনক।

টেকনিক্যাল সাব কমিটির সিদ্ধান্তঃ পদটি সকল criteria fulfill করেছে এবং বর্তমান কোভিড-১৯ সংক্রমণ পরিস্থিতিতে পদটি অত্যন্ত প্রয়োজনীয় বিধায় পদটির অনুকূলে Emergency Use Authorization প্রদানের জন্য সুপারিশ করা হয়।

ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্তঃ পদটি সকল criteria fulfill করেছে এবং বর্তমান কোভিড-১৯ সংক্রমণ পরিস্থিতিতে পদটি অত্যন্ত প্রয়োজনীয় বিধায় পদটির অনুকূলে Emergency Use Authorization প্রদানের অনুমোদন প্রদান করা হয়।

২. **মেডিক্যাল ডিভাইস এন্ড সার্জিক্যাল ইকুইপমেন্টস এর ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির ২৪ জুন, ২০২০ তারিখে অনুষ্ঠিত সভার সিদ্ধান্ত ঃ**

মেডিক্যাল ডিভাইস এন্ড সার্জিক্যাল ইকুইপমেন্টস এর ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সদস্যগণ স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্মারক নং- ৪৫.০০.০০০০.১৮২.২৪.১০১.১৮-১২৪, তারিখ: ০৪.০৬.২০২০ মোতাবেক কোভিড-১৯ চিকিৎসার জন্য পাবলিক হেলথ ইমারজেন্সির ক্ষেত্রে ঔষধ, ইনভেস্টিগেশনাল ড্রাগ, ভ্যাক্সিন এবং মেডিক্যাল ডিভাইস মূল্যায়নের নিমিত্তে গঠিত কমিটির ২১/০৬/২০২০ ও ২৩/০৬/২০২০ তারিখে অনুষ্ঠিত সভার কার্যবিবরণী অনুযায়ী ট ঝঋউ অ এর ঁস নৎবফ্ষধ মঁর ফবফ্ষহব ড়হ ংবৎড়ষড়মরূপধষ ঃবংঃ, ড ঐঙ মঁর ফবফ্ষহব ও আন্তর্জাতিক গাইডলাইন ও স্ট্যান্ডার্ডস মোতাবেক ঝঅজঝ-ঈঙ ঠ -২ অহঃরূড়ফু (ওমএ্ ওমগ) (উখওবঝ খধন নধংবফ্ জধঢ়রফ এপ্পংঃ কঋ) ঃবংঃ কঋ সমূহের জন্য নির্ধারিত নূন্যতম স্ট্যান্ডার্ডকে (ঈড়স নরহবফ (ওমএ + ওমগ) এর ন্যূনতম ঝবহংরূর ঋু ৯০% ও ঝঢ়বপরভরাঋু ৯৫%, ওমএ এর ক্ষেত্রে ন্যূনতম ঝবহংরূর ঋু ৯০% ও ঝঢ়বপরভরাঋু ৯৫%) সমর্থন করেন এবং উক্ত কমিটির নিম্নোক্ত সিদ্ধান্তের সঙ্গে একমত পোষণ করেন:

১.	ঝঅজঝ-ঈঙ ঠ -২ অহঃরূড়ফু (ওমএ্ ওমা) (উখওবঝ খধন নধংবফ্ জধঢ়রফ এপ্পংঃ কঋ) ঃবংঃ কঋ সমূহ স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়/স্বাস্থ্য অধিদপ্তর নীতিগতভাবে ঝবৎড় ংঁথা বরফ্ষধহপব এবং পড়হা ধফ্ষধংপবহঃ ঢ়ষধংস ধ ঃযবৎধঢ়ু তে ব্যবহারের সিদ্ধান্তের পর ঔষধ প্রশাসন অধিদপ্তর কর্তৃক রেজিস্ট্রেশন/ অনাপত্তি সনদ প্রদান করা হবে। এই কিটসমূহ ধপঁঃ ব ংঃধমব এ ফরূমহড়ংরু ব্যবহার করা যাবে না।
২.	ঔষধ প্রশাসন অধিদপ্তর কর্তৃক আমদানিকৃত কীটের অনুমোদন/ঘঙঈ / বস বৎমবহপু ঁং ব ধঁঃ যড়ৎুর ধঃরড়হ প্রদানের ক্ষেত্রে ঔষধ প্রশাসন অধিদপ্তরের মেডিক্যাল ডিভাইস রেজিস্ট্রেশন গাইডলাইন মোতাবেক কাগজপত্র দাখিল করতে হবে, যথা: ঋঝঈ/ঊট অ, ঈউ স ধৎশরূম সনদ, ঔঙ সনদ এবং ঠ ধফ্ষফধঃরড়হ ংঁফ ৎবঢ়ড়ৎঃ। কীটসমূহ প্রাথমিকভাবে স্বল্প সময়ের জন্য বস বৎমবহপু ঁং ব ধঁঃ যড়ৎুর ধঃরড়হ দেওয়া হবে। যদি কোন রেগুলেটরি অথরিটির অবজারভেশন না আসে সেক্ষেত্রে বস বৎমবহপু ঁং ব ধঁঃ যড়ৎুর ধঃরড়হ এর সময় বৃদ্ধি করা যাবে। প্রয়োজনে নিবন্ধন প্রদান করা হবে।
৩.	ঝঅজঝ-ঈঙ ঠ -২ অহঃরূড়ফু (ওমএ্ ওমা) (উখওবঝ খধন নধংবফ্ জধঢ়রফ এপ্পংঃ কঋ) ঃবংঃ কঋ সমূহ ঈঙ ঠ ঙঊ -১৯ ফরূমহড়ংরু এর কাজে ব্যবহার করা যাবে না। তবে ঝবৎড় ংঁৎ া বরফ্ষধহপব এবং পড়হা ধফ্ষধংপবহঃ ঢ়ষধংস ধ ঃযবৎধঢ়ু তে এবং গবেষণার কাজে ব্যবহার করা যেতে পারে। কীটগুলো চ ড়রহঃ ড়ভঈধৎব এ ব্যবহার করা যাবে না। অপব্যবহার রোধকল্পে এই ধরণের কিটগুলো শুধুমাত্র ল্যাবরেটরীতে ব্যবহার করার অনুমতি দেওয়া যেতে পারে। কীটগুলোর মোড়কের গায়ে লিখতে হবে - এপ্পরং রু হড়ঃ ধ ফরূমহড়ংঃরপ কঋ। এপ্পরং শরু ি রিক্ষনবংঁ বফ ড়হষু ভড়ৎ ফরূবপঃরূহম ধহঃরূড়ফু . ঘ ড়ঃ রু ধপঁঃ ব ংঃধমব.
৪.	ট ঝঋউ অ এর ঁস নৎবফ্ষধ মঁর ফবফ্ষহব ড়হ ংবৎড়ষড়মরূপধষ ঃবংঃ এবং আন্তর্জাতিক স্ট্যান্ডার্ড এর আলোকে র‍্যাপিড এন্টিবডি টেস্ট কিট এর জন্য ঈড়স নরহবফ (ওমএ + ওমা) এর ন্যূনতম ঝবহংরূর ঋু ৯০% ও ঝঢ়বপরভরাঋু ৯৫%, ওমএ এর ক্ষেত্রে ন্যূনতম ঝবহংরূর ঋু ৯০% ও ঝঢ়বপরভরাঋু ৯৫% নির্ধারিত হবে।
৫.	ঊখওবঝ গ বঃযড়ফ এর ক্ষেত্রে র‍্যাপিড এন্টিবডি টেস্ট কিট এর মতোই ঝবহংরূর ঋু ও ঝঢ়বপরভরাঋু নির্ধারিত হবে।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্তঃ ড্রাগ কন্ট্রোল কমিটি কর্তৃক টেকনিক্যাল সাব কমিটির সুপারিশ মঞ্জুর করা হয়। একই সাথে ঔষধ প্রশাসন অধিদপ্তরের স্মারক নং-উ এ উ অ/ঈড়ৎড়হধ ঠ ধপপ-১/২০/১৫০, তারিখঃ ০৩.১১.২০২০ মোতাবেক প্রণীত আমদানি ও স্থানীয়ভাবে উৎপাদনের নিমিত্তে ঔষধ প্রশাসন

অধিদপ্তরের মেডিক্যাল ডিভাইস গাইড লাইন-২০১৫ মোতাবেক ঈষধংং-ঈ ও ঈষধংং-উ মেডিক্যাল ডিভাইস, ওঠউ, ঈঙ ঠ ঙ্ঊ -১৯ এর জঞ-চঈঞ এব্বংঃ করু, অহঃরূড়ফু এব্বংঃ করু, অহঃরূবহ এব্বংঃ করু এর ঊস বৎমবহপু ট ংব অঁঃ যড়ৎুর ধঃরড়হ (ঊট অ)/ঘ ঙ ঈ প্রদান সংক্রান্ত নীতিমালা অনুমোদন করা হয়। (কপি সংযুক্ত)

৩. গণস্বাস্থ্য ফার্মাসিউটিক্যালস্ কর্তৃক প্রস্তুতকৃত এজ ঈঙ ঠ ওউ-১৯ জধঢ়রফ উড়ঃইষড়ঃ ঙস সঁহড়ধ ংংধু কীটটির বিষয়ে সিদ্ধান্তঃ

টেকনিক্যাল সাব কমিটির সিদ্ধান্তঃ গণস্বাস্থ্য ফার্মাসিউটিক্যালস্ কর্তৃক প্রস্তুতকৃত এজ ঈঙ ঠ ঙ্ঊ -১৯ জধঢ়রফউড়ঃইষড়ঃঙস সঁহড়ধ ংংধু কীটটির ঝবহংরূর রু (৬৯.৭%) গ্রহণযোগ্য মাত্রায় (৯০%) না হওয়ায় উক্ত কীটটির নিবন্ধন না দেওয়ার বিষয়ে সুপারিশ করা হয়।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্তঃ গণস্বাস্থ্য ফার্মাসিউটিক্যালস্ কর্তৃক প্রস্তুতকৃত এজ ঈঙ ঠ ঙ্ঊ -১৯ জধঢ়রফউড়ঃইষড়ঃঙস সঁহড়ধ ংংধু কীটটির ঝবহংরূর রু (৬৯.৭%) গ্রহণযোগ্য মাত্রায় (৯০%) না হওয়ায় উক্ত কীটটির নিবন্ধন না দেওয়ার সিদ্ধান্ত গৃহীত হয়।

৪. মেসার্স এ এফ সি এগ্রোবায়োটেক লিঃ কর্তৃক উৎপাদিত নিম্নোক্ত দুটি পদের অনুকূলে ঊস বৎমবহপু ট ংব অঁঃ যড়ৎুর ধঃরড়হ (ঊট অ) প্রদান করা হয়েছে।

১. অ ঋঈ উ বঃবপঃ হঈড়ঠ জঞ-চঈজ শরঃ.
২. অ ঋঈ চ ৎবঢ় ঠ রুধষ জঘ অ ঊীঃ ৎধপঃরড়হ করু.

পদ দুটির পারফরমেন্স ট্রায়াল রুফবঝঐরতে সম্পন্ন হয়েছে। অ ঋঈ উ বঃবপঃ হঈড়ঠ জঞ-চঈজ শরু এর ংবহংরূর রু ৯৬.৩ % ও ঝঢ়বপরভরূরু ১০০ % পাওয়া গিয়েছে। যা সন্তোষজনক। অ ঋঈ চ ৎবঢ় ঠ রুধষ জঘ অ ঊীঃ ৎধপঃরড়হ করু এর পারফরমেন্স ট্রায়ালে রেফারেন্স কীট (ঝউ ইরড়ংবহংড়ৎ, কড়ৎবধা রুধষ জঘ অ বীঃ ৎধপঃরড়হ শরু) এর অনুরূপ পড়হপবহঃৎধঃরড়হ ও ঢ়ঁৎর ঃ পাওয়া গিয়েছে।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্তঃ পদ দুটির পারফরমেন্স ট্রায়াল রিপোর্ট সন্তোষজনক হওয়ায় ড্রাগ কন্ট্রোল কমিটি কর্তৃক পদ দুটির অনুকূলে ঊস বৎমবহপু ট ংব অঁঃ যড়ৎুর ধঃরড়হ (ঊট অ) প্রদানের অনুমোদন প্রদান করা হয়।

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
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www.dgda.gov.bd

স্মারক নং- DGDA/Corona Vacc-1/20/ তারিখ ঃ

আমদানি ও স্থানীয়ভাবে উৎপাদনের নিমিত্তে ঔষধ প্রশাসন অধিদপ্তরের মেডিক্যাল ডিভাইস গাইড লাইন-২০১৫ মোতাবেক Class-C ও Class-D মেডিক্যাল ডিভাইস, IVD, COVID-19 এর RT-PCR Test Kit, Antibody Test Kit, Antigen Test Kit এর Emergency Use Authorization (EUA)/NOC প্রদান সংক্রান্ত নীতিমালা (Version-2)

ঔষধ প্রশাসন অধিদপ্তরের মেডিক্যাল ডিভাইস রেজিস্ট্রেশন গাইড লাইন-২০১৫ ও ১৭ মে, ২০২০ তারিখে প্রকাশিত স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের গেজেট (পৃষ্ঠা নং-৩৮২৫-৩৮২৬) এবং স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্মারক নং-৪৫.০০.০০০০.১৮২.২৪.১০১.১৮-১২৪, তারিখ: ০৪.০৬.২০২০ মোতাবেক গঠিত কোভিড-১৯ চিকিৎসার জন্য পাবলিক হেলথ ইমারজেন্সির ক্ষেত্রে ঔষধ, ইনভেস্টিগেশনাল ড্রাগ, ভ্যাক্সিন এবং মেডিক্যাল ডিভাইস মূল্যায়নের নিমিত্তে গঠিত কমিটির ২১.০৬.২০২০, ২৩.০৬.২০২০ এবং ০৮.০৭.২০২০ তারিখে অনুষ্ঠিত সভার সুপারিশ অনুযায়ী আমদানি ও স্থানীয়ভাবে উৎপাদনের নিমিত্তে Class-C / Class-D মেডিক্যাল ডিভাইস, IVD যেমন, Ventilator, COVID-19 এর RT-PCR Test Kit, Antibody Test Kit (Rapid ও laboratory ELISA method), Antigen Test Kit এর Emergency Use Authorization (EUA)/NOC প্রদানের ক্ষেত্রে নিম্নরূপ নীতিমালা প্রণয়ন করা হলঃ

(ক) আমদানির নিমিত্তে Class-C / Class-D মেডিক্যাল ডিভাইস, IVD যেমন, COVID-19 এর RT -PCR Test Kit, Antibody Test Kit (Rapid ও laboratory ELISA method), Antigen Test Kit এর Emergency Use Authorization (EUA)/NOC প্রদানের ক্ষেত্রে EU ভূক্ত যে কোন দেশ অথবা USA or UK or Switzerland or Canada or Australia or Japan এর যে কোন একটি দেশের Free Sale Certificate (FSC) এর কপি, CE marking certificate এর কপি, ISO-13485 ও ISO-9001:2015 সনদ এবং Validation study report দাখিল করতে হবে।

RT -PCR Test Kit, Antibody Test Kit, Antigen Test Kit এর Emergency Use Authorization (EUA)/NOC প্রদানের ক্ষেত্রে WHO emergency listed medical products on COVID-19 for diagnosis and immunological testing kits বিবেচনা করা হবে।

Class-C / Class-D মেডিক্যাল ডিভাইস/ In Vitro Diagnostics (IVD) উৎপাদনকারী দেশ EU ভূক্ত যে কোন দেশ অথবা USA or Canada or Australia or Japan না হলে সে ক্ষেত্রে উৎপাদনকারী প্রতিষ্ঠানের country of origin এর Free Sale Certificate (FSC) এর কপি এবং EU ভূক্ত যে কোন দেশ অথবা USA or UK or Switzerland or Canada or Australia or Japan এর যে কোন একটি দেশের Free Sale Certificate (FSC) এর কপি, CE marking certificate এর কপি, ISO-13485 ও ISO-9001:2015 সনদ এবং Validation study report দাখিল করতে হবে।

(খ) স্থানীয়ভাবে উৎপাদনের নিমিত্তে Class-C / Class-D মেডিক্যাল ডিভাইস, IVD, COVID-19 এর RT -PCR Test Kit, Antigen Test Kit, Antibody Test Kit (Rapid ও laboratory ELISA method) এর Emergency Use Authorization (EUA) প্রদানের ক্ষেত্রে নিম্নরূপ নির্দেশনা অনুসরণ করতে হবেঃ

- **COVID-19 এর RT-PCR Test Kit এর Emergency Use Authorization (EUA) প্রদানের ক্ষেত্রে:**

স্থানীয়ভাবে উৎপাদিত RT-PCR টেস্ট কীটসমূহের Third Party Performance Study Report সহ USFDA এর Molecular Template for Manufacturer অনুযায়ী প্রোডাক্টের তথ্যাদি Dossier আকারে জমা দিতে হবে। RT-PCR টেস্ট কীটসমূহের ক্ষেত্রে ন্যূনতম Sensitivity ৯৫% ও Specificity ১০০% বিবেচনা করা হবে ।

- **COVID-19 এর Antigen Test Kit এর Emergency Use Authorization (EUA) প্রদানের ক্ষেত্রে:**

USFDA সহ পৃথিবীর অন্যান্য authorized রেগুলেটরী অথরিটিকে অনুসরণপূর্বক antigen test kit এর Emergency Use Authorization/ NOC প্রদানের ক্ষেত্রে sensitivity ≥ ৮০% এবং Specificity ১০০% নির্ধারণ করা হয়েছে।
ঔষধ প্রশাসন অধিদপ্তর কর্তৃক স্থানীয়ভাবে উৎপাদিত antigen test kit এর Emergency Use Authorization প্রদানের ক্ষেত্রে Third Party Performance Study Report সহ USFDA এর Antigen Template for Manufacturer অনুসরণ পূর্বক প্রোডাক্টের তথ্যাদি Dossier আকারে জমা দিতে হবে। আবেদনের সাথে Cross-reactivity (Analytical Specificity) রিপোর্ট দাখিল করতে হবে।

যে সকল জায়গায় RT-PCR দ্বারা টেস্টের সুযোগ সুবিধা নেই সে সকল জায়গায় antigen test kit ব্যবহার করা যেতে পারে। Antigen test kit এ নেগেটিভ রেজাল্ট পাওয়া গেলে RT-PCR এ অবশ্যই টেস্ট করাতে হবে। এই টেস্ট কীটগুলোর অপব্যবহার রোধে কেবলমাত্র সরকার কর্তৃক অনুমোদিত ল্যাবরেটরী ও উপযুক্ত ল্যাবরেটরী সুবিধাসহ ক্লিনিক্যাল সেটআপে পয়েন্ট অফ কেয়ারে ব্যবহার করা যেতে পারে। তবে টেস্ট রিপোর্ট স্বাস্থ্য অধিদপ্তরে প্রেরণ করতে হবে।

- **COVID-19 এর Antibody Test Kit (Rapid ও laboratory ELISA method) এর Emergency Use Authorization (EUA) প্রদানের ক্ষেত্রে:**

ঔষধ প্রশাসন অধিদপ্তর কর্তৃক স্থানীয়ভাবে উৎপাদিত Antibody Test Kit এর Emergency Use Authorization প্রদানের ক্ষেত্রে USFDA এর হালনাগাদ Antibody Template ও Umbrella Guideline অনুসরণ পূর্বক Third Party Performance Study Report সহ প্রডাক্টের তথ্যাদি Dossier আকারে আবেদন জমা দিতে হবে।

USFDA এর umbrella guideline on serological test এবং আন্তর্জাতিক স্ট্যান্ডার্ড এর আলোকে র‍্যাপিড এন্টিবডি টেস্ট কিট এর জন্য Combined (IgG+ IgM) এর ন্যূনতম Sensitivity ৯০% ও Specificity ৯৫%, IgG এর ক্ষেত্রে ন্যূনতম Sensitivity ৯০% ও Specificity ৯৫% নির্ধারণ করা হয়েছে। ELISA Method এর ক্ষেত্রে র‍্যাপিড এন্টিবডি টেস্ট কিট এর মতোই Sensitivity ও Specificity নির্ধারিত হবে।

SARS-COV-2 Antibody(IgG & IgM) (ELISA Lab based & Rapid Test Kit) test Kit সমূহ COVID-19 diagnosis এর কাজে ব্যবহার করা যাবে না। তবে Sero surveillance এবং convalescent plasma therapy তে এবং গবেষণার কাজে ব্যবহার করা যেতে পারে। কীটগুলো Point of Care এ ব্যবহার করা যাবে না। অপব্যবহার রোধকল্পে এই ধরণের কিটগুলো শুধুমাত্র ল্যাবরেটরীতে ব্যবহার করার অনুমতি দেওয়া যেতে পারে। কীটগুলোর মোড়কের গায়ে লিখতে হবে - This is not a diagnostic Kit. This kit will be used only for detecting antibody. Not in acute stage.

- **স্থানীয়ভাবে উৎপাদনের নিমিত্তে অন্যান্য Class-C ও Class-D মেডিক্যাল ডিভাইস, IVD এর Emergency Use Authorization (EUA)/NOC প্রদানের ক্ষেত্রে Third Party Performance Study Report সহ প্রডাক্টের তথ্যাদি Dossier আকারে জমা দিতে হবে।**

স্বাঃ/-

মেজর জেনারেল মোঃ মাহবুবুর রহমান
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ফোনঃ ০২২২২২৮০৮০৩
E-mail: dgda.gov@gmail.com
তারিখ ঃ ০৩/১১/২০২০

স্মারক নং- DGDA/Corona Vacc-1/20/২৫০

সদয় অবগতির জন্য অনুলিপি প্রেরণ করা হল (জ্যেষ্ঠ ক্রমানুসারে নয়)ঃ

১. সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়।
২. কোভিড মনিটরিং সেল, মাননীয় প্রধানমন্ত্রীর কার্যালয়।
৩. মহাপরিচালক, স্বাস্থ্য অধিদপ্তর।
৪. অতিরিক্ত মহাপরিচালক, প্রশাসন, স্বাস্থ্য অধিদপ্তর।
৫. অতিরিক্ত সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়।
৬. পরিচালক, রোগ নিয়ন্ত্রণ ও লাইন ডাইরেক্টর, সিডিসি, স্বাস্থ্য অধিদপ্তর।
৭. পরিচালক, সিএমএসডি।
৮. মাননীয় মন্ত্রী মহোদয়ের একান্ত সচিব, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা।
৯. মহাসচিব, বাংলাদেশ ঔষধ শিল্প সমিতি।
১০. সভাপতি, মেডিক্যাল ডিভাইস ইম্পোর্টার্স এসোসিয়েশন।
১১. সভাপতি, বাংলাদেশ মেডিক্যাল ইন্সট্রুমেন্ট এন্ড হসপিটাল ইকুইপমেন্ট ডিলারস এন্ড ম্যানুফেকচারার্স এসোসিয়েশন।
১২. সভাপতি, বাংলাদেশ সার্জিক্যাল এসোসিয়েশন ও ডায়গনস্টিকস রিএজেন্ট এন্ড ইকুইপমেন্টস ট্রেডার্স এসোসিয়েশন অব বাংলাদেশ।

মহাপরিচালক 03 NOV 2020
ঔষধ প্রশাসন অধিদপ্তর

Annex-I

Sl. No.	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication &Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur Acme Laboretories Ltd. **Radiant Pharmaceutical Ltd** Genvio Pharma Ltd. Drug International Ltd, Unit-3. Delta Pharma Ltd. Veritas Pharmaceuticals Ltd. Opsonin Pharma Ltd	Lopinavir 200 mg + Ritonavir 50 mg Tablet	Lopinavir USP 200 mg + Ritonavir USP 50 mg Tablet	Antiviral **Therapeutic Class** : 032	The combination is an HIV-1 protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older).	Contraindication: • Hypersensitivity to the combination (e.g., toxic epidermal necrolysis, StevensJohnson syndrome, erythema multiforme, urticaria, angioedema) or any of its ingredients, including ritonavir. • Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated plasma levels may result in serious and/or lifethreatening events. • Co-administration with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross resistance. Side effects: Commonly reported adverse reactions included diarrhea, nausea, vomiting, hypertriglyceridemia and hypercholesterolemia.		টৰাখউ অ ই ঘঋ -৭৬	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**
2.	Opsonin Pharma Ltd	Lopinavir 100 mg + Ritonavir 25 mg tablet	Lopinavir USP 100 mg + Ritonavir USP 25 mg	Antiviral **Therapeutic Class** : 032	HIV-1 infection	**Contraindications:** Hypersensitivity (e.g., toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme, urticaria, angioedema) or any of its ingredients, including ritonavir. Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated plasma levels may result in serious and/or lifethreatening events. Co-administration with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations maybe associated with the potential for loss of virologic response and possible resistance and cross resistance. **Side Effects:** Commonly included diarrhea, nausea, vomiting, hypertriglyceridemia and hypercholesterolemia	New	টৰাখউ অ ই ঘঋ -৭৬	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**

Sl. No.	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication &Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
3.	Opsonin Pharma Ltd	Lopinavir 8 gm + Ritonavir 2 gm / 100 ml oral solution	Lopinavir USP 8 gm + Ritonavir USP 2 gm / 100 ml oral solution	Antiviral **Therapeutic Class** : 032	HIV-1 infection	Contraindications: Hypersensitivity (e.g., toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme, urticaria, angioedema) or any of its ingredients, including ritonavir. Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated plasma levels may result in serious and/or lifethreatening events. Co-administration with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross resistance. Side effects: Commonly included diarrhea, nausea, vomiting, hypertriglyceridemia and hypercholesterolemia.	New	টৰাখউ অ ই ঘঋ -৭৬	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**
4.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur Incepta Pharmaceuticals Ltd, Savar, Dhaka. Beacon Pharmaceuticals Ltd. Ranata Limited. The Ibnsina Pharmaceutical Industries Ltd, Gazipur. Acme Laboretories Ltd. Ariatopharma Ltd. Concord Pharmaceuticals Ltd. Orion Pharma Ltd.	Favipiravir 200 mg Tablet	Favipiravir INN 200 mg	Antiviral **Therapeutic Class** : 032	It is indicated for the treatment of novel or re-emerging pandemic influenza virus infection (limited to cases in which other influenza antiviral drugs are ineffective or not sufficiently effective)	Contraindication: Favipiravir is contraindicated in women who might be or are pregnant and in lactating women because of its association with embryonic deaths and teratogenicity in animal studies and men should use the most effective contraceptive methods including condoms. Side Effect: Major side effects are increase of blood uric acid, diarrhea, decrese of neutrophil, an increase of AST (GOT) and increase of ALT (GPT).		চ গউ অ, ঔঢ়ধহ	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**

Sl. No.	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication &Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	General Pharmaceuticals Ltd Genvio Pharma Ltd. Drug International Ltd, Unit-3. Nipro JMI Pharma Ltd. Delta Pharma Ltd. ESKAYF Pharmaceuticals Ltd. SMC Enterprise Ltd. Advanced Chemicals Ltd. Square Pharmaceuticals Ltd, Gazipur. Ziska Pharma Ltd. Techno Drug Ltd, Unit-2. Unimed Unihealth Pharmaceuticals Ltd. Veritas Pharmaceuticals Ltd. Populer Pharmaceuticals Ltd. Bio Pharma Ltd. Opsonin Pharma Ltd									

Sl. No.	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication &Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
5.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur Incepta Pharmaceuticals Ltd, Savar, Dhaka. Nafco Pharma Ltd. Nipro JMI Pharma Ltd. Kemiko Pharmaceuticals Ltd. EURO Pharma Ltd. Pharmik Laboratories Ltd. Somatec Pharmaceuticals Ltd. Sharif Pharma. Libra Infusion Ltd. Pacific Pharmaceuticals Ltd. Unimed Unihealth Pharmaceuticals Ltd. Vergo Pharma Ltd. Team Pharmaceuticals Ltd EON Pharmaceuticals Ltd. Ethical Drugs Ltd. Populer Pharmaceuticals Ltd. Bio Pharma Ltd. ESKAYF Pharmaceuticals Ltd.	Isopropyl Alcohol 75% v/v **(active)** Glycerol 1.45% (v/v) Hydrogen peroxide 1.123% (v/v) Solution/ Gel	Isopropyl Alcohol BP 75% v/v Glycerol 1.45% (v/v) Hydrogen peroxide 1.123% (v/v)	Antiseptic and Disinfectants **Therapeutic Class** : 029	This WHO recommended handrub formulation is used to clean the hands to kill or to reduce the growth of microorganisms. It is also used both for hygienic hand antisepsis and for presurgical hand preparation.	Contraindication: It is not recommended to those, who have allergy to any of its components (Isopropyl alcohol, Hydrogen peroxide and Glycerol) Side Effects: Irritative skin reactions can occasionally occur. Generalised allergic reactions have also been reported but are extremely rare.		ড ঐঙ জবপড়স স বহফবফ	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**

Sl. No.	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication &Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA/BNF/ MHRA Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
6.	Opsonin Pharma Limited, Rupatoli, Barishal. ESKAYF Pharmaceuticals Ltd.	Ethanol 80 % (v/v) **(active)** Glycerol 1.45% (v/v) Hydrogen peroxide 0.125% (v/v) Solution/ Gel	Ethanol 80 % (v/v) (active) Glycerol 1.45% (v/v) Hydrogen peroxide 0.125% (v/v)	Antiseptic and Disinfectants **Therapeutic Class** : 029	Ethanol is present in oral rinses and skin cleansers, and in small quantities it is used as to kill or remove microbial growth & production. Glycerol is used as preservative. Hydrogen peroxide used as mild antiseptic for cleaning & rubbing.	**Contraindication**: Avoid contact with eyes, brain, meninges and middle ear; not for use in body cavities; alcoholic solutions not suitable before diathermy. **Side effects:** occasional sensitivity	New	ড ঐঙ জবপড়স স বহফবফ	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**
7.	Sunman-Birdem Pharma Ltd. Nafco Pharma Ltd. ESKAYF Pharmaceuticals Ltd. Labaid Pharma Ltd. Pacific Pharmaceuticals Ltd.	Ethanol 96% **(active)** Glycerol 98% Hydrogen peroxide 3% Solution/ Gel	Ethanol 96% Glycerol 98% Hydrogen peroxide 3%	Antiseptic and Disinfectants **Therapeutic Class** : 029	Ethanol is present in oral rinses and skin cleansers, and in small quantities it is used as to kill or remove microbial growth & production. Glycerol is used as preservative. Hydrogen peroxide used as mild antiseptic for cleaning & rubbing.	**Contraindication**: Avoid contact with eyes, brain, meninges and middle ear; not for use in body cavities; alcoholic solutions not suitable before diathermy. **Side effects:** occasional sensitivity	New	ড ঐঙ জবপড়স স বহফবফ	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**
8.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh. Opsonin Pharma Limited, Rupatoli, Barishal.	Cobicistat 150 mg + Darunavir ethanolate 867.2 mg equivalent to Darunavir 800 mg tablet	Cobicistat INN 150 mg + Darunavir ethanolate INN 867.2 mg equivalent to Darunavir INN 800 mg	Antiviral **Therapeutic Class** : 032	Darunavir and Cobicistat is a two-drug combination of darunavir, a human immunodeficiency virus (HIV-1) protease inhibitor, and cobicistat, a CYP3A inhibitor, and is indicated for the treatment of HIV-1 infection and treatment-experienced adults with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V).	Contraindications: Darunavir and Cobicistat is contraindicated in patients receiving certain co-administered drugs for which altered plasma concentrations are associated with serious and/or life threatening events or loss of therapeutic effect. **Side effects:** The most common side effects of darunavir, one of the medicines in Darunavir and Cobicistat , include: Diarrhea, nausea, rash, headache, stomach-area (abdominal) pain, vomiting etc.	New	ই ঘঋ ৭৮	**পদটি অনুমোদনের সুপারিশ করা হয়।**	**পদটি অনুমোদন করা হয়।**

বিবিধ আলোচনাঃ

০৪.০৬.২০২০ তারিখে অনুষ্ঠিত ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটির সভায় উপস্থাপিত Remdesivir inj সংক্রান্ত আলোচনাঃ

পৃথিবীর অনেক রেগুলেটরী অথরিটিই (Regulatory Authority) Remdesivir inj কে করোনা ভাইরাসে আক্রান্ত রোগীর চিকিৎসায় ব্যবহারের জন্য Emergency Use Authorization প্রদান করেছে। যেমন, USFDA, PMDA, UKMHRA. স্বাস্থ্য ও পরিবারকল্যাণ মন্ত্রণালয় কর্তৃক ১৩ মে, ২০২০ তারিখে স্মারক নং-৪৫.০০.০০০০.১৮২.৯৯.০১৭.০৮-১১০ এর পরিপ্রেক্ষিতে ঔষধ প্রশাসন অধিদপ্তর কর্তৃক ২১ মে, ২০২০ তারিখে মেসার্স বেক্সিমকো ফার্মাসিউটিক্যালস লিঃ এবং ২৪ মে, ২০২০ তারিখে মেসার্স এসকেএফ ফার্মাসিউটিক্যালস লিঃ কে Emergency Use Authorization প্রদান করা হয়। পরবর্তীতে আরও চারটি প্রতিষ্ঠানের অনুকূলে Remdesivir inj এর Emergency Use Authorization প্রদান করা হয়। যা ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটি অত্যন্ত সময়োপযোগী উদ্যোগ বলে মতামত দেন।

ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্তঃ

Remdesivir inj এর Emergency Use Authorization প্রদান করার সিদ্ধান্তটি গৃহীত হয়।

Annex-J বিবিধ আলোচনা

ক্রমিক নং	বিষয়	প্রস্তাবনা	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
১.	অসড়ী ু পরষ্কারু ঝড়ফরঁস ঝঃবৎরষবইচ ১.০৬ মস বয় ঃড় ১ মস অসড়ী ু পরষ্কারু/ঠরধষ ওলবপঃরড়হ. পদটি উঈঈ -২১৮ তে অনুমোদিত কিন্তু ভুলবশত পদটি ভেটেরিনারীতে ব্যবহৃত হবে তা উল্লেখ ছিল না।	অসড়ী ু পরষ্কারু ঝড়ফরঁস ঝঃবৎরষবইচ ১.০৬ মস বয় ঃড় ১ মস অসড়ী ু পরষ্কারু/ঠরধষ ওলবপঃরড়হ (াব ঃ) হিসেবে পদটি উঈঈ -২১৮ এর কার্যবিবরণীতে সংশোধনের প্রস্তাব করা হল।	উঈঈ -২১৮ এর কার্যবিবরণীতে নিম্নরূপ সংশোধনের প্রস্তাব করা হয়ঃ অসড়ী ু পরষ্কারু ঝড়ফরঁস ঝঃবৎরষবইচ ১.০৬ মস বয় ঃড় ১ মস অসড়ী ু পরষ্কারু/ঠরধষ ওলবপঃরড়হ (াব ঃ)	উঈঈ -২১৮ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন অনুমোদন করা হয়ঃ অসড়ী ু পরষ্কারু ঝড়ফরঁস ঝঃবৎরষবইচ ১.০৬ মস বয় ঃড় ১ মস অসড়ী ু পরষ্কারু/ঠরধষ ওলবপঃরড়হ (াব ঃ)
২.	Iron (III) Isomaltoside 1000 INN 200 mg eq to Elemental Iron 100 mg পদটি উঈঈ -২৫০ তে অনুমোদিত। Iron (III) Isomaltoside 1000 INN 400mg/ml vial eq. to Elemental Iron 100 mg ইনসেপ্টা ফার্মাসিউটিক্যালস লিঃ উঈঈ -২৫০ এর কার্যবিবরণীতে নিম্নরূপ সংশোধনের প্রস্তাব করেছেঃ Iron (III) Isomaltoside 1000 INN 400mg/ml vial eq. to Elemental Iron 100 mg	উঈঈ -২৫০ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন করার প্রস্তাব করা হলঃ Iron (III) Isomaltoside 1000 INN 400mg/ml vial eq. to Elemental Iron 100 mg	উঈঈ -২৫০ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন করার প্রস্তাব করা হয়ঃ Iron (III) Isomaltoside 1000 INN 400mg/ml vial eq. to Elemental Iron 100 mg.	উঈঈ -২৫০ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন অনুমোদন করা হয়ঃ Iron (III) Isomaltoside 1000 INN 400mg/ml vial eq. to Elemental Iron 100 mg.
৩.	Gaviscon (Sodium Alginate 500mg/10 ml) ড্রাগ কন্ট্রোল কমিটির ২১১ তম সভায় অনুমোদিত।	উঈঈ -২১১ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন করার প্রস্তাব করা হলঃ (Sodium Alginate USP 5gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm)/100ml oral suspension	উঈঈ -২১১ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন করার প্রস্তাব করা হয়ঃ (Sodium Alginate USP 5gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm)/100ml oral suspension.	উঈঈ -২১১ এর কার্যবিবরণীতে নিম্নরূপ সংশোধন অনুমোদন করা হয়ঃ (Sodium Alginate USP 5gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm)/100ml oral suspension.

১. পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপিতঃ

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
০১.	গ /ঝ ইবী রসপড় চযধৎস ধপবঁ ঃরপধষং খঃফ. এঢ়হমর এধু রঢ়ঁ ৎ.	জধনবঢ়ৎধু ড়ষব ঝড়ফরঁ স উব যধু বফ ৎবষবধৎব চ বষস্কাংং ১৫% ি/ি (গঁ ঢ়ং) চয. এৎধফব ১৩৩.৩৩৩ স ম (উয়. ঃড় ২০ স ম ড়ভ জধনবঢ়ৎধু ড়ষব ঝড়ফরঁ স , গ টচঝ এঞ্জনষবঃ	জধনবঢ়ৎধু ড়ষব ঝড়ফরঁ স উব যধু বফ ৎবষবধৎব চ বষস্কাংং ১৫% ি/ি (গঁ ঢ়ং) চয. এৎধফব ১৩৩.৩৩৩ স ম (উয়. ঃড় ২০ স ম ড়ভ জধনবঢ়ৎধু ড়ষব ঝড়ফরঁ স গ টচঝ এঞ্জনষবঃ	অহঃরঁ ষপকধহঃ (চচও) ঈড়ফব-০৬৭.	ওহফরপধৎবফ ভ্রুৎ ঃযব ঃৎবধঃস বহঃ ড়ভফঁ ড়ফবহধষ ঁ ষপকৎ, মধংঃৎরপঁ ষপকৎ, ং স ঢ়ঃড়স ধঃরপ বৎড়ংরা ব ড়ভৎ ষপকৎধঃর ব মধংঃৎড়ড়বংড়ঢ়যধমবধষ ৎবঅী ফরাংবধংব, মধংঃৎড়ড়বংড়ঢ়যধমবধষ ৎবঅী ফরাংবধংব ষড়হম- ঃবৎস স ধহধমবস বহঃ, ং স ঢ়ঃড়স ধঃরপ ঃৎবধঃস বহঃ ড়ভস ড়ফবৎধঃব ঃড়া বৎু ংবা বৎব মধংঃৎড়ড়বংড়ঢ়যধমবধষ ৎবঅী ফরাংবধংব, ু ড়ষস্কাহমবৎ-বষস্কাংড়হ ং হফৎড়স ব ধহফ রহ পড়স নরহধঃরড়হ ি রিয় ধঢ়ঢ়ৎড়ঢ়ৎরধঃব ধহঃরাধপঃবৎরঙ্কা ঃযবৎধঢ়ব ঁঃরপ ৎবমরস বহং ভ্রুৎ ঃযব বৎধফরপধৎরড়হ ড়ভ যবষরাড়নধপঃবৎ ঢু ষড়ৎররহ ঢ়ধঃরাবহঃং ি রিয় ঢ়বঢ়ঃরপ ঁ ষপকৎ ফরাংবধংব	**Contraindication**: ওঃরং পড়হঃৎধরহফরপধৎবফ রহ ঢ়ধঃরাবহঃং ি রিয় শহড়ি হ যু ঢ়বৎংবহংরাঃর রুঃ ঃড় জঅ ইউচ জঅ তঙ খউ, ং নংঃরঁঃ ঃবফ নবহু রসরফু ড়ষবংড়ৎ ঃড় ধহু পড়স ঢ়ড়হবহঃ ড়ভঃযব ভ্রুৎসঁ ষধঃরড়ৎ. **Side Effects**: উৎু স ড়ঁ ঃয, এও ফরাংঁ ৎনধহপব, ষয়ব বৎ ফু ংভঁ হপঃরড়হ, ঃধংঃব ফরাংঁ ৎনধহপব. ঐু ঢ়বৎংবহংরাঃর রুঃ ৎবধপঃরড়হং রহপঁষ ফহমু ৎধংয,ঁ ৎঃরপধৎরধ, ধহমরড়রফসব ধ, নৎড়হপষড়ংঢ়ধংস , ধহধঢ়যু ষধীরং.	জধনবঢ়ৎধু ড়ষব ঝড়ফরঁ স ওঘঘ ২০ স ম এঞ্জনষবঃ	**রেফারেন্স নাই।** DCC- 220 তম সভায় Rabeprazole Sodium INN 20 mg Tablet হিসেবে অনুমোদিত। Rabeprazole MUPS 20mg Tablet Beacon Pharmaceuticals Ltd. এর রেজিস্ট্রেশন রয়েছে। Rabeprazole MUPS 20mg Tablet হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।
০২	ইব ধপড়হ চযধৎস ধপবঁ ঃরপধষং খঃফ. কধ ঃযধষব ইয ধষঁ শধ, গু স বহংরহময	তড়হরংধস রফষ ৫০স ম ঙউ ঞ	তড়হরংধস রফষ টঝচ ৫০স ম	অহঃরাড়হাঁ ষংধহঃ ঈড়ফব-০৪৭	তড়হরংধস রফষ পধঢ়ং ষবং ধৎব রহফরপধৎবফ ধং ধফষ্ণ হপঃর ব ঃযবৎধঢ়ু রহ ঃযব ঃৎবধঃস বহঃ ড়ভ ঢ়ধৎঃরাষংবৎবুঁ ৎবং রহ ধফঁ ষহ ি রিয় বঢ়রাবঢ়ুঃ .	**Contraindication**: তড়হরংধস রফষ রং পড়হঃৎধরহফরপধৎবফ রহ ঢ়ধঃরাবহঃং ি যড় যধা ব ফবস ড়হংঃৎধঃবফ যু ঢ়বৎংবহংরাঃর রুঃ ঃড় ং ষভ্রুহধস রফষং ড়ৎু ড়হরংধস রফষ. **Side-effect**: এঞ্জব স ড়ংঃ পড়স স ড়হয়ু ড়নংবথা বফ ধফা বৎংব বা বহংং ৎবষধঃক্ষ ঃড় ঃৎবধঃস বহঃ ি রিয় তড়হরংধস রফষ (ধহ রহপরফহপব ধঃ ষবধঃ ৪% মৎবধঃবৎ গ্লধহ ঢ়ষধপ্পনড়) রহ পড়হঃৎড়ষস্কাফ পষরু রপক্কা ংৎরাষং ধহফ ংযড়ি হ রহ ফবংপবহফরহম ড়ৎফবৎ ড়ভ ভ্রবয়ঁ বহপু ি বৎব ংড়স হড়ষবহপব,	তড়হরংধস রফষ ৫০স ম ঐধৎফ এ বষধঃরহ ঈধঢ়ং ষব	**রেফারেন্স নাই।** DCC- 244 তম সভায় তড়হরংধস রফষ ৫০স ম ঐধৎফ এ বষধঃরহ ঈধঢ়ং ষব হিসেবে অনুমোদিত। তড়হরংধস রফষ ৫০স ম ঙউ ঞBeacon Pharmaceuticals Ltd. এর রেজিস্ট্রেশন রয়েছে।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						ধহড়ৎবী রধ,ফবু রহবংং, ধঃধী রধ, ধমরপ্পঃরড়হ/রুৎবরপ্পনরমুঃ, ধহফ ফরভ্রপঁ যুঃ ি রিয়ু স বস ড়ুৎ ধহফ/ড়ৎ পড়হ পবহঃৎধঃরড়ু.		তড়হরংধস রফব ৫০স ম ঙউ এঃহিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।		
০৩	ই বধপড়হ চ যধৎস ধপবঁ ঃরপধ ষংখ ঃফ. কধঃয ধষর, ই যধষঁ শধ, গ ু স বহংরহমষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২০ স ষ/২০স ষা রধষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২০ স ম/২০স ষ া রধষ		ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ ধং রহফরপধঃঝরহ ঃযব ধংবঢ় ঃরপঢ়ৎবঢ় ধৎধঃরড়ু ড়ভঢ় ধৎবহঃবৎধষ ংড়ষঁ ঃরড়ু.	**Contraindication**: ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ রং ধ যবস ড়ুয় ঃরপ ধমবহঃ ফঁ ব ঃড় রঃংযু ঢ় ড়ঃড়ৎরপবুঃ. এঝবৎবভড়ৎব রঃ রংপড়হঃৎধরহফরপধঃরড়ু ভড়ৎ রহঃৎধা বহড়ঁ ং ধফস রুরুংঃৎধঃরড়ু ি রিয়ড়ঁ ঃ ধফফরঃরাবং. ঝরফব-বভ্রপঃং: ড যবহঁ ংবফ রহ ংস ধষয ফড়ংবং, হড় ঈঙগ গঙ ঘ ংরফব বভ্রপঃং যধা ব নববহ ৎবঢ় ড়ৎঃবফ ি রিয়ু ঃযরং ঢ় ৎড়ফঁ পঃ. ঝববশ স বফরপধয ধঃঃবহঃরড়ু ৎরমযঃ ধি ধু রভহু ড়ভ ঃযবংব ঝউঠউ জউ ংরফব বভ্রপঃং ড়পপঁ ৎ ি যরষবঃধশরহম ংঃবৎরষবি ধঃবৎ (ঃযব ধপঃরাব রুমৎবফরবহঃ পড়হঃধরহবফ রহ ড ধঃবৎ ভড়ৎ ওল্লপঃরড়ু, ঝঃবৎরষব)	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১স ষ, ২স ষ,৫স ষ্ ১০স ষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২০ স ষ/২০স ষ া রধষ ইতিমধ্যে বেক্সিমকো, ইনসেপ্টা, অপসোনিন, কেমিকো ও হেলথকেয়ার ফার্মা এর রেজিট্রেশন রয়েছে। ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২০ স ষ/২০স ষা রধষহিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।
০৪	ওপবঢ় ঃধ চ যধৎস ধপবঁ ঃরপধ ষংখ ঃফ. উয ধস ৎধর ট হরঃ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১ স ষ /অস ঢ় ড়ঁ ষব	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১ স ষ / অস ঢ় ড়ঁ ষব		ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ ধং রহফরপধঃঝরহ ঃযব ধংবঢ় ঃরপঢ়ৎবঢ় ধৎধঃরড়ু ড়ভঢ় ধৎবহঃবৎধষ ংড়ষঁ ঃরড়ু.	**Contraindication**: ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ রং ধ যবস ড়ুয় ঃরপ ধমবহঃ ফঁ ব ঃড় রঃংযু ঢ় ড়ঃড়ৎরপবুঃ. এঝবৎবভড়ৎব রঃ রংপড়হঃৎধরহফরপধঃরড়ু ভড়ৎ রহঃৎধা বহড়ঁ ং ধফস রুরুংঃৎধঃরড়ু ি রিয়ড়ঁ ঃ ধফফরঃরাবং. ঝরফব-বভ্রপঃং: ড যবহঁ ংবফ রহ ংস ধষয ফড়ংবং, হড় ঈঙগ গঙ ঘ ংরফব বভ্রপঃং যধা ব নববহ ৎবঢ় ড়ৎঃবফ ি রিয়ু ঃযরং ঢ় ৎড়ফঁ পঃ. ঝববশ স বফরপধয ধঃঃবহঃরড়ু ৎরমযঃ ধি ধু রভহু ড়ভ ঃযবংব ঝউঠউ জউ ংরফব বভ্রপঃং ড়পপঁ ৎ ি যরষবঃধশরহম ংঃবৎরষবি ধঃবৎ (ঃযব ধপঃরাব রুমৎবফরবহঃ পড়হঃধরহবফ রহ ড ধঃবৎ ভড়ৎ ওল্লপঃরড়ু, ঝঃবৎরষব)	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১স ষ, ২স ষ,৫স ষ্ ১০স ষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১ স ষা রধষইতিমধ্যে বেক্সিমকো, ইনসেপ্টা, অপসোনিন, কেমিকো ও হেলথকেয়ার ফার্মা এর রেজিট্রেশন রয়েছে। ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১ স ষ /অস ঢ় ড়ঁ ষব হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
০৫	ঙ্কপবঢ়ঃধ চযধৎস ধপবঁ ঃরপধ ষংখঃফ. উয ধস ৎধর টহরু	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২ স ষ /অস ঢ়ড়ঁ ষব	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২ স ষ / অস ঢ়ড়ঁ ষব		ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ ধং রহফরপধঃৰক রহ ঃযব ধংবঢ় ঃরপঢ়ৎবঢ় ধৎধঃরড়ু ড়ভঢ় ধৎবহঃবৎধষ ংড়ষঁ ঃরড়ু.	**Contraindication**: ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ রং ধ যবস ড়ষু ঃরপ ধমবহঃ ফঁ ব ঃড় রঃংযু ঢ়ড়ঃড়হরপরুঃ. এরাবৎবভড়ৎব রঃ রংপড়হঃৎধরহফরপধঃরড়ু ভড়ৎ রহঃৎধা বহড়ঁ ং ধফস রুহরুঃৎধঃরড়ু ি রিয়াড়ঁ ঃ ধফফরঃরাবং. ঝরফৰ-বভল্লপঃং: ড যবহঁ ংবফ রহ ংস ধষষ ফড়ংবং, হড় ঈঙগ গঙ ঘ ংরফৰ বভল্লপঃং যধা ব নববহ ৎবঢ়ড়ৎঃবফ ি রিয়া ঃযরং ঢ়ৎড়ফঁ পঃ. ঝাববশ স বফরপধষ ধঃঃবহঃরড়ু ৎরমযঃ ধি ধু রভধহু ড়ভ ঃযবংব ঝউঠউ জউ ংরফৰ বভল্লপঃং ড়পপঁ ৎ ি যরষবঃধশরুহম ংঃবৎরষবি ধঃবৎ (ঃযব ধপঃরা ব রুহমৎবফরবহঃ পড়হঃধরহবফ রহ ড ধঃবৎ ভড়ৎ ঙ্কল্লপঃরড়ু, ঝঃবৎরষব)	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১স ষ, ২স ষ,৫স ষ্ ১০স ষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১ স ষা রধষইতিমধ্যে বেক্সিমকো, ইনসেপ্টা, অপসোনিন, কেমিকো ও হেলখকেয়ার ফার্মা এর রেজিট্রেশন রয়েছে। ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২ স ষ /অস ঢ়ড়ঁ ষব হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।
০৬	ঙ্কপবঢ়ঃধ চযধৎস ধপবঁ ঃরপধ ষংখঃফ. উয ধস ৎধর টহরু	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ৫ স ষ /অস ঢ়ড়ঁ ষব	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ৫ স ষ / অস ঢ়ড়ঁ ষব		ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ ধং রহফরপধঃৰক রহ ঃযব ধংবঢ় ঃরপঢ়ৎবঢ় ধৎধঃরড়ু ড়ভঢ় ধৎবহঃবৎধষ ংড়ষঁ ঃরড়ু.	**Contraindication**: ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ রং ধ যবস ড়ষু ঃরপ ধমবহঃ ফঁ ব ঃড় রঃংযু ঢ়ড়ঃড়হরপরুঃ. এরাবৎবভড়ৎব রঃ রংপড়হঃৎধরহফরপধঃরড়ু ভড়ৎ রহঃৎধা বহড়ঁ ং ধফস রুহরুঃৎধঃরড়ু ি রিয়াড়ঁ ঃ ধফফরঃরাবং. ঝরফৰ-বভল্লপঃং: ড যবহঁ ংবফ রহ ংস ধষষ ফড়ংবং, হড় ঈঙগ গঙ ঘ ংরফৰ বভল্লপঃং যধা ব নববহ ৎবঢ়ড়ৎঃবফ ি রিয়া ঃযরং ঢ়ৎড়ফঁ পঃ. ঝাববশ স বফরপধষ ধঃঃবহঃরড়ু ৎরমযঃ ধি ধু রভধহু ড়ভ ঃযবংব ঝউঠউ জউ ংরফৰ বভল্লপঃং ড়পপঁ ৎ ি যরষবঃধশরুহম ংঃবৎরষবি ধঃবৎ (ঃযব ধপঃরা ব রুহমৎবফরবহঃ পড়হঃধরহবফ রহ ড ধঃবৎ ভড়ৎ ঙ্কল্লপঃরড়ু, ঝঃবৎরষব)	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১স ষ, ২স ষ,৫স ষ্ ১০স ষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ২ স ষ /অস ঢ়ড়ঁ ষব ইতিমধ্যে বেক্সিমকো, ইনসেপ্টা, অপসোনিন, কেমিকো ও হেলখকেয়ার ফার্মা এর রেজিট্রেশন রয়েছে। ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ৫ স ষ / অস ঢ়ড়ঁ ষবহিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।
০৭	ঙ্কপবঢ়ঃধ চযধৎস ধপবঁ ঃরপধ ষংখঃফ. উয ধস ৎধর টহরু	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১০ স ষ /অস ঢ়ড়ঁ ষব	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১০ স ষ / অস ঢ়ড়ঁ ষব		ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ ধং রহফরপধঃৰক রহ ঃযব ধংবঢ় ঃরপঢ়ৎবঢ় ধৎধঃরড়ু ড়ভঢ় ধৎবহঃবৎধষ ংড়ষঁ ঃরড়ু.	**Contraindication**: ঝঃবৎরষবি ধঃবৎ ভড়ৎ রহল্লপঃরড়ু টঝচ রং ধ যবস ড়ষু ঃরপ ধমবহঃ ফঁ ব ঃড় রঃংযু ঢ়ড়ঃড়হরপরুঃ. এরাবৎবভড়ৎব রঃ রংপড়হঃৎধরহফরপধঃরড়ু ভড়ৎ রহঃৎধা বহড়ঁ ং ধফস রুহরুঃৎধঃরড়ু ি রিয়াড়ঁ ঃ ধফফরঃরাবং.	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১স ষ, ২স ষ,৫স ষ্ ১০স ষ	ড ধঃবৎ ভড়ৎ রহল্লপঃরড়ু ১ স ষা রধষইতিমধ্যে বেক্সিমকো, ইনসেপ্টা, অপসোনিন, কেমিকো ও হেলখকেয়ার ফার্মা এর রেজিট্রেশন রয়েছে।	পোস্ট অ্যাপ্রুভালের সুপারিশ করা হয়।	পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						ঝরফধ-বভ্ভরপঃং: ড যবহঁ ংবফরহংস ধষষ ফড়ংবং, হড়ঈঙগ গঙ ঘ ংরফধ বভ্ভরপঃং যধা ব নববহ ৎবঢ়ড়ৎঃবফি রিক্ষ ঃযরং ঢ়ৎড়ফঁ পঃ. ঝববশ স বফরূপধষ ধঃঃবহঃরড়হ ৎরমযঃ ধি ধু রভধহু ড়ভ ঃযবংব ঝউঠউ জউ ংরফধ বভ্ভরপঃং ড়পপঁ ৎি যরষবঃধশরহম ংঃবৎরষবি ধঃবৎ (ঃযব ধপঃরাব রহমৎবফরবহঃ পড়হঃধরহবফ রহড ধঃবৎ ভ্ভৎ ওল্লপঃরড়হ, ঝঃবৎরষব)		ড ধঃবৎ ভ্ভৎ রহল্লপঃরড়হ ১০ স ষ /অস ঢ়ড়ঁ ষব হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।		
০৮	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Cholecalciferol 500 mcg Eqv.to Vitamin D_3 20,000 IU/100 ml (25mcg/5ml) Oral Solution	Cholecalciferol BP 500 mcg Eqv.to Vitamin D_3 20,000 IU/100 ml (25mcg/5 ml)	Vitamin	Vitamin D is essential for normal bone growth and development and to maintain bone density. Vitamin D acts as a hormone and increases reabsorption of Calcium and Phosphorus by the kidneys and thus increases bone turnover. It is also used in the prevention and treatment of vitamin D deficiency states.	**Contraindications:** ● Hypersensitivity to the active substance (cholecalciferol) or to any of the excipients ● Hypercalcaemia and/or hypercalciuria ● Nephrolithiasis (Renal calculi) ● Hypervitaminosis ● Severe renal impairment **Side effects:** Few side-effects can generally occur including hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of	Vitamin D_3 400IU, 1000IU, 2000 IU Tablet, 800 IU Soft Gelatine Capsule, 20,000 IU, 40,000IU Capsule & 5mg/ml Injection	**রেফারেন্স নাই।** আবেদিত Cholecalciferol 25mcg/5ml Syrup নামীয় পদটির ডিসিসি পাওয়া যাচ্ছে না কিন্তু পদটি ইতোঃপূর্বে Incepta Pharmaceuticals Ltd., Healthcare Pharmaceuticals Ltd., & Unimed Unihealth Pharmaceuticals Ltd.সহ কয়েকটি ঔষধ উৎপাদনকারী প্রতিষ্ঠানের নামে অন্তর্ভূক্ত আছে এবং উক্ত প্রতিষ্ঠানগুলো	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						hypercalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation with the administration of Cholecaciferol.		পদটি উৎপাদন ও বাজারজাত করছে।		
০৯	**SHINIL Pharma Ltd.**	Tolfenamic Acid 200 mg Bolus **(VET)**	Tolfenamic Acid 200 mg	NSAID	Tolfenamic acid is recommended for the alleviation of inflammation and pain associated with osteoarthritis in dogs with hip dysplasia; as an aid in the treatment of upper respiratory diseases and as symptomatic treatment of fever in cats.	**Contra indication:** It is contraindicated in animal with dehydration, hypovolemia, hypotension, as it increases the risk of renal toxicity. Animals with a hypersensitivity to Tolfenamic acid or with a known sensitivity to non steroidal anti-inflammatory drugs or animals with coagulative disorders should not be treated with this drug. **Side effect:** Gastro-intestinal intolerance which is generally reversible upon withdrawal of the drug. **Precautions :** Do not exceed the prescribed dosage. Although studies in	Tolfenamic Acid 200 mg	Tolfenamic Acid Bolus (Tolfenamic Acid 200 mg) ইতিমধ্যে Eskayef Pharmaceuticals ltd., ACME Pharma ও Advent Pharma এর রেজিট্রেশন রয়েছে। Tolfenamic Acid Bolus (Tolfenamic Acid 200 mg) হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						laboratory animals have not shown effects on the reproduction, it is not advised to prescribe this drug to breeding. Treatment should be discontinued prior to elective surgery.				
১০	SHINIL Pharma LTD.	Sodium Bicarbonate 75 mg Injection **(VET)**	Sodium Bicarbonate 75 mg	Salt & sugar substitute	Metabolic acidosis. Acute carbohydrate engorgement. Severe primary lactic acidosis. Barbiturate toxicity. Severe diarrhea which is often accompanied by a significant loss of bicarbonate in body.	**Contraindications:** Sodium Bicarbonate is contraindicated in animal that are losing chloride ion from body by vomiting and receiving diuretics. **Side effects:** Sometimes overdose may cause alkalosis. **Precautions:** Incompatible with calcium containing solution.	Sodium Bicarbonate 75 mg	Sodium Bicarbonate USP 75 mg Injection ইতিমধ্যে Square Pharmaceuticals ltd., Opsonin Pharma ও Advent Pharma এর রেজিট্রেশন রয়েছে। Sodium Bicarbonate USP 75 mg Injection) হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।
১১.	Advanced Chemical Industries Limited, 7 Hajeeganj,	Sodium Bicarbonate USP 7.5g/100ml Injection **(Vet)**	Sodium Bicarbonate USP 7.5g / 100ml	Electrolyte replenisher and systemic alkalizer	Metabolic acidosis, drug intoxication including Barbiturate toxicity,	**Contraindication:** Sodium Bicarbonate Injection, USP is contraindicated in patients who are losing chloride by vomiting or from	Sodium Bicarbonate USP 7.5g/100ml Injection	Sodium Bicarbonate USP 7.5g/100ml Injection ইতিমধ্যে The ACME Laboratories Ltd., Bridge	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Godnayl, Narayanganj.			Veterinary Drugs (077)	Salicylates or methyl alcohol toxicity, severe diarrhea, alkalinization of urine.	continuous gastrointestinal suction, and in patients receiving diuretics known to produce a hypochloremic alkalosis . **Side-effects:** Overly aggressive therapy with Sodium Bicarbonate Injection, USP can result in metabolic alkalosis (associated with muscular twitchings, irritability and tetany) and hypernatremia. Inadvertent extravasation of intravenously administered hypertonic solutions of sodium bicarbonate have been reported to cause chemical cellulitis because of their alkalinity, with tissue necrosis, ulceration or sloughing at the site of infiltration. Prompt elevation of the part, warmth and local injection of lidocaine or hyaluronidase are recommended to prevent sloughing of extravasated I.V. infusions.		Pharmaceuticals Ltd., Chemist Laboratories Ltd., Eskayef pharmaceuticals Ltd., Opsonin Pharma Limited ও Jayson Pharmaceuticals Ltd এর রেজিট্রেশন রয়েছে। Sodium Bicarbonate USP 7.5g/100ml Injection হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।		

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						Warnings and precautions: This is a sterile single dose vial. No preservatives have been added. Discard unused portion after use. Do not use if solution is hazy, cloudy or contains a precipitate. Store at a temperature between 15°-30° C (59°-86° F). Avoid freezing. Bicarbonate therapy is directed at producing a substantial correction of low total CO2 content and blood pH, but risks of overdosage and alkalosis should be avoided. Repeated fractional doses and periodic monitoring by appropriate laboratory tests are therefore recommended to minimize the possibility of overdosage. Sodium Bicarbonate addition to parenteral solutions containing calcium should be avoided except where compatibility has been previously established. Precipitation or haze may result from sodium				

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						bicarbonate-calcium admixtures, and the resulting solution should not be administered				
১২.	Techno Drugs Ltd. Satirpara, Narsingdi	Tolfenamic Acid BP 200 mg/Bolus (Vet)	Tolfenamic Acid BP 200 mg	NSAID	Effective in the relief of pain, fever & inflammation. Mainly used in Mastitis, Pneumonia, Arthritis.	Contraindication: Do not use in animals that shows hypersensitivity to Tolfenamic Acid. Side Effect: Vomiting, Diarrhea	Tolfenamic Acid BP 200 mg	Tolfenamic Acid BP 200 mg/Bolus (Vet) ইতিমধ্যে The ACME Laboratories Ltd., Eskayef pharmaceuticals Ltd. ও Advent Pharmaceuticals Ltd এর রেজিট্রেশন রয়েছে। Tolfenamic Acid BP 200 mg/Bolus (Vet) হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।
১৩.	Techno Drugs Ltd. Satirpara, Narsingdi	Prednisolone Sodium Phosphate BP 7.5 mg/ml Injection (vet) + Dexamethasone Sodium Phosphate BP 2.5 mg/ml Injection (vet)	Prednisolone Sodium Phosphate BP 7.5 mg/ml + Dexamethasone		It is indicated for arthritis, pregnancy toxemia, shock due to trauma, milk fever, cardiac shock, cystic	Contraindication: Except for emergency therapy, do not use in animals with chronic nephritis and hypercorticalism. Existence of congestive heart failure, diabetes, osteoporosis.	Prednisolone Sodium Phosphate BP 7.5 mg/ml + Dexamethasone Sodium Phosphate	Prednisolone Sodium Phosphate BP 7.5 mg/ml + Dexamethasone Sodium Phosphate BP 2.5 mg/ml Injection (Vet) ইতিমধ্যে Renata Ltd., Chemist Lab	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।	পদটির USFDA/ UKMHRA/ EMA/ BNF Ref. এর রেফারেন্স নাই বিধায় রেজিস্ট্রেশন বাতিল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			Sodium Phosphate BP 2.5 mg/ml		ovarian disease in ruminants.	Side Effect: Weight loss, anorexia, polydipsia, polyuria, Vomiting, Diarrhea, allergic reaction, bone resorption, collagen synthesis inhibition, delayed bone wound healing, diarrhea, gastrointestinal irritation.	BP 2.5 mg/ml	ও Guardian Healthcare Ltd এর রেজিট্রেশন রয়েছে। Prednisolone Sodium Phosphate BP 7.5 mg/ml + Dexamethasone Sodium Phosphate BP 2.5 mg/ml Injection (Vet) হিসেবে ডিসিসি এর রেফারেন্স পাওয়া যাচ্ছে না বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।		
14.	**General Pharmaceutical Ltd., Gazipur**	Montelukast Sodium USP 10.400mg (Equivalent to 10 mg Motelukast) Chewable Tablet	Montelukast Sodium USP 10.400mg (Equivalent to 10 mg Motelukast)	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease(COPD) Therapeutic Code: 044	Montelukast is indicated for- • The Prophylaxis and chronic treatment of asthma in patients 12 months of age and older. • Acute prevention of exercise-induced bronchoconstriction (EIB) in patients 6 years of age and older. Relief of symptoms of allergic rhinitis (AR): seasonal allergic rhinitis (SAR) in	**Contra-Indication:** Hypersensitivity to any component of this product **Warnings and Precautions**: Do not prescribe MONTELUKAST to treat an acute asthma attack . •Advise patients to have appropriate rescue medication available). •Inhaled corticosteroid may be reduced gradually. Do not abruptly substitute MONTELUKAST for inhaled or oral corticosteroids. •Patients with known aspirin sensitivity should continue to avoid aspirin or non-steroidal anti-inflammatory agents while taking MONTELUKAST. •Neuropsychiatric events have been reported with MONTELUKAST. Instruct patients to	Montelukast 4mg, 5mg, 10mg Tablet & Montelukast 4mg, 5mg Chewable Tablet	**রেফারেন্স নাই** Montelukast Sodium USP 10.400mg (Equivalent to 10 mg Motelukast DCC-216 তে অনুমোদিত। DCC-216 এর কার্যবিবরণীতে কোন ডোজেস ফরম উল্লেখ ছিল না। পদটি ট্যাবলেট হিসেবে ৯৩ টি প্রতিষ্ঠানের অনুকূলে রেজিস্ট্রেশন প্রদান করা হয়েছে এবং Chewable	পদটির প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভালের জন্য সুপারিশ করা হয়।	পদটির প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					patients 2 years of age and older, and perennial allergic rhinitis (PAR) in patients 6 months of age and older	be alert for neuropsychiatric events. Evaluate the risks and benefits of continuing treatment with MONTELUKAST if such events occur and . •Systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, has been reported. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy . •Inform patients with phenylketonuria that the 4-mg and 5-mg chewable tablets contain phenylalanine **Adverse Reactions:** Most common adverse reactions (incidence ≥5% and greater than placebo listed in descending order of frequency): upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis		Tablet হিসেবে ড্রাগ ইন্টারন্যাশনাল ও সান ফার্মার অনুকূলে রেজিস্ট্রেশন প্রদান করা হয়েছে। পদটি পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।		
15.	**General Pharmaceutical Ltd., Gazipur**	Cholecalciferol (Vitamin-$\mathbf{D_3}$) (1000000 IU/gm) USP 2.000mg (Equivalent to 2000 IU Cholecalciferol USP) Liquid Fill Hard Gelatin Capsule	Cholecalciferol (Vitamin-$\mathbf{D_3}$) (1000000 IU/gm) USP 2.000mg (Equivalent to 2000 IU Cholecalcife		Vitamin D is essential for normal bone growth and development and to maintain bone density. Vitamin D acts as a hormone and increases reabsorption of Calcium and	**Contraindications:** Cholecalciferol is contraindicated in all diseases associated with hypercalcaemia. **Side effects:** Common side effect are including; hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of hypercalcaemia), anorexia, headache, nausea, vomiting,	Cholecalcifero 2000 IU Tablet Cholecalcifero 20000 IU Capsule Cholecalcifero 40000 IU Capsule	**রেফারেন্স নাই** Cholecalciferol 2000 IU DCC-245 এ Tablet হিসেবে অনুমোদিত। কিন্তু square pharmaceuticals এর অনুকূলে Capsule	পদটির প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভালের জন্য সুপারিশ করা হয়।	পদটির প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
			rol USP) Liquid Fill		Phosphorus by the kidneys and increased bone turnover. Prevention and Treatment of vitamin D deficiency states	abdominal pain or stomach ache and constipation with the administration of Cholecaciferol.		হিসেবে রেজিস্ট্রেশন প্রদান করা হয়েছে। পদটি পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হল।		
16.	**Advanced Chemical Industries Limited, 7 Hajeeganj, Godnayl, Narayanganj.** Beximco Pharmaceuticals Ltd. (নতুন আবেদন) Square Pharmaceuticals Ltd, Salgaria, Pabna. (নতুন আবেদন) Eskayef Pharmaceuticals Limited, Tongi, Gazipur. (নতুন আবেদন)	Sodium Alginate BP 5g + Sodium Bicarbonate BP 2.13g + Calcium Carbonate USP 3.25g/100ml Suspension	Sodium Alginate BP, Sodium Bicarbonate BP and Calcium Carbonate USP	Antacid Adsorbent Therapeutic Code: 007	This suspension is used for the treatment of acid related symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy.	**Contraindication:** This suspension is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or any of the excipient. **Side-effects:** Very rarely patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. Ingestion of large quantities of calcium carbonate may cause alkalosis, hypercalcaemia, acid rebound, milk alkali syndrome or constipation. **Warnings and precautions:** This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment).	Existing Gavix (Sodium Alginate USP 5gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm)/100ml suspension	MHRA Sodium Alginate BP 5g Advanced Chemical Industries Limited এর অনুকূলে রেজিস্ট্রেশন প্রদান করা হয়েছে, যার excipient এ Sodium Bicarbonate BP 2.13g + Calcium Carbonate USP 3.25g/100ml হিসেবে অনুমোদিত। মূলত Sodium Alginate BP 5g + Sodium Bicarbonate BP 2.13g + Calcium Carbonate USP 3.25g/100ml API হবে এবং এই কম্বিনেশনটি ড্রাগ কন্ট্রোল কমিটি কর্তৃক অনুমোদন নেই বিধায় পোস্ট অ্যাপ্রুভালের জন্য উপস্থাপন করা হয়েছে।	পদটি পোস্ট অ্যাপ্রুভালের জন্য সুপারিশ করা হয়।	পদটি পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
17.	Advanced Chemical Industries Limited, 7 Hajeeganj, Godnayl, Narayanganj.	Calcium Carbonate (Coral Source) USP 327 mg + Calcium Lactogluconate Ph.Grade 1000 mg + Colecalciferol BP 4.00 mg (eqv. to 400 IU Vitamin D3) + Ascorbic Acid (DC Grade) BP 500 mg Effervescent Tablet	Calcium Carbonate (Coral Source) USP 327 mg + Calcium Lactogluconate Ph.Grade 1000 mg + Colecalciferol BP 4.00 mg (eqv. to 400 IU Vitamin D3) + Ascorbic Acid (DC Grade) BP 500 mg	Vitamins & Combinations	This combination is indicated for: 1. As an adjunct to specific therapy for osteoporosis 2. Increased demand for Calcium, Vitamin-C and Vitamin-D, e.g. pregnancy, lactation, periods of rapid growth (childhood, adolescence), in old age; during infectious disease and convalescence 3. Treatment of calcium, vitamin-C & vitamin-D deficiency 4. Osteoporosis 5. Premenstrual syndrome 6.Postmenopausal problems 7. Adjuvant in colds and influenza	Contraindications: This combination is contraindicated in patients with known hypersensitivity to this combination or any components of this product. It is also contraindicated hypercalcemia, severe hypercalciuria, severe renal failure, patients with hyperoxalauria, iron overload, sarcoidosis, vitamin-D overdosage, primary hyperparathyroidism, larger doses may lead to gastrointestinal tract upset, bone metastasis or other malignant bone disease and glucose-6-phosphate dehydrogenase deficiency Side Effects: In rare case, mild gastrointestinal disturbances (bloating, diarrhea) can occur. In predisposed patients prolonged treatment with high doses may promote the formation of calculi in the urinary tract. Following administration of vitamin-D supplements occasional skin rash has been reported. Hypercalciuria and in rare cases hypocalcaemia have been seen in long term treatment with vitamin-D at high doses. Warning and Precautions : For patients with mild hypercalciuria (exceeding 300 mg = 7.5 mmol/24 hours), with mild or moderate impairment of renal function or with	Existing	Acical CX Effervescent Tablet DAR No. 005-1163-062 (Advanced Chemical Industries Limited) Cavic-C Plus Effervescent Tablet (Incepta Pharmaceuticals)	পদটির প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভালের জন্য সুপারিশ করা হয়।	পদটির প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
						a history of urinary concrements, monitoring of calcium excretion in the urine is required. If necessary, the dosage should be reduced or therapy should be discontinued. Since citrate salts have been reported to increase aluminium absorption, this preparation which contains citric acid as a constituent, should be used with caution in patients with severely impaired renal function, especially those receiving aluminium-containing preparations				
18.	**General Pharmaceutical Ltd., Unit-2 Gazipur**	Human Recombinant Erythropoietin Alfa 5,000 IU/ 0.5 ml Prefilled Syringe SC/IV Injection	Human Recombinant Erythropoiet in Alfa 5,000 IU)/ 0.5 ml Prefilled Syringe SC/IV Injection	Drugs Use in Anemia & Others Blood Disorder Code-0045	Treatment of anemia associated with chronic renal failure (renal anemia) in patients on dialysis. Treatment of symptomatic renal anemia in Patients not yet undergoing dialysis. Treatment of anemia in adult patients with solid tumors receiving chemotherapy. Treatment of anemia in adult patients with adult patients with multiple myeloma, low grade non- Hodgkin's	Contraindication: pure red cell aplasia following erythropoietin therapy;uncontrolled hypertension; patients unable to receive thromboprophylaxis; avoid injections containing benzyl alcohol in neonates Side-effect: diarrhoea, nausea, vomiting; dosedependent increase in blood pressure or aggravation of hypertension; in isolated patients with normal or low blood pressure, hypertensive crisis withencephalopathy-like symptoms and generalised tonic-clonic seizures requiring immediate medical attention; headache; dose-dependent increase in platelet	2000 IU/.5 ml; 3000 IU/0.3 ml, 4000 IU/.4ml; 10,000 IU/ml Injection	BNF-76 Page-978 Erythropoietin Beta 5,000 IU/ Prefilled Syringe SC/IV Injection DCC-216 এ অনুমোদিত। Erythropoietin Beta BP 5000 IU/0.3ml DCC-245 এ অনুমোদিত। Erythropoietin Alfa 5,000 IU)/ 0.5 ml Prefilled Syringe SC/IV Injection হিসেবে ACI,	পদটি পোস্ট অ্যাপ্রুভালের জন্য সুপারিশ করা হয়।	পদটি পোস্ট অ্যাপ্রুভাল করা হয়।

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					lymphoma or chronic lymphocytic leukemia, who have a relative erythropoietin deficiency and are receiving anti-tumor therapy. Deficiency is defined as an inappropriately low serum erythropoietin level in relation to the degree of anemia. Increasing the yield of autologous blood from patients in a pre-donation program. Its use in this indication must be balanced against the reported increased risk of thromboembolic events. Treatment should only be given to patients with moderate anemia (Hb 10-13 g/dL [6.21-8.07 mmol/L], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major	count (but thrombocytosis rare) regressing during treatment.		Aristopharma, Beacon, Drug International, Healthcare, Incepta, square এর রেজিস্ট্রেশন প্রদান করা হয়েছে।		

No	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA, UKMHRA, EMA এবং BNF Ref.	টেকনিক্যাল সাব কমিটির মতামত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
					elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).					

২. ঔষধ নিয়ন্ত্রণ কমিটির -২৫১ তম সভার সিদ্ধান্ত মোতাবেক বিশেষজ্ঞদের মতামত গ্রহণ করা হয়েছে এরূপ পদের বিষয়ে সিদ্ধান্তঃ (আমদানির নিমিত্তে):

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	বিশেষজ্ঞদের মতামত	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
1.	Fresenius Kabi Austria GmbH, Hafnerstraße 36, 8055 Graz, Austria **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	Omegaven "Fresenius" emulsion for infusion, 100ml	(Highly refined fish oil100mg + purified egg phospholipids (egg lecithin) 12mg + glycerol Ph. Eur. 25mg)/ml	Caloric Agents	Parenteral nutrition supplementation with long chain omega-3-fatty acids, especially eicosapentaenoic and docosahexaenoic acid, when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** Hypokalaemia, hyperhydration, hypotonic dehydration, unstable metabolism, acidosis **Side effects:** Abdominal pain, nausea, vomiting, shivering, tiredness, headache, thrombocytopenia, haemolysis, anaphylactic reaction, rash, urticaria, priapism	New	CPP – Austria, Germany	ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, ব্রিগেডিয়ার জেনারেল, বিভাগীয় প্রধান, মেডিক্যাল অনকোলজি, ক্যান্সার সেন্টার, সিএমএইচ মতামত প্রদান করেছেনঃ ঔষধটি Patient of oncology, Geriatrics Patients, Patients suffering from malnutrition, I.C.U patients, Post-Operative surgical Patients দের চিকিৎসায় ঔষধটি ব্যবহার করা যেতে পারে মর্মে মতামত প্রদান করেছেন। কর্ণেল মাসুদুল আলম মজুমদার, কর্ণেল, সিনিয়র ইন্টেনসিভিস্ট ও বিভাগীয় প্রধান, ক্রিটিক্যাল কেয়ার সেন্টার ও ইমার্জেন্সী এন্ড ক্যাজুয়ালটি সেন্টার, সিএমএইচ, ঢাকা মতামত প্রদান করেছেনঃ ঔষধটি ইমিউন ফাংশন ইমপ্রুভ করা সহ আরো অনেক ধরনের জটিলতায় ব্যবহৃত হয়। ঔষধটি আইসিইউ, সার্জিক্যাল এবং বার্ণ রোগীদের উন্নত চিকিৎসার জন্য অত্যাবশ্যকীয়।	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদনের সুপারিশ করা হয়।	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	বিশেষজ্ঞদের মতামত	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
2.	Fresenius Kabi AB, 751 74 Uppsala, Sweden **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	SmofKabiven emulsion for infusion, 986ml (Three Chamber Bag)	1st chamber contains: Amino acid solution with electrolytes corresponding to Aminoven 10% to 500ml 2nd chamber contains: Glucose 42% to 298ml 3rd chamber contains: SMOFlipid 20% to 188ml	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients -Severe liver insufficiency -Severe blood coagulation disorders -Severe renal insufficiency without access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions	New	CPP-Sweden, Germany	ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, ব্রিগেডিয়ার জেনারেল, বিভাগীয় প্রধান, মেডিক্যাল অনকোলজি, ক্যান্সার সেন্টার, সিএমএইচ মতামত প্রদান করেছেনঃ ঔষধটি Patient of oncology, Geriatrics Patients, Patients suffering from malnutrition, I.C.U patients, Post-Operative surgical Patients দের চিকিৎসায় ঔষধটি ব্যবহার করা যেতে পারে মর্মে মতামত প্রদান করেছেন। কর্ণেল মাসুদুল আলম মজুমদার, কর্ণেল, সিনিয়র ইন্টেনসিভিস্ট ও বিভাগীয় প্রধান, ক্রিটিক্যাল কেয়ার সেন্টার ও ইমার্জেন্সী এন্ড ক্যাজুয়ালটি সেন্টার, সিএমএইচ, ঢাকা মতামত প্রদান করেছেনঃ ঔষধটি ইমিউন ফাংশন ইমপ্রুভ করা সহ আরো অনেক ধরনের জটিলতায় ব্যবহৃত হয়। ঔষধটি আইসিইউ, সার্জিক্যাল এবং বার্ণ রোগীদের উন্নত চিকিৎসার জন্য অত্যাবশ্যকীয়। ঔষধটি ব্যবহারের ফলে রোগীদের মধ্যে উপরোক্ত রোগ জটিলতা ও রোগী মৃত্যু হার কমে আসে।	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদনের সুপারিশ করা হয়।	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদন করা হয়।
3.	Fresenius Kabi AB, 751 74 Uppsala, Sweden	SmofKabiven emulsion for infusion, 1477ml	1st chamber contains: Amino acid solution with electrolytes corresponding	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active	New	CPP-Sweden, Germany	ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, ব্রিগেডিয়ার জেনারেল, বিভাগীয় প্রধান, মেডিক্যাল অনকোলজি, ক্যান্সার সেন্টার, সিএমএইচ মতামত প্রদান করেছেনঃ ঔষধটি Patient of oncology, Geriatrics	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদনের সুপারিশ করা হয়।	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	বিশেষজ্ঞদের মতামত	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Local agent: Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	(Three Chamber Bag)	to Aminoven 10% to 750ml 2nd chamber contains: Glucose 42% to 446ml 3rd chamber contains: SMOFlipid 20% to 281ml		enteral nutrition is impossible, insufficient or contraindicated.	substances or excipients -Severe liver insufficiency -Severe blood coagulation disorders -Severe renal insufficiency without access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions			Patients, Patients suffering from malnutrition, I.C.U patients, Post-Operative surgical Patients দের চিকিৎসায় ঔষধটি ব্যবহার করা যেতে পারে মর্মে মতামত প্রদান করেছেন। কর্ণেল মাসুদুল আলম মজুমদার, কর্ণেল, সিনিয়র ইন্টেনসিভিস্ট ও বিভাগীয় প্রধান, ক্রিটিক্যাল কেয়ার সেন্টার ও ইমার্জেন্সী এন্ড ক্যাজুয়ালটি সেন্টার, সিএমএইচ, ঢাকা মতামত প্রদান করেছেনঃ ঔষধটি ইমিউন ফাংশন ইমপ্রুভ করা সহ আরো অনেক ধরনের জটিলতায় ব্যবহৃত হয়। ঔষধটি আইসিইউ, সার্জিক্যাল এবং বার্ণ রোগীদের উন্নত চিকিৎসার জন্য অত্যাবশ্যকীয়। ঔষধটি ব্যবহারের ফলে রোগীদের মধ্যে উপরোক্ত রোগ জটিলতা ও রোগী মৃত্যু হার কমে আসে।		
4.	Fresenius Kabi AB, 751 74 Uppsala, Sweden **Local agent:** Radiant Export Import Enterprise	SmofKabiven Perifer emulsion for infusion, 1206ml (Three Chamber Bag)	1st chamber contains: Glucose 13% to 656ml 2nd chamber contains: Amino acid solution with electrolytes corresponding	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients -Severe liver insufficiency	New	CPP - Sweden, Germany	ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, ব্রিগেডিয়ার জেনারেল, বিভাগীয় প্রধান, মেডিক্যাল অনকোলজি, ক্যান্সার সেন্টার, সিএমএইচ মতামত প্রদান করেছেনঃ ঔষধটি Patient of oncology, Geriatrics Patients, Patients suffering from malnutrition, I.C.U patients, Post-Operative surgical Patients দের চিকিৎসায়	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদনের সুপারিশ করা হয়।	বিশেষজ্ঞদের মতামতের ভিত্তিতে অনুমোদন করা হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	বিশেষজ্ঞদের মতামত	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত
	Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh		to Aminoven 10% to 380ml 3rd chamber contains: SMOFlipid 20% to 170ml			-Severe blood coagulation disorders -Severe renal insufficiency without access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions			ঔষধটি ব্যবহার করা যেতে পারে মর্মে মতামত প্রদান করেছেন। কর্ণেল মাসুদুল আলম মজুমদার, কর্ণেল, সিনিয়র ইন্টেনসিভিস্ট ও বিভাগীয় প্রধান, ক্রিটিক্যাল কেয়ার সেন্টার ও ইমার্জেন্সী এন্ড ক্যাজুয়ালটি সেন্টার, সিএমএইচ, ঢাকা মতামত প্রদান করেছেনঃ ঔষধটি ইমিউন ফাংশন ইমপ্রুভ করা সহ আরো অনেক ধরনের জটিলতায় ব্যবহৃত হয়। ঔষধটি আইসিইউ, সার্জিক্যাল এবং বার্ণ রোগীদের উন্নত চিকিৎসার জন্য অত্যাবশ্যকীয়। ঔষধটি ব্যবহারের ফলে রোগীদের মধ্যে উপরোক্ত রোগ জটিলতা ও রোগী মৃত্যু হার কমে আসে।		

৩. ঔষধ নিয়ন্ত্রণ কমিটির -২৫১ তম সভার সিদ্ধান্ত মোতাবেক বাতিল ও বহানকৃত ভিটামিন কম্বিনেশন জাতীয় পদ সংশোধন প্রসঙ্গেঃ

(ক) নিম্নোক্ত পদসমূহ দীর্ঘদিন যাবৎ বাজারজাত হয়ে আসছে কিন্তু ডিসিসি এর রেফারেন্স খুজে পাওয়া যাচ্ছে না। টেকনিক্যাল সাব কমিটির সদস্যবৃন্দ পদসমূহের প্রয়োজন আছে বিধায় পোস্ট অ্যাপ্রুভালের সুপারিশ করেন। যার পরিপ্রেক্ষিতে ড্রাগ কন্ট্রোল কমিটি কর্তৃক পদসমূহ পোস্ট অ্যাপ্রুভাল করা হয় ঃ

১. Elemental Iron 48 mg + Folic Acid 500 mcg + Zinc Sulphate Monohydrate 61.8 mg Tablet ।

২. Dexpanthanol 25 mg + Nicotinamide 500 mg + Pyridoxine Hydrochloride 50 mg +Riboflavin 20 mg + Vitamin B_1 250 mg/10 ml Injection ।

৩. Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B_1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Tablet ।

৪. Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B_1 5 mg Capsule ।

৫. Calcium Carbonate 327 mg + Calcium Lactate Gluconate 1 gm + Vitamin C 500 mg Tablet ।

৬. Calcium (Coral Calcium) 500 mg + Vitamin D_3 200 IU Tablet ।

৭. D-Panthenol 5 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 4 mg + Vitamin B_1 50 mg/2 ml Injection ।

৮. Nicotinamide 10 mg + Pantothenic acid 5 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 1mg + Vitamin A 5000 IU + Vitamin B_1 1.6 mg + Vitamin C 50 mg + Vitamin D 1000 IU/ml Paediatric Drops ।

৯. Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B_1 5 mg Tablet ।

১০. Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B_1 5 mg/5 ml Syrup ।

১১. Nicotinamide 400 mg + Pyridoxine Hydrochloride 40 mg + Riboflavin 50 mg + Vitamin B_1 100 mg + Zinc 200 mg/100 ml Syrup ।

১২. Iron (III) Hydroxide Polymaltose Complex, Folid Acid & Zinc Sulphate Tablet (Iron (III) Hydroxide Polymaltose Complex INN 188mg eq. to Elemental Iron 47mg, Folic Acid BP 0.50mg, Zinc Sulphate Monohydrate USP 61.80mg eq. to Elemental Zinc 22.5mg)

১৩. Vitamin-E Ascorbic Acid, Lutein Zinc, Copper Soft Gelatin Capsule.
Vitamin E (as 50% diluted dry Vit. E Acetate) BP 30mg, Ascorbic Acid BP 60mg Letein (As 5% diluted Letein) Ph. Gr 6mg Zinc (Zincoxide) BP 15mg Copper (Coper oxide) 2mg

১৪. Calcium (Coral Calcium) 600 mg + Vitamin D_3 400 IU Tablet

১৫. Dried Ferrous Sulphate BP 150 mg + Folic Acid BP 500 mcg + Zinc sulphate monohydrate USP 61.8mg 22.5 mg TR Capsule

16. Super Anti-oxidant Vitamin Plus Multimineral Tablet & Soft Gelatin Capsule

Vitamin A (as Beta Carotene) BP 2000IU Vitamin C (Ascorbic Acid) BP 200 mg Vitamin E (Vitamin E Acetate) BP 50IU Vitamin K BP 75 mcg Zinc (Oxide) BP 15mg Selenium (Sodium Selenate) USP 70mcg Copper (Cupric Oxide) Ph. Gr.1mg

17. Alneed Plus Capsule TR Pellets

Ferrous Sulphate (dried) TR Pellets BP 150mg, Folic Acid BP 0.5mg, Thiamine Mononitrate USP 2mg, Riboflavin USP 2mg, Pyridoxine HCl BP 1mg, Nicotinamide BP 10mg, Ascorbic Acid USP 50mg and Zinc Sulphate Monohydrate BP 61.80mg (Eq. to. Zinc 22.5mg)

18.Vitamin-E Ascorbic Acid, Lutein Zinc, Copper Capsule

Vitamin E (as 50% diluted dry Vit. E Acetate) BP 30mg, Ascorbic Acid BP 60mg Lutein (As 5% diluted Letein) Ph. Gr 6mg Zinc (Zincoxide) BP 15mg Copper (Coper oxide) 2mg

19.Super Anti-oxidant Vitamin Plus Multimineral Tablet & Soft Gelatin Capsule

Vitamin A (as Beta Carotene) BP 2000IU Vitamin C (Ascorbic Acid) BP 200 mg Vitamin E (Vitamin E Acetate) BP 50IU Vitamin K BP 75 mcg Zinc (Oxide) BP 15mg Selenium (Sodium Selenate) USP 70mcg Copper (Cupric Oxide) Ph. Gr.1mg Manganese Sulphate) BP 3mg Soft Gelatin Capsule

20.Super Anti-oxidant Vitamin Plus Multimineral Tablet & Soft Gelatin Capsule

Vitamin A (as Beta Carotene) BP 2000IU Vitamin C (Ascorbic Acid) BP 200 mg Vitamin E (Vitamin E Acetate) BP 50IU Vitamin K BP 75 mcg Zinc (Oxide) BP 15mg Selenium (Sodium Selenate) USP 70mcg Copper (Cupric Oxide) Ph. Gr.1mg Manganese Sulphate) BP 3mgTablet

21.Vitamin C & E Soft Gelatin Capsule

Ascorbic Acid (Vit-C) BP 250mg Dl-alfa tocopheryl acetate (Vit-E) BP 200mg
22.Betacarotene (oily dispersion 30%) BP/USP 20mg (eqv. to 6 mg) + Ascorbic acid BP/USP 200 mg + Vitamin E BP/USP 50 mg Soft Gelatin Capsule

23.Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg +Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B_1 1.5 mg + Vitamin D 10 mcg +Vitamin E 15 IU + Zinc Sulphate 41.16 mg Soft Gelatin Capsule

24. Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 162 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6 mcg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 109 mg +Potassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin

A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B_1 1.5 mg + Vitamin D3 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Tablet

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্তঃ উপরোক্ত ২৪ (চব্বিশ) টি পদ পোস্ট অ্যাপ্রুভাল করা হয়।

(খ) নিম্নোক্ত পদসমুহ ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটি কর্তৃক বহাল রাখার সুপারিশ করা হয় ঃ

1. **Water-Soluble Vitamins (Vitamin B1 2.5mg + Vitamin B2 3.6mg + Nicotinamide 40mg + Vitamin B6 4mg + Pantothenic Acid 15mg+ Ascorbic Acid 100mg + Biotin 60µg +Folic Acid 0.4mg + Cyanocobalamin 5µg)/Vial Lyophilized Dry Powder for Injection (ডিসিসি-২৪০)**

   Thiamine Nitrate (Vitamin B1) BP 3.10mg eq. to 2.5mg Thiamine + Riboflavin Sodium Phosphate (Vitamin B2) BP 4.90mg eq. to 3.6mg Riboflavin+ Nicotinamide BP 40mg+ Pyridoxine Hydrochloride (Vitamin B6) BP 4.90mg eq. to 4mg Pyridoxine + Pantothenic Acid (as Dexpanthenol) BP 15mg + Sodium Ascorbate BP 113.00mg eq. to 100mg Ascorbic Acid + Biotin BP 0.06mg + Folic Acid BP 0.4mg + Cyanocobalamin (Vitamin B12) BP 0.005mg/Vial

2. **Calcium + Vitamin D3 + Multimineral Chewable Tablet (**ডিসিসি-২৩০)

   Vitamin D3 (as Dry Vit D3, Colecatciferol 850000IU/g) USP 200IU, Calcium (as Dibasic Calcium Phosphate Anhydrous & Calcium Carbonate Heavy) USP 600mg Copper (as Cupric Oxide Pharma Grade 1mg Magnesium (as Magnesium Oxide Heavy) USP 40mg Manganese (as Manganese Sulphate) USP 1.8mg Zinc (as Zinc Oxide) USP 7mg Boron (as Sodium Borate) USP 250mcg

3. **Calcium + Vitamin D and Mineral Tablet (**ডিসিসি-২৩০)

   Calcium Carbonate USP 1500mg (eq. to elemental calcium 600mg) Cholecalciferol **(Vit-D3) USP 5mcg** Magnesium Hydroxide USP 95.98mg (eq. to elemental Magnesium 40mg) Zinc Sulphate Monohydrate USP **20.584mg (eq. to elemental Zinc 7.5mg)** Manganese Sulphate Monohydrate USP 5.538mg (eq. to elemental manganese 1.8mg) Boron Citrate Ph. Gr. 4.623 mg (eq. to elemental Boron 0.25mg) Copper Sulphate anhydrous USP 2.512mg (eq. to elemental copper 1mg)

4. **Vitamin-E Ascorbic Acid, Lutein Zinc, Copper Capsule (ডিসিসি-২২৬)**
   Vitamin E (as 50% diluted dry Vit. E Acetate) BP 30mg, Ascorbic Acid BP 60mg Letein (As 5% diluted Letein) Ph. Gr 6mg Zinc (Zincoxide) BP 15mg Copper (Coper oxide) 2mg.

5. **Vitamin B-Complex Plus Zinc Syrup**

Thiamine HCl BP 0.10 gm
Riboflavin 5 Phosphate Sodium 0.0548 gm (eq. to Riboflavin 0.04 g)
Pyridoxine HCl BP 0.040 gm
Nicotinamide BP 0.400 gm
Zinc Sulphate (as monohydrate) 0.548 gm (eq. to Elemental Zinc 0.2gm)/100 ml

6. **Iron Polymaltose Complex + Vitamin B Complex + Zinc Syrup**

Iron (III) Hydroxide Polymaltose Complex INN 4gm (eq. to. Elemental Iron 1gm)
Thiamine HCl BP 0.10gm
Riboflavin 5 Phosphate Sodium BP 0.0548 gm (eq. to. Riboflavin 0.04gm)
Pyridoxine HCl BP 0.04gm
Nicotinamide BP 0.40gm
Zinc Sulphate BP 0.549gm (eq. to elemental zinc 0.2gm)/100ml

7. **Calcium 600 mg + Cholecalciferol 400 IU Tablet** (**ডিসিসি -২৪১)**

Calcium Carbonate USP 1500 mg eq. to Elemental Calcium 600 mg + Vitamin D3 USP 4 mg eq. to 400 IU Cholecalciferol

8. Carbonyl Iron 50mg, Folic Acid 0.5mg & Zinc Sulphate 61.8mg Pellets Capsule Multicolored Pellets 395mg (Active : Carbonyl Iron INN 50mg, Folic Acid BP 0.5mg, Zinc Sulphate Monohydrate BP 61.80mg) (**ডিসিসি -২২৬)**
9. Carbonyl Iron and Folic Acid TR Capsule
   Carbonyl Iron Ph. Gr. 51mg (eq. to 50mg elemental iron) + Folic Acid USP 0.50mg + Zinc Sulphate Monohydrate USP 61.8 mg (**ডিসিসি -২২৬)**

10.Alneed Plus Capsule TR Pellets

Ferrous Sulphate (dried) TR Pellets BP 150mg, Folic Acid BP 0.5mg, Thiamine Mononitrate USP 2mg, Riboflavin USP 2mg, Pyridoxine HCl BP 1mg, Nicotinamide BP 10mg, Ascorbic Acid USP 50mg and Zinc Sulphate Monohydrate 61.80mg (Eq. to. Zinc 22.5mg) (**ডিসিসি -২২৮)**

11. Iron(III) Hydroxide Polymaltose complex, Folic Acid, Thiamine HCl, Riboflavin, Pyridoxine HCl, Nicotinamide & Zinc Sulphate Blended Pellets Capsule

Elemental Iron 47mg (as Iron (III) Hydroxide Polymaltose Complex), Folic Acid 0.5mg, Thiamine 5mg, Riboflavin 2mg, Pyridoxine HCl 2mg, Nicotinamide 20mg & Zinc Sulphate Monohydrate 61.80mg (**ডিসিসি -২৩০)**

12. Ferrous Fumarate 200 mg + Folic Acid 400 mcg Capsule
13. Ferrous Fumarate 200 mg + Folic Acid 400 mcg Tablet (**ডিসিসি -২৩৮)**
14. Calcium 600 mg + Cholecalciferol 400 IU Tablet (**ডিসিসি -২৪১)**

Calcium Carbonate USP 1500 mg eq. to Elemental Calcium 600 mg + Vitamin D3 USP 4 mg eq. to 400 IU Cholecalciferol

15. **Calcium + Vitamin D Tablet** (**ডিসিসি -২৩০)**

Calcium Carbonate USP 1250mg (eq. to 500mg calcium) and Cholecalciferol (Vit-D3) USP 200IU

16. Potassium Citrate 1.5gm+Citric acid monohydrate 250 mg/5ml Oral Solution (**ডিসিসি -২৩৮)**

Potassium Citrate USP 30.00gm + Citric acid monohydrate USP 5gm/100ml

17. **Cavic-C Plus Tablet** (**ডিসিসি -২২৮)**

Calcium Carbonate USP 327mg Calcium Gluconate USP 578mg Calcium Lactate USP 422mg (as calcium Lactogluconate 1gm) Ascorbic Acid (Vit C) USP 500mg Colecolciferol (Vit-D) BP 400IU

18. **Water Soluble and Fat-Soluble Vitamins (Alpha Tocopherol (Vitamin-E) 11.20IU + Ascorbic Acid 125mg + Biotin 69µg + Colecalciferol (Vitamin D3) 220IU + Cyanocobalamin (Vitamin B12) 6µg + Folic Acid 414µg + Nicotinamide 46mg + Pantothenic Acid 17.25mg + Pyridoxine Hydrochloride 5.50mg + Retinol (Vitamin A) 3500IU + Riboflavin (Vitamin B2) 4.14mg + Thiamine (Vitamin B1) 3.51mg Lyophilized dry Powder for Injection in Vial**

Di Alpha Tocopherol (Vitamin-E) BP 11.20IU + Ascorbic Acid BP 125mg + Biotin BP 69µg
+ Colecalciferol (Vitamin D3) BP 220IU + Cyanocobalamin (Vitamin B12) BP 6µg + Folic Acid BP 414µg + Nicotinamide (Vitamin B3) BP 46mg + Pantothenic Acid (as Dexpanthenol) BP 17.25mg + Pyridoxine Hydrochloride BP 5.50mg eq. to 4.53 Pyridoxine + Retinol (Vitamin A) BP 3500IU (**ডিসিসি -২৪০)**

19. **Vitamin + Multimeniral Syrup**

Vitamin A (as Beta Carotene) BP 8500 IU
Vitamin A (as Retinol Palmitate) BP 8500 IU
Vitamin C (as Ascorbic Acid) BP 1350 mg
Vitamin D3 (as Cholecalciferol) BP 2750 IU
Vitamin E (as d-Alpha-tocopherol Acetate) BP 200 IU
Vitamin B1 (as Thiamine HCl BP 20 mg
Riboflavin Sodium 5-Phosphate) 20 mg
Vitamin B12 (Cyanocobalamin) BP 0.06 mg
Biotin BP 0.65 mg
Pantothenic Acid (d-pantothenol) BP 70 mg
Calcium (as Calcium Lactate) BP 550 mg

Iodine (as Potassium Iodide) BP 0.50 mg
Magnesium (as Magnesium Lactate) Ph. Gr. 150 mg
Zinc (as Zinc Gluconate) USP 50 mg
Selenium (as Selenomethionine) USP 0.35 mg
Manganese (as Manganese Gluconate) USP 15 mg
Chromium (as Chromium Polynicotinate) Ph. Gr. 0.07 mg
Potassium (as Potassium Citrate) USP 140 mg
PABA (Para-Amino-Benzoic Acid) Ph. Gr. 10 mg
Inositol Ph. Gr. 200 mg
Choline Bitartrate USP 200 mg (**ডিসিসি -২৩৩)**

20. **Multivitamin Syrup**

Vitamin A BP 40,000IU
(as Vit. A Propionate)
Vitamin D (as Colecalciferol)
BP 4000IU
Vitamin C (Ascorbic Acid) BP 0.35 gm
Vitamin B1 (Thiamine HCl) BP 0.014 gm
Vitamin B2 (Riboflavin Sodium Phosphate) BP 0.017 gm
Vitamin B6 (Pyridoxine HCl) BP 0.007 gm
Vitamin E (as Alpha Tocopherol) BP 0.030gm
Nicotinamide BP 0.18gm
Cod Liver Oil BP 2gm/100ml (**ডিসিসি -২৩৩)**

21. **Multivitamin & Multimeniral Chewable Tablet for Children** (**ডিসিসি -২৩৮)**

Vitamin A (As 20% Beta-Carotene) USP 3.040 mg eqv. to Vitamin A 1015 IU, Vitamin A (As Dry Vitamin A Acetate,Type500-50) USP 5.7155 mg eqv. to Vitamin A 2485 IU, Vitamin C (As Ascorbic Acid 97% DC) USP 61.8560 mg eqv. to Vitamin C 60 mg, Vitamin D(As Dry Vitamin D3, Colecalciferol 100000 IU/g) USP 4.0 mg eqv. to Vitamin D 400 IU, Vitamin E(As Dry Vitamin E Acetate 50%) USP 60.0 mg eqv. to Vitamin E 30 IU, Vitamin K(As Dry Vitamin K 1 5%) USP 0.20 mg eqv. to Vitamin K 10 mcg, Vitamin B1(As Thiamine Mononitrate) USP 1.50 mg , Vitamin B2(Riboflavin) USP 1.70 mg, Vitamin B6(Pyridoxine HCl) USP 2.0 mg, Vitamin B12 (As Cyanocobalamin 0.1%) USP 6.0 mg eqv. to Vitamin B12 6 mcg, Folic Acid USP 0.40 mg, Niacin USP 20.00 mg, Biotin USP 0.0450 mg, Pantothenic Acid(As Calcium Pantothenate) USP 10.8690 mg eqv. to

Pantothenic Acid 10 mg,Calcium & Phosphorous(As Dibasic Calcium Phosphate Anhydrous) USP 219.5850 mg eqv. to Calcium 64.69 mg & Phosphorous 50 mg), Calcium (As Calcium Carbonate USP 107.2750 mg eqv. to Calcium 43.31 mg, Copper (As Cupric Oxide) PH. Grade 2.5034 mg eqv.to Copper 2 mg, Chromium(As Chromic Chloride) USP 0.1025 mg Chromium 20 mcg, Iron(As Dried Ferrous Sulphate) BP 56.9340 mg eqv. to Iron 18 mg , Iodine(As Potassium Iodide) USP 0.1962 mg eqv. to Iodine 150 mcg, Magnesium(As Magnesium Oxide) USP 73.6920 mg eqv. to Magnasium 40 mg, Manganese(As Manganese Sulphate) USP 3.0761 mg eqv. to Manganese 1 mg, Molybdenum(As Sodium Molybdate Dihydrate) 0.0504 mg eqv. to Molybdenum 20 mcg, Zinc(As Zinc Oxide) USP 18.6705 mg eqv. to Zinc 15 mg Chewable Tablet

22. **Vitamin 2500 IU + Vitamin C 120 mg+ Vitamin D 800 IU+ Vitamin E 30 IU+ Vitamin K 25 mcg+ Thiamin (B1) 2.3 mg+ Riboflavin (B2) 2.6 mg+ Niacin 30 mg+ Vitamin B6 3 mg+Folic Acid 400 mcg+ Vitamin B_{12} 9 mcg+ Biotin 300 mcg+ Pantothenic Acid 10 mg+ Calcium 300 mg+ Iron 18 mg+ Magnesium 50 mg+ Zinc 15 mg+ Selenium 20 mcg+ Copper 2 mg+ Manganese 2 mg + Chromium 120 mcg Tablet** (**ডিসিসি -২৪১)**

Vitamin A (As Beta-Carotene 20%) USP 7.50 mg eq. to Vitamine A 2500IU+ Vitamin C(As
Ascorbic Acid) USP 123.711mg eq. to Vitamin C 120mg+ Vitamin D (As Dry vitamin D3 Colecalciferol 1,00,000IU/g) USP 8.000mg eq.to vitamin D 800 IU+ Vitamin E (As Dry vitamin E Acetate 50%) USP 60.00 mg eq. to vitamin E 30 IU+ Vitamin K (As Dry vitamin K1 5%) USP 0.500 mg eq. to vitamin K 25 mcg +Thiamine Mononitrate USP 2.300mg (Vitamin B1)+Riboflavin USP 2.60 mg (Vitamin B2) + Niacin USP 30.00 mg + Pyridoxine Hydrochloride USP 3.00mg (Vitamin B6)+Folic Acid USP0.400mg+ Cyanocobalamin (As Cyanocobalamin 0.1%) USP 9.00 mg eq.to Vitamin B12 9 mcg+Biotin USP 0.300mg+ Calcium Pantothenate USP 10.869 mg eq .to Pantothenic Acid 10 mg +Calcium Carbonate BP 750.00 mg eq.to Calcium 300 mg + Dried ferrous Sulphate USP 56.934mg eq. to Iron 18 mg+ Magnesium Oxide USP 92.115 mg eq. to Magnesium 50mg + Zinc Oxide USP 18.6705 mg eq .to Zinc15mg + Sodium Selenate Anhydrous USP 0.0478 mg eq .to Selenium 20 mcg+ Cupric Oxide Ph. Grade 2.5034 mg eq .to Copper 2 mg+ Manganese Sulfate USP 6.1522 mg eq. to Manganese 2 mg+ Chromic Chloride USP 0.6147mg eq.to Chromium 120 mcg.

23. **B-Complex + Folic Acid + Vit-C Capsule** (**ডিসিসি -২৩১)**

Thiamine Mononitrate USP 50 mg + Riboflavin USP 25 mg + Pyridoxine HCL USP 10 mg + Cyanocobalamin 1% USP 0.05 mg (eq. to 0.005mg of cyanocobalamin) Nicotinamide USP 100 mg + Calcium D-Pantothenate USP 25 mg + Folic Acid USP 0.555 mg (eq. to 0.5 mg of Folic Acid) Ascorbic Acid USP 178.57 mg (eq. to 175 mg of Ascorbic Acid)

24. **Vitamin B-Complex Plus Zinc Syrup** (**ডিসিসি -২৩১)**

Thiamine HCl BP 0.10 gm
Riboflavin 5 Phosphate Sodium 0.0548 gm (eq. to Riboflavin 0.04 g)
Pyridoxine HCl BP 0.040 gm
Nicotinamide BP 0.400 gm
Zinc Sulphate (as monohydrate) 0.548 gm (eq. to Elemental Zinc 0.2gm)/100 ml

25. **Adult Multivitamin and Multimineral A-Z Tablet (Without beta-carotene)** (ডিসিসি -২৩৩)

Vitamin C (As ascorbic Acid 97% DC grade) USP 60 mg,
Vitamin D (As Colicalciferol 850000 IU/g) USP 400 IU,
Vitamin E (As Vitamin E Acetate 50%) USP 30 IU,
Vitamin K USP (As Dry Vitamin K_1 5%) 25 mcg ,
Vitamin B_1 (As Thiamine Monoitrate) USP 1.50 mg ,
Vitamin B_2 (As Riboflavin) USP 1.70 mg,
Niacin USP 20mg,
Vitamin B_6 (As Pyridoxine Hydrochloride) USP 2mg,
Folic Acid USP 400 mcg ,
Vitamin B_{12} (As Cyanocobalamin 0.1%) USP 6 mcg,
Biotin (As D-Biotin) BP 30 mcg,
Pantothenic acid USP (As Calcium Pantothenate) 10 mg,
Calcium Carbonate(Heavy) USP 52.490 mg eq. 20.975 mg Calcium,
Dibasic Calcium Phosphate Anhydrous USP 478.695 mg eq. to 141.025 mg
Calcium & 109 mg Phosphorous,
Iron BP (Dried Ferrous Sulphate) 18 mg,
Iodine USP (As Potassium Iodide) 150 mcg,
Magnesium USP(As Magnesium Oxide)100 mg ,
Zinc (As Zinc Oxide) USP 15 mg,
Selenium Ph. grade (As Sodium Selenate Anhydrous) 20 mcg,
Copper Ph. grade (As Cupric Oxide) 2 mg,
Manganese USP(As manganese Sulphate Monohydrate)2 mg,
Chromium USP 120 mcg (As Chromic Chloride Hexahydrate),
Molybdenum BP(As Sodium Molybdate Dihydtate)75 mcg,
Potassium Chloride USP 152.52 mg eq. to 80 mg Potassium & 72 mg Chloride,
Boron Ph .grade (As Boron Citrate Blend 5%)150 mcg,
Nickel Ph. grade (As Nickel Sulphate) 5 mcg,
Silicon Ph. grade (As Sodium Metasilicate Nonahydrate) 2 mg,
Tin BP (As Stannous Chloride) 10 mcg,
Vanadium Ph. grade (As Sodium Metavandate Tetrahydrate) 10 mcg,

Lutein(As Lutein 5%) USP 250 mcg.

26. **Vitamin-E Ascorbic Acid, Lutein Zinc, Copper Capsule** (**ডিসিসি -২২৬)**

ঠরঃধসরহ ঊ (ধ্ং ৫০% ফরষঁঃবফ ফুৎ ঠরঃ. ঊ অপ বঃধপ্ল) ইচ ৩০সম , অংপড়ৎনরপঅপরফইচ ৬০সম খবঃবরহ(অং ৫% ফরঁঙ্কবফ খবঃবরহ)চয. এৎ ৬স ম
তরহপ(তরহপড়ীরফব)ইচ ১৫সম
Copper (Coper oxide) 2mg

27. **Multivitamin & Multimineral Tablet For Pregnant Woman** (**ডিসিসি -২৩৮)**

Vitamin B_1 (Thiamine nitrate BP) 500 mcg, Vitamin B2 (Riboflavin BP) 750 mcg, Nicotinamide BP 7.5 mg, Vitamin B_6 (Pyridoxine Hydrochloride BP) 750 mcg, Vitamin B_{12} (Cyanocobalamin) BP 1.5 mcg, Folic Acid BP 250 mcg, Vitamin C (Ascorbic acid BP) 15 mg, Vitamin D (Cholecalciferol BP) 250 IU, Vitamin E (as dry Vitamin-E Acetate 50%) BP 5.2 IU, Betacarotene BP 3 mg, Calcium (as dibasic calcium phosphate anhydrous BP) 59 mg, Phosphorus (as dibasic calcium phosphate anhydrous BP) 45.6 mg, Magnesium (as magnesium oxide - heavy) BP 15 mg, Iron (as ferrous fumarate BP) 5mg, Zinc (as zinc sulphate monohydrate BP) 8 mg, Iodine* (as potassium iodide BP) 125 mcg. Tablet For Pregnant Woman

28. **Vitamin A (20% as beta-carotene) 2500 IU + Vitamin C 120 mg+ Vitamin D 400 IU+ Vitamin E 30 IU+ Vitamin K 25 mcg+ Thiamin (B1) 3.75 mg + Riboflavin (B2) 4.25 mg + Niacin 30 mg+ Vitamin B6 5 mg+ Folic Acid 400 mcg+ Vitamin B12 15 mcg+ Biotin 300 mcg+ Pantothenic Acid 10 mg+ Calcium 200 mg+ Iron 9 mg+ Magnesium 100 mg+ Zinc 15 mg+ Selenium 20 mcg+ Copper 2 mg+ Manganese 2 mg + Chromium 120 mcg Tablet** (**ডিসিসি -২৪১)**

Beta-Carotene 20% USP 1.4970mg eq. to Vitamin A 500IU + Dry Vitamin A Acetate Type 500-60 USP 4.00mg eq .to Vitamin A 2000 IU + Ascorbic Acid 97% DC USP 123.7110 mg (eq. to Vitamin C 120mg) + Dry Vitamin D3 Colecalciferol 1,00,000IU/g USP 4.00mg eq. to Vitamin D 400 IU + Dry Vitamin E Acetate 50% USP 60.00 mg eq. to Vitamin E 30 IU+ Vitamin K1 5% USP 0.500 mg eq. to Vitamin K 25 mcg +Thiamine Mononitrate USP 3.750 mg (Vitamin B1)+Riboflavin USP 4.250 mg +Niacin USP 30.00 mg + Pyridoxine Hydrochloride USP 5.00 mg (Vitamin B6)+Folic Acid USP 0.4000mg + Cyanocobalamin 0.1% USP 15.00 mg eq. to Vitamin B12 15 mcg + Biotin USP 0.300mg+ Calcium Pantothenate USP 10.8692 mg eq. to Pantothenic Acid 10 mg +Calcium Carbonate BP 499.4775 mg eq.to calcium 200.00 mg+ Dried Ferrous Sulphate BP 28.4650mg eq.to Iron 9.00 mg+ Magnesium Oxide USP 165.8100 mg eq.to Magnesium 100mg + Zinc Oxide USP 18.6720 mg eq.to Zinc15mg+ Sodium Selenate Anhydrous Ph.Grade 0.0478 mg eq.to Selenium 20 mcg + Cupric Oxide Ph.Grade 2.5036 mg eq.to Copper 2 mg+ Manganese Sulfate USP 6.1522 mg eq.to Manganese 2.00 mg+ Chromic Chloride USP 0.6149mg eq. to Chromium 120 mcg.

২৯. **Calcium Citrate 1200 mg + Calcitriol 0.250 mcg Tablet** (**ডিসিসি -২৪১)**

Calcium Citrate USP 1200 mg eqv. to elemental Calcium 252 mg + Calcitriol BP 0.250 mcg

30. **Vitamin B1 + Vitamin-B6 + Vitamin B12 Inj.** (ডিসিসি -২৩০)

Thiamine HCl BP 100mg
Pyridoxine HCl BP 100mg
Cyanocobalamin BP 1mg/3ml Ampoule

31. **Thiamine Mononitrate 100mg + Pyridoxine HCl 200mg + Cyanocobalamin 200mcg Tablet** (ডিসিসি -২৩০)

Thiamine Mononitrate USP 100mg + Pyridoxine HCl BP 200mg + Cyanocobalamin USP 200mcg

32. **Iron Polymaltose Complex + Vitamin B Complex + Zinc Syrup (ডিসিসি -২৩০)**

Iron (III) Hydroxide Polymaltose Complex INN 4gm (eq. to. Elemental Iron 1gm)
Thiamine HCl BP 0.10gm
Riboflavin 5 Phosphate Sodium BP 0.0548 gm (eq. to. Riboflavin 0.04gm)
Pyridoxine HCl BP 0.04gm
Nicotinamide BP 0.40gm
Zinc Sulphate BP 0.549gm (eq. to elemental zinc 0.2gm)/100ml

৩৩. **L-lysine 50mg + Vitamin A 1500 IU + Vitamin D3 100 IU + Vitamin E 10 IU + Vitamin B1 0.25mg + Vitamin B2 0.25mg + Vitamin B6 0.25mg + Vitamin B12 2mcg + Vitamin C 50mg + Nicotinamide 2.5mg + Folic Acid 0.25mg Tablet** (ডিসিসি -২৪১)

L-lysine USP 50mg + Vitamin A BP 1500 IU + Vitamin D3-BP 100 IU + Vitamin E BP10 IU + Vitamin B1 BP 0.25mg + Vitamin B2 BP 0.25mg + Vitamin B6-BP 0.25mg + Vitamin B12 BP 2mcg + Vitamin C BP 50mg + Nicotinamide BP 2.5mg + Folic Acid BP 0.25mg

34. **Zinc + Vitamin B-Complex Tablet** (ডিসিসি -২৩৩)

Zinc Sulphate Monohydrate USP 27.45 mg (eq. to 10 mg Elemental Zinc)
Thiamine HCl BP 5 mg
Riboflavin 5-Phosphate BP 2.75 mg
Pyridoxine HCl BP 2 mg
Nicotinamide BP 20 mg

35. **Iron + Zinc + Vitamin A + Folic Acid + Vitamin C/Sachet** (ডিসিসি -২৩২)

Iron (as Fumarate) BP 12.50 mg
Zinc (as Gluconate) USP 5 mg
Vitamin A (as Acetate) USP 0.300 mg
Folic Acid USP 0.160 mg
Vitamin C (as Ascorbic Acid) USP 30mg/Sachet

36. **Multiple Micronutrient Powder in 1gm Per sachet** (**ডিসিসি -২৩৮)**

Vitamin A (as Acetate) USP 0.40 mg
Vitamin C (as L-Ascorbic Acid) USP 30.00mg
Vitamin D (as Cholecalciferol) USP 0.005 mg
Vitamin E (as Dl-alpha Tocopherol) USP 5.00 mg
Vitamin B1 (Thiamin Mononitrate) USP 0.50 mg
Riboflavin (as Phosphate ester mono sodium salt) USP 0.50 mg
Niacin (as Niacinamide) USP 6.00 mg
Pyridoxine (as Hydrochloride) USP 0.50 mg
Vitamin B12 (Cyanocobalamin) USP 0.0009 mg
Folic Acid USP 0.150 mg
Iron (as Ferrous Fumarate) USP 10.00 mg
Zinc)as Zinc Gluconate) USP 4.10 mg
Copper (as Cupric Gluconate) USP 0.56 mg
Selenium (as Sodium Selenite) USP 0.017 mg
Iodine (as Potassium Iodide) USP 0.09 mg

37. Betacarotene 6 mg + Vitamin C 200 mg + Vitamin E 50 mg Tablet (DCC-209)
38. Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg +Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B_1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Capsule **(ডিসিসি-১৯৩)**
39. Multivitamin and Multimineral A-Z Tablet & Soft Gelatin Capsule (**ডিসিসি -২২৮)**

Vitamin A (as Beta Carotene & Vitamin A Palmitate) BP 5000 IU Vitamin C (Ascorbic Acid) BP 60mg Vitamin D3 BP 400 IU Vitamin E (as E Acetate) BP 30 IU Vitamin K BP 25 mcg Thiamin (as Mononitrate) BP 1.5mg Riboflavin BP 1.7mg Niacin USP 20mg Vitamin B6 (Pyridoxine HCl) BP 2mg Folic Acid BP 400 mcg Vitamin B12 BP 6 mcg Biotin BP 30 mcg Pantothenic Acid (as Calcium Pantothenate) BP 10 mg Calcium (Calcium Carbonate) BP 162mg Iron (Ferrous Sulphate) BP 18 mg Phosphorous (Calcium Phosphate) BP 109 mg Iodine (Potassium Iodide) BP 150 mcg Magnesium (Magnesium Oxide) BP 100mg Zinc (oxide) 15mg Selenium (Sodium Selenate) BP 20mcg Copper (cupric oxide) BP 2.0mg Manganese (Sulphate) BP 2.0mg Chromium (Chloride) 120 mcg Molybdenum (Sodium Molybdate) BP 75mcg Chloride (Sodium Chloride) BP 72 mg Potassium (Chloride) BP 80 mg Boron (Boron Citrate) Ph. Gr. 150 mcg Nickel (Nickelous Sulphate) Ph. Gr. 5 mcg Silicon (Dioxide) BP 2 mg Tin (Stannous Fluoride) USP 10 mcg Vanadium (Sodium Metavandate) Ph. Gr. 10 mcg Lutein (Marigold Extract) Ph. Gr. 250mcg

40. Multivitamin and Multimineral A-Z Tablet for people over 45 years of age and Soft Gelatin Capsule (**ডিসিসি -২২৮)**

Vitamin A (as Beta Carotene & Vitamin A Palmitate) BP 5000 IU Vitamin C (Ascorbic Acid) BP 60mg Vitamin D BP 400 IU Vitamin E (as E Acetate) BP 45 IU Vitamin K BP 10 mcg Thiamin (as Mononitrate) BP 1.5mg Riboflavin BP 1.7mg Niacin USP 20mg Vitamin B6 (Pyridoxine HCl) BP 3mg Folic Acid BP 400 mcg Vitamin B12 BP 25 mcg Biotin BP 30 mcg Pantothenic Acid (as Calcium Pantothenate) BP 10 mg Calcium (Calcium Carbonate) BP 200 mg Phosphorous (Calcium Phosphate) BP 48 mg Iodine (Potassium Iodide) BP 150 mcg Magnesium (Magnesium Oxide) BP 100mg Zinc (oxide) 15mg Selenium (Sodium Selenate) BP 20mcg

Copper (Copper Lysinate) Ph. Gr. 2mg Manganese (Glycinate) Bp/Ph.Gr 2mg Chromium (Chloride) Ph. Gr. 150mcg Molybdenum (Sodium Molybdate) BP 75 mcg Chloride (Sodium Chloride) BP 72 mg Potassium (Chloride) BP 80 mg Boron (Boron Citrate) Ph. Gr. 150 mcg Nickel (Nickelous Sulphate) Ph. Gr. 5 mcg Silicon (Dioxide) BP 2 mg Vanadium (Sodium Metavandate) Ph. Gr. 10 mcg Lutein (Marigold extract) Ph. Gr. 250 mcg

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্তঃ উপরোক্ত ৪০ (চল্লিশ) টি পদ বহাল রাখা হয়।

(খ) নিম্নোক্ত পদসমূহ ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব কমিটি কর্তৃক বাতিলের সুপারিশ করা হয় ঃ

1. Ferrous Fumarate 200 mg + Folic Acid 350 mcg Capsule ।
2. Ferrous Fumarate 308 mg + Folic Acid 350 mcg Tablet ।
3. Ascorbic Acid 60 mg + Boron (As Sodium Borate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Gluconate) 1 mg + Magnesium (As Magnesium Oxide) 20 mg + Manganese (As Manganese Sulphate) 1 mg + Vitamin D3 (As Cholecalciferol) 200 IU + Vitamin E 15 IU + Zinc (As Zinc Oxide) 7.5 mg Tablet ।
4. Ferrous Fumarate 200 mg + Folic Acid 200 mcg Tablet ।
5. Alendronic Acid 10 mg + Vitamin D3 400 IU Tablet ।
6. Ascorbic Acid (As Ascorbic Acid) 25 mg + Ascorbic Acid (Sodium Ascorbate) 25 mg + Dexpanthanol 1.25 mg + Nicotinamide 5 mg + Pyridoxine Hydrochloride 0.35 mg + Riboflavin 0.4 mg + Vitamin D 140 IU + Vitamin A 666.67 IU + Vitamin B1 0.3 mg + Vitamin E 2 IU/5 ml Syrup ।
7. Calcium Pantothenate 5 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 4 mg + Vitamin B1 50 mg/2 ml Injection ।
8. Ascorbic Acid 100 mg + Nicotinamide 1 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2.85 mg + Vitamin A 5000 IU + Vitamin B1 1.67 mg + Vitamin D 666 IU/ml Paediatric Drops ।
9. Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg+ Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Capsule ।
10. Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg +Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg +Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg+ Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Capsule ।
11. Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg+ Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg +

Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Tablet ।

12. Cod Liver Oil 50 mg + Pantothenic acid 5 mg + Vitamin B1 1.6 mg + Vitamin B2 1 mg+ Vitamin B3 10 mg + Vitamin B6 1 mg + Vitamin C 50 mg/ml Paediatric Drops ।
13. Copper 0.56mg + Folic Acid 0.15 mg + Iodine 0.09 mg + Iron 10 mg + Niacin 6 mg+ Pyridoxine 0.5 mg + Riboflavin 0.5 mg + Selenium 0.017 mg + Vitamin A 0.4 mg + Vitamin B_1 0.5 mg + Vitamin B_{12} 0.0002 mg + Vitamin C 30 mg + Vitamin D 0.005 mg + Vitamin E 5 mg + Zinc mg Sachet ।
14. Pantothenic acid 500 mg + Pyridoxine Hydrochloride 100 mg + Riboflavin 100 mg +Vitamin A 5 Lac IU + Vitamin B1 160 mg +Vitamin C 5 gm + Vitamin D 1 gm/100 ml Paediatric Drops ।
15. Pyridoxine Hydrochloride 100 mg + Riboflavin 5 mg + Vitamin B1 100 mg Injection
16. Pyrimethamine 1 gm + Sodium Salicylate 5 gm + Sulphaquinoxaline 5 gm + Vitamin A 1 gm + Vitamin K 20 mg/100 ml Liquid ।
17. Vitamin C 200 mg + Vitamin E 50 mg Tablet ।
18. Vitamin C 250 mg + Vitamin E 200 mg Tablet ।

19. Folic Acid 2.5mg + Vitamin B6 25mg + Vitamin B12 2mg Tablet (**ডিসিসি -২৩০)**

Folic Acid USP 2.5mg, Vit B6 (as Pyridoxine HCl) USP 25mg & Vitamin B12 (as Cyanocobalamin 1.0%) USP 2mg

20. Iron Polymaltose complex + Folic Acid + Vitamin B12 Capsule (**ডিসিসি -২৩০)**

Iron (as Iron Polymaltose Complex INN) 100mg, Folic Acid USP 1mg & Vitamin B12 (as cyanocobalamin) USP 25 mcg

21. Iron Polymaltose complex + Folic Acid + Vitamin B12 Syrup (**ডিসিসি -২৩০)**

Iron (as Iron polymaltose Complex) INN 2gm, Folic Acid USP 20mg & Vitamin B12 (As Cyanocobalamin) USP 500mcg/100ml

22. Carbonyl Iron, Folic Acid, Thiamin Mononitrate,Riboflovin, Pyridoxine HCl,Nicotinamide & Ascorbic Acid Blended Pellets Capsule (**ডিসিসি -২২৮)**

Elemental Iron (as Carbonyl Iron) INN 50mg, Folic Acid USP 0.500mg, Thiamine Mononitrate USP 2mg, Riboflavin USP 2mg, Pyridoxine HCl USP 1mg, Nicotinamide USP 10mg & Ascorbic Acid USP 50mg

23. Elemental Iron 100 mg + Folic Acid 350 mcg + Vitamin C 50 mg + Zinc 22.5 mg Tablet (**ডিসিসি -২৩৮)**
24. Folic Acid 0.4 mg+ Iron (as ferrous fumerate) 60mg Tablet (**ডিসিসি -২৩৭)**

Folic Acid BP 0.4mg & Ferrous Fumarate Ph. Gr. 182.54 mg eq. to Elemental Iron 60 mg

25. Ferrous Fumarate 200 mg + Folic Acid 200 mcg Capsule (**ডিসিসি -১২৪)**
26. Ferrous Fumarate 200 mg + Folic Acid 200 mcg Tablet (**ডিসিসি -১২৪)**

27. Calcium 500 + Vitamin D 400 IU Tablet (**ডিসিসি -২৩৯)**

Calcium Carbonate USP 1250 mg (eq. to 500 mg Elemental Calcium) + Cholecalciferol USP 4 mg (eq. to Vitamin D 400 IU)

28. Elemental Calcium 225.0mg + Vitamin D3 800IU Tablet (**ডিসিসি -২৪৪)**

Calcium Carbonate (from Coral Grains) IP 562.50mg eq. to Elemental Calcium 225 mg + Vitamin D3 IP 800 IU

29. Vitamin B-Complex + Vitamin C (**ডিসিসি -২৩০)**

Thiamine monohydrate USP 10mg Riboflavin USP 10mg Pyridoxine HCl USP 3mg Cyanocobalamin 1% USP 0.05mg (eq. to 0.005mg of Cyanocobalamin) Nicotinamide USP 50mg Calcium Pantothenate USP 12.50mg Folic Acid USP 1.11mg eq. to. 1 mg of Folic Acid Ascorbic Acid USP 153.0mg (eq. to 150mg of Ascorbic Acid) Capsule

30. Potassium Bicarbonate 200 mg + Potassium Chloride 448 mg Tablet (**ডিসিসি -২৩৮)**
31. Multivitamin Syrup (**ডিসিসি -২৩৩)**

Vitamin A 13332 IU Vitamin D 2800 IU Vitamin E Acetate 40 IU Ascorbic Acid 250mg Sodium Ascorbate 280mg Thiamine Hydrochloride 6mg Riboflavin 8mg Nicotinamide 100mg Pyridoxine Hydrochloride 7mg Dexpanthenol 24.906mg/100ml

32. Ferrous Sulfate TR, Folic Acid Vit. B Complex & Ascorbic Acid Capsule (**ডিসিসি -২২৪)**

Ferrous Sulphate (dried) TR Pellets BP 1 50mg Folic Acid BP 0.50mg Thiamine Mononitrate USP 2mg Riboflavin USP 2mg Pyridoxine HCl BP 1mg Nicotinamide USP 10mg Ascorbic Acid USP 50mg

33. Carbonyl Iron, Folic Acid, Thiamin Mononitrate, Riboflovin, Pyridoxine HCl,Nicotinamide & Ascorbic Acid Blended Pellets Capsule

Elemental Iron (as Carbonyl Iron) INN 50mg, Folic Acid USP 0.500mg, Thiamine Mononitrate USP 2mg, Riboflavin USP 2mg, Pyridoxine HCl USP 1mg, Nicotinamide USP 10mg & Ascorbic Acid USP 50mg (**ডিসিসি -২২৮)**

34. Ascorbic Acid 75 mg + Calcium Pantothenate 5 mg + Cyanocobalamin 2 mcg +
Nicotinamide 13 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 10 mg + Vitamin A 5000 IU + Vitamin B_1 1.5 mg + Vitamin D 400 IU + Vitamin E 5 IU Capsule (**ডিসিসি -১৯৩)**
35. Ascorbic Acid 75 mg + Calcium Pantothenate 5 mg + Cyanocobalamin 2 mcg +Nicotinamide 13 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 10 mg + Vitamin A 5000 IU + Vitamin B_1 1.5 mg + Vitamin D 400 IU + Vitamin E 5 IU Tablet (**ডিসিসি -১৯৩)**
36. Carbonyl Iron, Folic Acid, Vitamin B Comples, Ascorbic Acid and Zinc Sulphate Blended Pellets Capsule (**ডিসিসি -২২৯)**

Elemental Iron INN (as Carbonyl Iron) 50mg, Folic Acid USP 0.5gm Thiamine Monohydrate USP 2.20mg Riboflavin USP 2.20mg Pyridoxine HCl USP 1mg Nicotinamide USP 10mg Ascorbic Acid USP 50mg and Zinc Sulphate Monohydrate USP 61.80mg

37. Calcium 250mg + Vitamin D3 250 IU Gummy Tablet (**ডিসিসি -২৪৪)**

Calcium Phosphate BP 715mg eq. to Elemental Calcium 250mg + Dry Vitamin D3 100 In house 2.5mg eq. to Colecalciferol 250 IU

38. Calcium Phosphate 500mg + Vitamin D3 500 IU Gummy Tablet (**ডিসিসি -২৪৪)**

Calcium Phosphate BP 1430.00 mg eq. to Elemental Calcium 500mg + Dry Vitamin D3 100 In house 5mg eq. to Colecalciferol 500 IU

39. Sodium Ascorbate BP 225mg eq. to 200mg of Vit C Dry Vitamin E Acetate (50%) BP 400mg eq. to 200rng of Vitamin E (**ডিসিসি -২১৬)**

ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্তঃ উপরোক্ত ৩৯ (উনচল্লিশ) টি পদ বাতিল করা হয়।

১. **<u>রেনিটিডিন সংক্রান্ত বিষয়াদিঃ</u>**

TGA, Australia গত ২৮.০১.২০২০ তারিখে তাদের দেশের সকল প্রকার Ranitidine ঔষধের রেজিস্ট্রেশন সাময়িক বাতিল করেছে। USFDA গত ০১.০৪.২০২০ তারিখে প্রেস রিলিজের মাধ্যমে সকল ঔষধ উৎপাদনকারী প্রতিষ্ঠানকে বাজার হতে Ranitidine HCl প্রত্যাহার করার অনুরোধ করেছে। USFDA উল্লেখ করেছে যে, সময়ের সাথে সাথে Ranitidine HCl এ NDMA Impurities পরিমাণ বৃদ্ধি পায়। অধিক তাপমাত্রায় সংরক্ষণের ফলে Ranitidine HCl এ NDMA Impurity গ্রহণযোগ্য মাত্রার চেয়ে অধিক হয়। USFDA রোগীদের Ranitidine HCl ঔষধ ব্যবহার না করার জন্য পরামর্শ প্রদান করেছে। এ বিষয়ে ঔষধ প্রশাসন অধিদপ্তরের সাথে ঔষধ শিল্প সমিতির বিগত ০৩.০৯.২০২০ তারিখে একটি সভা অনুষ্ঠিত হয়। উক্ত সভায় দেশে Ranitidine উৎপাদন ও বাজারজাতকরণ বন্ধের সুপারিশ করা হয়।

ইতোপূর্বে Ranitidine HCl এ NDMA Impurity গ্রহণযোগ্য মাত্রার চেয়ে অধিক থাকায় অত্র অধিদপ্তর হতে স্মারক নং- ডিজিডিএ/২৯-০২/০৯/৮৫২৭, তারিখ: ১৩.১১.২০১৯ মোতাবেক Ranitidine HCl ঔষধের উৎপাদন, বিক্রয়, বিতরণ, রপ্তানী বন্ধ স্থগিত করে The Daily Star Newspaper-এ বিজ্ঞপ্তি প্রকাশ করা হয়।
Ranitidine HCl এ NDMA Impurity গ্রহণযোগ্য মাত্রার চেয়ে অধিক থাকায় অত্র অধিদপ্তর স্মারক নং-ডিজিডিএ/রেনিটিডিন রিকল/২০১৯/১০৭, তারিখ ১৪.১১.২০১৯ মোতবেক সকল প্রকার Ranitidine HCl ঔষধের উৎপাদন, বিক্রয়, বিতরণ, রপ্তানী বন্ধ করা হয় এবং ২০.১১.২০১৯ তারিখের মধ্যে সকল উৎপাদনকারী প্রতিষ্ঠানকে নিজস্ব চ্যানেলের মাধ্যমে বাজার থেকে প্রত্যাহার পূর্বক ঔষধ প্রশাসন অধিদপ্তরকে অধিদপ্তরকে অবহিত করার জন্য বলা হয়।

বর্তমান পরিস্থিতিতে Ranitidine HCL উৎপাদন ও বাজারজাতকরণের বিষয়ে সিদ্ধান্ত গ্রহণের জন্য বিষয়টি উপস্থাপন করা হল।

টেকনিক্যাল সাব কমিটির মতামত: Ranitidine HCl এর রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্তঃ Ranitidine HCl এর রেজিস্ট্রেশন বাতিল করা হয়।

২. **এন্টিবায়োটিকের মোড়ক সামগ্রী লাল রং করার বিষয়ে সিদ্ধান্ত গ্রহণঃ**

অ্যান্টিবায়োটিকের অপ্রয়োজনীয় ব্যবহার, ভুল ডোজ প্রয়োগ এবং সামগ্রিকভাবে দূর্বল সংক্রমণ-প্রতিরোধ ক্ষমতার ফলে মানবদেহে অ্যান্টিবায়োটিক রেজিস্ট্যান্ট এর সৃষ্টি হচ্ছে, যা মারাত্মক পরিস্থিতির সৃষ্টি করছে। অ্যান্টিবায়োটিকের যথাযথ ব্যবহার নিশ্চিত করার জন্য জনসচেতনতা সৃষ্টির বিকল্প নেই। এ লক্ষ্যে বিগত ১৬ এপ্রিল, ২০১৮ তারিখে অহঃরস রপাৎড়ঁারধষজবংরুঃধহপব (অগজ) বিষয়ে ঔষধ প্রশাসন অধিদপ্তরে অনুষ্ঠিত সভায় অ্যান্টিবায়োটিক ঔষধের মোড়ক সামগ্রী লাল রঙের করার সুপারিশ করা হল। পরবর্তীতে নভেম্বর, ২০২০ সালে ঈউ ঈ কর্তৃক অহঃরস রপাৎড়ঁারধষ জবংরুঃধহপব (অগজ) বিষয়ে অনুষ্ঠিত এক সভায় প্রফেসর সায়েদুর রহমান, ফার্মাকোলজি ডিপার্টমেন্ট, বিএসএমএমইউ জনসচেতনতা সৃষ্টির লক্ষ্যে অ্যান্টিবায়োটিক ঔষধের মোড়ক সামগ্রী লাল রঙের করার সুপারিশ

করেন এবং এ মর্মে বিজ্ঞাপন প্রচারের আহবান করেন যে, " ***লাল রঙের মোড়কের ঔষধ ডাক্তারের প্রেসক্রিপশন ছাড়া খাবেন না*** ।" তিনি বলেন এতে করে দেশে জনসাধারণের মধ্যে একটি ব্যাপক প্রচারণার সৃষ্টি হবে এবং জনসচেতনতা বৃদ্ধি পাবে। এ বিষয়ে সিদ্ধান্ত গ্রহণের জন্য বিষয়টি উপস্থাপন করা হল।

টেকনিক্যাল সাব কমিটির মতামত: এ বিষয়ে ঔষধ প্রশাসন অধিদপ্তর ঔষধ শিল্প সমিতির সাথে আলোচনাক্রমে সিদ্ধান্ত গ্রহণ করবে।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত: এ বিষয়ে ঔষধ প্রশাসন অধিদপ্তর ঔষধ শিল্প সমিতির সাথে আলোচনাক্রমে সিদ্ধান্ত গ্রহণ করবে।

৩. ড্রাগ কন্ট্রোল কমিটির সিদ্ধান্ত অনুযায়ী আমদানিকৃত ভেটেরিনারী ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে ২৪ টি দেশের মধ্যে যে কোন একটি দেশের ফ্রি-সেল সার্টিফিকেট গ্রহণ করা হয় তন্মধ্যে রাশিয়া অন্তর্ভূক্ত ছিল। কিন্তু জাতীয় ঔষধনীতি-২০১৬ তে ৪.৪ (গ) ২ নং অনুচ্ছেদে আমদানিকৃত ভেটেরিনারী ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে উল্লেখিত দেশসমূহের মধ্যে রাশিয়াকে বাদ দেওয়া হয়েছে। এতে করে একটি বিড়ম্বনার সৃষ্টি হচ্ছে বিধায় আমদানিকৃত ভেটেরিনারী ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে রাশিয়ার ফ্রি-সেল সার্টিফিকেটকে বিবেচনা করা হবে কিনা এতদ্ববিষয়ে সদয় সিদ্ধান্তের জন্য বিষয়টি উপস্থাপন করা হল। উল্লেখ্য রাশিয়া একটি ঙ ওউ (ড ড়ৎফ ঙ ৎমধহ্রধঃ রড়হ ভ্ড়ৎ অহরস ধষ ঐবধষ্ফয) ভূক্ত দেশ।

টেকনিক্যাল সাব কমিটির মতামত: আমদানিকৃত ভেটেরিনারী ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে রাশিয়ার ফ্রি-সেল সার্টিফিকেট বিবেচনা করার সুপারিশ করা হয়। জাতীয় ঔষধনীতি-২০১৬ তে ৪.৪ (গ) ২ নং অনুচ্ছেদে রাশিয়াকে অন্তর্ভূক্ত করার সুপারিশ করা হয়।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত: আমদানিকৃত ভেটেরিনারী ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে রাশিয়ার ফ্রি-সেল সার্টিফিকেট বিবেচনা করার সিদ্ধান্ত গৃহীত হয়। জাতীয় ঔষধনীতি-২০১৬ তে ৪.৪ (গ) ২ নং অনুচ্ছেদে রাশিয়াকে অন্তর্ভূক্ত করার সুপারিশ করা হয়।

৪. ড্রাগ কন্ট্রোল কমিটির ২৫১ তম সভার সিদ্ধান্ত মোতাবেক mosquito repellent জাতীয় পদের রেজিস্ট্রেশন ঔষধ প্রশাসন অধিদপ্তর হতে প্রদান করা হবে না। এক্ষেত্রে Pesticide Technical Advisory Committee (PTAC) হতে অ্যাপ্রুভাল নেওয়ার বিষয়ে সুপারিশ করা হয়।

ড্রাগ কন্ট্রোল কমিটির সভার সিদ্ধান্ত: ড্রাগ কন্ট্রোল কমিটির ২৫১ তম সভার সিদ্ধান্ত মোতাবেক mosquito repellent জাতীয় পদের রেজিস্ট্রেশন ঔষধ প্রশাসন অধিদপ্তর হতে প্রদান করা হবে না। এক্ষেত্রে Pesticide Technical Advisory Committee (PTAC) হতে অ্যাপ্রুভাল নেওয়ার বিষয়ে সিদ্ধান্ত গৃহীত হয়।