

**ঔষধ নিয়ন্ত্রণ কমিটির ০৯ সেপ্টেম্বর ২০২৫ তারিখে অনুষ্ঠিত ২৫৬ তম সভার কার্যবিবরণী**

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্বাস্থ্য সেবা বিভাগের সচিব জনাব মোঃ সাইদুর রহমান ঐর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৫৬ তম সভা বিগত ০৯ সেপ্টেম্বর ২০২৫ তারিখ সকাল ১০.০০ ঘটিকায় মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

**সভায় কমিটির নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জ্যেষ্ঠতার ক্রমানুসারে নয়) :**

- ১। মেজর জেনারেল মোঃ শামীম হায়দার, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর, মহাখালী, ঢাকা।
- ২। অধ্যাপক ডা. মোঃ শাহিনুল আলম, উপাচার্য, বাংলাদেশ মেডিকেল বিশ্ববিদ্যালয়, শাহবাগ, ঢাকা।
- ৩। জনাব মুহাম্মদ মোজাম্মেল হোসেন খান, যুগ্মসচিব ঔষধ প্রশাসন অনুবিভাগ, স্বাস্থ্য সেবা বিভাগ।
- ৪। ব্রিগেডিয়ার জেনারেল এস এম রাহিদ সারোয়ার, আর্মড ফোর্সেস মেডিকেল সার্ভিসেস, ঢাকা ক্যান্টনমেন্ট, ঢাকা।
- ৫। ডা. মোঃ শাহিনুর আলম, পরিচালক, প্রাণিসম্পদ অধিদপ্তর, ফার্মগেট, ঢাকা।
- ৬। অধ্যাপক ড. মোঃ আব্দুর রশিদ, প্রাক্তন ডিন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয় ও সহ-সভাপতি, বাংলাদেশ ফার্মাসিউটিক্যাল সোসাইটি, ঢাকা।
- ৭। ডা. ওয়াসিফ আলী খান, ইমেরিটাস বিজ্ঞানী, এন্টেরিক ও রেসপিরেটরি ইনফেকশিয়াস, ইনফেকশিয়াস ডিজিসেস ডিভিশন, আইসিডিডিআর'বি, মহাখালী, ঢাকা।
- ৮। অধ্যাপক ড. মো. সেলিম রেজা, ডিন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়, ঢাকা।
- ৯। অধ্যাপক ডা. ফারুক আহাম্মদ, বিভাগীয় প্রধান, মেডিসিন বিভাগ, ঢাকা মেডিকেল কলেজ, ঢাকা।
- ১০। অধ্যাপক ডা. মোঃ মোস্তাফিজুর রহমান বিভাগীয় প্রধান, শিশু বিভাগ, স্যার সলিমুল্লাহ মেডিকেল কলেজ, মিটফোর্ড, ঢাকা।
- ১১। অধ্যাপক ডা. রোজিনা হক, অধ্যাপক ও বিভাগীয় প্রধান, ফার্মাকোলজি বিভাগ, চট্টগ্রাম মা ও শিশু হাসপাতাল মেডিকেল কলেজ, চট্টগ্রাম, প্রতিনিধি, সভাপতি, বাংলাদেশ ফার্মাকোলজিক্যাল সোসাইটি।
- ১২। ডা. ইলোরা শারমীন, সহযোগী অধ্যাপক, চেয়ারপার্সন, ফার্মাকোলজি বিভাগ, বাংলাদেশ মেডিকেল বিশ্ববিদ্যালয়, ঢাকা।
- ১৩। অধ্যাপক ডা. জাকির হোসেন হাবীব, মুখ্য বৈজ্ঞানিক কর্মকর্তা, ভাইরোলজী বিভাগ, আইইউসিআর, মহাখালী, ঢাকা।
- ১৪। জনাব স্বপন কুমার মন্ডল, উপসচিব ও রেজিস্ট্রার (অতিরিক্ত দায়িত্ব), বাংলাদেশ হোমিওপ্যাথিক চিকিৎসা শিক্ষা কাউন্সিল, ঢাকা।
- ১৫। জনাব মুহাম্মদ মাহবুবুল হক, সচিব, বাংলাদেশ ফার্মেসী কাউন্সিল, ঢাকা।
- ১৬। হাকীম আ.খ. মাহবুবুর রহমান, ইউনানী বিশেষজ্ঞ, বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড, ঢাকা।
- ১৭। কবিরাজ শ্রী কৃষ্ণ কান্ত রায়, আয়ুর্বেদিক বিশেষজ্ঞ, বাংলাদেশ ইউনানী ও আয়ুর্বেদিক বোর্ড, ঢাকা।

**সভার আলোচ্য সূচী :**

- ক) স্থানীয়ভাবে উৎপাদনের জন্য ১৮১ টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

**সভার আলোচনাঃ**

সবাইকে স্বাগত জানিয়ে সভাপতি সভার কার্যক্রম শুরু করেন। অতঃপর তিনি কমিটির সদস্য সচিব ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক-কে সভার আলোচ্যসূচী মোতাবেক বিষয়বস্তু উপস্থাপনের জন্য অনুরোধ করেন।





**ক) স্থানীয়ভাবে উৎপাদনের জন্য ১৮১ টি হিউম্যান ওষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের বিষয়ে আলোচনা ও সুপারিশ:**

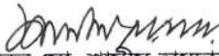
স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ওষধের রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ১৮১ টি ওষধ সভায় উপস্থাপন করা হলে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয়ঃ

ক। অনুমোদনের জন্য সুপারিশকৃত = ১১৬ টি  
খ। নামঞ্জুরের জন্য সুপারিশকৃত = ৬৫ টি;

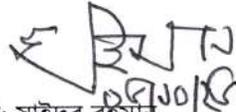
**ওষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত:** টেকনিক্যাল সাব কমিটির সুপারিশের বিষয়ে বিস্তারিত আলোচনার পর নিম্নলিখিত সুপারিশ করা হয়ঃ

অনুমোদন করা হয়	: ১০৭ টি
নামঞ্জুর করা হয়	: ৬০ টি
পরবর্তী ওষধ নিয়ন্ত্রণ কমিটির সভায় পুনর্মূল্যায়নের সিদ্ধান্ত গৃহীত হয়	: ০৩ টি
পরবর্তী টেকনিক্যাল সাব কমিটির সভায় পুনর্মূল্যায়নের সিদ্ধান্ত গৃহীত হয়	: ০৬ টি
পরবর্তী ওষধ নিয়ন্ত্রণ কমিটির সভায় চক্ষু বিশেষজ্ঞ এর মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়	: ০৩ টি
পরবর্তী ওষধ নিয়ন্ত্রণ কমিটির সভায় স্ত্রীরোগ বিশেষজ্ঞ এর মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়	: ০১ টি
পরবর্তী ওষধ নিয়ন্ত্রণ কমিটির সভায় চর্ম রোগ বিশেষজ্ঞ এর মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়	: ০১ টি; (Annex-A)

আর কোন আলোচ্য বিষয় না থাকায় সভায় উপস্থিত সবাইকে ধন্যবাদ জানিয়ে সভাপতি সভার সমাপ্তি ঘোষণা করেন।

  
মেজর জেনারেল মো: শামীম হায়দার  
মহাপরিচালক  
ওষধ প্রশাসন অধিদপ্তর  
ও  
সদস্য-সচিব, ওষধ নিয়ন্ত্রণ কমিটি

05 OCT 2025

  
মো: সাইদুর রহমান  
সচিব  
স্বাস্থ্য সেবা বিভাগ  
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়  
ও  
সভাপতি, ওষধ নিয়ন্ত্রণ কমিটি

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার্ভিস প্রদানকারী প্রতিষ্ঠান	ঔষধ নিয়ন্ত্রণ কমিশনের সিদ্ধান্ত
1.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Prinitespi 40.00mg Tablet	Prinitespi INN 40.00mg	Anticancer Therapeutic Code No: 0710	Prinitespi is indicated for the treatment of gastrointestinal stromal tumor that has progressed after cancer chemotherapy.	<b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Prinitespi or any other components of this product. <b>Precaution:</b> There is no data available. <b>Warning:</b> As per precaution. <b>Side effects:</b> The most common side effects are diarrhea, eye disorder, bone marrow toxicity, hepatic dysfunction, renal dysfunction, rash etc.	New	PMDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।
2.	EVEREST Pharmaceuticals Ltd, BSCIC I/A, Kanchipur, Narayanagri, BANGLADESH	Rosuvastatin 2.5mg Tablet	Rosuvastatin Calcium USP 2.505mg Eqv. to Rosuvastatin 2.5mg	Lipid Lowering Therapeutic Code: 061	Hypercholesterolemia & familial hypercholesterolemia	<b>Contraindications:</b> • Known hypersensitivity to product components • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels • Women who are pregnant or may become pregnant • Nursing mothers. <b>Side effects:</b> Most frequent adverse reactions (rate $\geq 2\%$ ) are headache, myalgia, abdominal pain, asthenia, and nausea <b>Warning and precautions:</b> Skeletal muscle effects (e.g., myopathy and rhabdomyolysis); Risks increase with use of 40 mg dose, advanced age ( $\geq 65$ ), hypothyroidism, renal impairment, and combination use with cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, or certain other lipid-lowering drugs. Advise patients to promptly report unexplained muscle pain, tenderness, or weakness and discontinue it if signs or symptoms appear • Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminases can occur. Monitor liver enzymes before and during treatment.	5mg, 10mg 20mg & 40mg Tablet	PMDA	অনুরোধের সুপারিশ করা হয়।	পরবর্তী টেকনিক্যাল সার্ভিস প্রদানকারী গুনসুপারিশের সিদ্ধান্ত গৃহীত হয়।
3.	EVEREST Pharmaceuticals Ltd, BSCIC I/A, Kanchipur, Narayanagri Incepta Pharmaceuticals Ltd., Zhabo, Dhaka	Febuxostat 20 mg Tablet	Febuxostat INN 20mg Tablet	Uricosuric & Anti-Gout Agents Therapeutic Code:076	Febuxostat is indicated to lower serum uric acid levels in patients with gout who have an inadequate response or intolerance to allopurinol, or for whom treatment with allopurinol is inappropriate.	<b>CONTRAINDICATIONS:</b> Febuxostat is contraindicated in patients: • Being treated with azathioprine or mercaptopurine • With a history of hypersensitivity to febuxostat or to any other ingredient in the formulation. For a complete listing of ingredients. <b>Side effects:</b> Liver problems; Diarrhea, Rash, Nausea, Dizziness <b>Warnings &amp; Precautions:</b> Patients with gout and established cardiovascular (CV) disease treated with	40mg, 80mg & 120mg	PMDA	অনুরোধের সুপারিশ করা হয়।	পরবর্তী ঔষধ নিয়ন্ত্রণ কমিশনের সিদ্ধান্ত গৃহীত হয়।

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKMHRA/ EMA/PMDA/ TGA	ঔষধ নিয়ন্ত্রণ কর্তৃক কঠোর নিষেধাজ্ঞা	ঔষধ নিয়ন্ত্রণ কর্তৃক সীমিত
4.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagiri, BANGLADESH	Mosapride Citrate Dihydrate 2.5 mg Tablet	Mosapride Citrate Dihydrate INN 2.647 mg Eqv. to Mosapride Citrate 2.5 mg Tablet	Antiemetic Therapeutic Code:018	Gastrointestinal symptoms accompanying chronic gastritis (heartburn, nausea/vomiting)	<p>Febuxostat had a higher rate of CV death compared to those treated with allopurinol in a CV outcomes study.</p> <p>• Consider the risks and benefits of Febuxostat when deciding to prescribe or continue patients on Febuxostat. Febuxostat should only be used in patients who have an inadequate response or intolerance to allopurinol, or for whom treatment with allopurinol is inappropriate</p> <p><b>CONTRAINDICATIONS:</b> Mosapride Citrate is contraindicated in the following patients: Patients with GI hemorrhage, mechanical obstruction, or perforation; Patients with a history of hypersensitivity to any of the ingredients of this product.</p> <p><b>SIDE EFFECTS:</b> Mosapride citrate side effects include dry mouth, abdominal pain, dizziness, headache, insomnia, malaise, nausea, diarrhea and sometimes constipation.</p> <p><b>WARNINGS &amp; PRECAUTIONS:</b> If any improvement of gastrointestinal symptoms is not observed after the administration for a given period of time (usually for 2 weeks), Mosapride citrate should not be administered aimlessly for a long period.</p>	New	PMDA	ঔষধজন্য তেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	বর্তমানে ঔষধজন্য তেই বিধায় নামঞ্জুর করা হয়।
5.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagiri, BANGLADESH	Mosapride Citrate Dihydrate 5 mg Tablet	Mosapride Citrate Dihydrate INN 5.293 mg Eqv. to Mosapride Citrate 5 mg Tablet	Antiemetic Therapeutic Code: 018	Gastrointestinal symptoms accompanying chronic gastritis (heartburn, nausea/vomiting)	<p><b>CONTRAINDICATIONS:</b> Mosapride Citrate is contraindicated in the following patients: Patients with GI hemorrhage, mechanical obstruction, or perforation; Patients with a history of hypersensitivity to any of the ingredients of this product.</p> <p><b>SIDE EFFECTS:</b> Mosapride citrate side effects include dry mouth, abdominal pain, dizziness, headache, insomnia, malaise, nausea, diarrhea and sometimes constipation.</p> <p><b>WARNINGS &amp; PRECAUTIONS:</b> If any improvement of gastrointestinal symptoms is not observed after the administration for a given period of time (usually for 2 weeks), Mosapride citrate should not be administered aimlessly for a long period.</p>	New	PMDA	ঔষধজন্য তেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	ঔষধজন্য তেই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটিস শক্তির সিদ্ধান্ত	ইবং নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
6.	Healthcare Pharmaceuticals Ltd Square Pharmaceuticals PLC, Kalikotir, Gazipur Beacon Pharmaceuticals PLC, Kathali, Bhaluka, Mymensingh EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchnpur, Narayanagnj Incepta Pharmaceuticals Ltd., Zirabo, Dhaka	Enarodustat 2 mg Tablet	Enarodustat INN 2mg	Drug used in Anaemia and other Blood disorder Therapeutic code: 045	Anaemia associated with CKD	Contraindications: Side effects: The most commonly reported adverse reactions include hypertension, retinal bleeding and eczema, diarrhoea, constipation & dizziness. Warnings and Precautions: Blood test may be conducted periodically to measure serum concentration of hemoglobin, etc. Iron is necessary to obtain a sufficient effect. If you are prescribed with iron preparation, you should take it as instructed by doctor. If you are a female patient with a possibility of pregnancy, you should use an adequate contraception while you are taking this medicine and for a certain period of time after you finish taking this medicine. Avoid breastfeeding while taking this medicine and for four days after you discontinued to take it. Lactical transfer has been reported in animal experiments.	New	PMDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।
7.	Healthcare Pharmaceuticals Ltd Square Pharmaceuticals PLC, Kalikotir, Gazipur Beacon Pharmaceuticals PLC, Kathali, Bhaluka, Mymensingh EVEREST	Enarodustat 4 mg Tablet	Enarodustat INN 4mg	Drug used in Anaemia and other Blood disorder Therapeutic code: 045	Anaemia associated with CKD	Contraindications: Side effects: The most commonly reported adverse reactions include hypertension, retinal bleeding and eczema, diarrhoea, constipation & dizziness. Warnings and Precautions: Blood test may be conducted periodically to measure serum concentration of hemoglobin, etc. Iron is necessary to obtain a sufficient effect. If you are prescribed with iron preparation, you should take it as instructed by doctor. If you are a female patient with a possibility of pregnancy, you should use an adequate contraception while you are taking this medicine and for a certain period of time after you finish taking this medicine. Avoid breastfeeding	New	PMDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	ঔষধিকাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
8.	Incepta Pharmaceuticals Ltd.; Dharmrai Unit, Dhaka  Nuvista Pharma Ltd.	Luliconazole 5g/100g Solution	Luliconazole INN 5g/ 100g	Therapeutic Class: Antifungal Agents  Therapeutic code: 020	As topical treatment in adult patients with mild to moderate tinea unguium with symptoms of distal and lateral subungual onychomycosis	<b>Contraindication:</b> Patients with a past history of hypersensitivity to any of the ingredients of Luliconazole, External Solution for Nails 5% w/w  <b>Precautions:</b> 1. Luliconazole, External Solution for Nails 5% w/w should be used in patients with a confirmed diagnosis of tinea unguium based on the results from direct microscopy or culture, etc. 2. The efficacy and safety of Luliconazole, External Solution for Nails 5% w/w have not been established in severe patients	Luliconazole 1% Cream	PMDA	ঔষধিকাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
9.	Incepta Pharmaceuticals Ltd.; Dharmrai Unit, Dhaka  Pharmasia Limited, Bhawal, Mirzapur, Gazipur  Orion Pharma Ltd. D/28/2, Sumilpara, Siddhirganj, Narayanganj	Olanexidine Gluconate 1.5% Solution	Olanexidine Gluconate 1.5%	Therapeutic Class: Antiseptic and Disinfectants  Therapeutic code: 029	Preoperative skin preparation	<b>Contraindication:</b> Olanexidine gluconate solution is contra-indicated in patients with known hypersensitivity to Olanexidine gluconate. <b>Side-effects:</b> burning or irritation <b>Warnings and Precautions:</b> No data available.	New	PMDA	ঔষধিকাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউয়ান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাইন কপি রাখা হবে	ঔষধ নিয়ন্ত্রণ কর্তৃক প্রিন্ট করা হবে
10.	Incepta Pharmaceuticals Ltd., Zirabo, Zirabo, Dhaka	Amenamewir 200mg Tablet	Amenamewir INN/in-house 200mg	Therapeutic Class: Antiviral Therapeutic code: 032	For the treatment of: Herpes Zoster, Herpes Simplex, Herpes Genitals.	<b>Contraindication:</b> Hypersensitivity, Severe Renal Impairment, Pregnancy and Breastfeeding, Pediatric Use Immunocompromised Patients, Certain Medical Conditions <b>Side-effects:</b> Headache, Nausea, Fatigue, Skin Irritation, Abdominal Pain, Vomiting, Diarrhea <b>Warnings and Precautions:</b> Pregnancy and Breastfeeding, Pediatric Use, Immunocompromised Patients, Certain Medical Conditions	New	PMDA	অনুমোদনের সুপারিশ করা হবে।	অনুমোদন করা হবে।
11.	Incepta Pharmaceuticals Ltd., Zirabo, Dhaka	Levofloxacin 1.5gm/100ml Otic Solution	Levofloxacin Hemihydrate USP 1.5375gm/100ml eqv. to Levofloxacin 1.5gm/100ml	Therapeutic Class: Ear and nose preparation Therapeutic code: 050	Levofloxacin otic solution is a topical quinolone antimicrobial indicated for the treatment of corneal ulcer caused by susceptible strains of the following bacteria: <i>Corynebacterium</i> species* <i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Streptococcus pneumoniae</i> <i>Vitridans</i> group <i>streptococci</i> * <i>Pseudomonas aeruginosa</i> <i>Serratia marcescens</i> * *Efficacy for this organism was studied in fewer than 10 infections.	<b>Contraindication:</b> Contraindicated in patients with a history of hypersensitivity to levofloxacin, to other quinolones, or to any of the components in this medication. <b>Side Effect:</b> The most frequently reported adverse reactions in the overall study population were headache and a taste disturbance following instillation. These reactions occurred in approximately 8-10% of patients. <b>Warnings and Precautions:</b> Hypersensitivity and anaphylaxis have been reported with systemic use of levofloxacin. Prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. Patients should not wear contact lenses if they have signs or symptoms of corneal ulcer.	New	PMDA	অনুমোদনের সুপারিশ করা হবে।	অনুমোদন করা হবে।
12.	Navana Pharmaceuticals Limited EVEREST Pharmaceuticals Ltd. BSC/C I/A, Kanachpur, Narayanganj, BANGLADESH Opsonin Pharma	Ceclislat 120 mg Tablet	Ceclislat INN 120mg	Anti-obesity Therapeutic Code: 015	Obesity (limited to patients with type 2 diabetes mellitus and dyslipidemia, and with a BMI > 25 kg/m <sup>2</sup> in spite of dietary treatment and/or exercise therapy).	<b>Contraindications:</b> Ceclislat is also contraindicated with warfarin and levofloxacin as this could cause increased risk of bleeding and hypothyroidism. <b>Side Effects:</b> Ceclislat may have some major or minor side effects on your body. Such as: Headache, Vomiting or Nausea, Unusual weakness or tiredness, Itching or rash on the skin, Yellow-colored skin <b>Warnings and Precautions:</b> • It is advised to take Ceclislat as per a doctor's prescription and based on the medical condition.	New	PMDA	অনুমোদন নেই রিসার্চ নামমাত্রের সুপারিশ করা হবে।	অনুমোদন নেই রিসার্চ নামমাত্রের সুপারিশ করা হবে।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UK/MHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার ফিলাস্ট	ঔষধ নিয়ন্ত্রণ কমিটির ফিলাস্ট
13.	Navana Pharmaceuticals Limited Nuvisia Pharma Ltd.	Imidafenacin 0.1 mg Tablet	Imidafenacin INN 0.1 mg	Other Classification Therapeutic Code: 075	Symptoms associated with overactive bladder: urinary urgency, urinary incontinence	<p><b>Contraindications:</b> Imidafenacin tablets are contraindicated in the following patients-</p> <ul style="list-style-type: none"> <li>• Patients with urinary retention</li> <li>• Patients with occluded pyloric region/duodenum/intestine or paralytic ileus</li> <li>• Patients with decreased gastrointestinal movements and muscular tension</li> <li>• Patients with narrow-angle glaucoma</li> <li>• Patients with myasthenia gravis</li> </ul> <p>Patients with a history of hypersensitivity to any of the components of these products</p> <p><b>Side Effects:</b> Clinically significant adverse reactions to Imidafenacin are acute glaucoma, urinary retention, and hepatic dysfunction. The most common adverse effects observed with Imidafenacin are dry mouth and constipation.</p> <p><b>Warnings and Precautions:</b> Careful administration should be administered with care in the following patients-</p> <p>Patients with dysuria, arrhythmia, hepatic dysfunction, renal dysfunction, dementia or cognitive dysfunction, cerebrovascular disorder, ulcerative colitis and hyperthyroidism.</p> <p><b>Contraindication:</b> Contraindicated in patients with:</p> <ul style="list-style-type: none"> <li>• Uncontrolled hypertension or known hypersensitivity to ergot derivatives.</li> <li>• History of cardiac valvular disorders, as suggested by anatomical evidence of valvulopathy of any valve, determined by pre-</li> </ul>	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
14.	Nuvisia Pharma Ltd	Cabergoline 0.25mg Tablet	Cabergoline USP 0.25mg Tablet	long-acting dopamine agonist and prolactin inhibitor	Cabergoline Tablets are indicated for the treatment of hyperprolactinemic disorders, either idiopathic or due to pituitary adenomas.	<p><b>Contraindication:</b> Contraindicated in patients with:</p> <ul style="list-style-type: none"> <li>• Uncontrolled hypertension or known hypersensitivity to ergot derivatives.</li> <li>• History of cardiac valvular disorders, as suggested by anatomical evidence of valvulopathy of any valve, determined by pre-</li> </ul>	Cabergoline 500mcg, 1mg & 2mg Tablet	PMDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHPRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাফ কপিটির সত্তর ফিলাজ	ঊষধ নিরূপণ কপিটির ফিলাজ
15.	Opsonin Pharma Limited, Rupatali, Barishal  Pharmasia Limited, Bhawal, Mirzapur, Gazipur  Ziska Pharmaceuticals Ltd.	Sofipronium Bromide 5.0 % Gel	Sofipronium Bromide INN 5 %	Skin & Mucous Membrane Preparation  Therapeutic Code: 071	indicated for the treatment of primary axillary hyperhidrosis.	<p>treatment evaluation including echocardiographic demonstration of valve leaflet thickening, valve restriction, or mixed valve restriction-stenosis.</p> <ul style="list-style-type: none"> <li>History of pulmonary, pericardial, or retroperitoneal fibrotic disorders.</li> </ul> <p><b>Contraindications:</b> Patients with angle-closure glaucoma (anticholinergic effects may increase intraocular pressure and worsen symptoms.) Patients with urinary dysfunction due to prostatic hypertrophy Patients with a history of hypersensitivity to the components of this drug.</p> <p><b>Side effects:</b> 1% to less than 5%: Skin: Application site dermatitis, application site itching, application site eczema, sebum deficiency Digestive organ: Dry mouth.</p> <p><b>0.1% to less than 1%:</b> Skin: Application site erythema, skin exfoliation Digestive organ: Angular cheilitis Others: Urinary glucose positive.</p> <p><b>Precautions &amp; warnings:</b> Anticholinergic effects may cause ocular accommodation disorders (visual impairment, blurred vision, etc.), dizziness, and drowsiness, so patients should be careful when engaging in dangerous machinery operations. In environments where sweating is promoted, body temperature may rise due to the antiperspirant effect of this drug. If symptoms suggestive of heat stroke appear, instruct the patient to take appropriate measures.</p> <p>Anticholinergic effects may inhibit the contraction and movement of gastrointestinal smooth muscle, leading to decreased gastrointestinal motility. If gastrointestinal symptoms occur, instruct the patient to discontinue use and consult a medical institution.</p> <p><b>Contraindications:</b> Mirodronic acid should not be given to patients with hypersensitivity to Mirodronic acid or to any of its excipients.</p>	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
16.	Opsonin Pharma Limited, Rupatali, Barishal	Mirodronic acid Hydrate 1 mg Tablet	Mirodronic acid Hydrate INN 1 mg	Drug used in Osteoporosis	It is indicated for the treatment of osteoporosis who are at high risk for fracture.		New	PMDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অ্যুভিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কমান্ডির সত্তর সিদ্ধান্ত হয়।	ঔষধ নিয়ন্ত্রণ কমিশনের সিদ্ধান্ত
17.	Pharmasia Limited, Bhowal, Mirzapur, Gazipur	Statifoxacin Granules 10%	Statifoxacin Hydrate INN 10.66gm eq to Statifoxacin 100.0mg	Fluroquinolone antibiotic	Statifoxacin can be used for infections caused by the following bacteria: Statifoxacin-susceptible Staphylococcus sp., Streptococcus sp., Streptococcus pneumoniae, Moraxella sp., Enterococcus (Branhamella) catarrhalis, Escherichia coli, Citrobacter sp., Klebsiella sp., Enterobacter sp., Serratia sp., Proteus sp., Morganella morganii, Haemophilus influenzae, Pseudomonas aeruginosa, Legionella pneumophila, Peptostreptococcus sp., Prevotella sp., Porphyromonas sp., Fusobacterium sp., Chlamydia trachomatis, Chlamydia pneumoniae and Mycoplasma pneumoniae.	Statifoxacin can be used for infections caused by the following bacteria: Statifoxacin-susceptible Staphylococcus sp., Streptococcus sp., Streptococcus pneumoniae, Enterococcus sp., Moraxella (Branhamella) catarrhalis, Escherichia coli, Citrobacter sp., Klebsiella sp., Serratia sp., Proteus sp., Morganella morganii, Haemophilus influenzae, Pseudomonas aeruginosa, Legionella pneumophila, Peptostreptococcus sp., Prevotella sp., Porphyromonas sp., Fusobacterium sp., Chlamydia trachomatis, Chlamydia pneumoniae and Mycoplasma pneumoniae.	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	নামঞ্জুর করা হয়।
18.	The ACME Laboratories Ltd, Dhanrai, Dhaka Navana Pharmaceuticals Limited Square Pharmaceuticals	Diquafosol Sodium 3% w/v Ophthalmic Solution 5 ml	Diquafosol Sodium INN 3% w/v	Eye Preparations Therapeutic Code: 052	Indicated for the treatment of dry eye.	<b>Contra-indications:</b> None <b>Side-effects:</b> Eye irritation, eye discharge, conjunctival hyperaemia, eye pain, eye itching, foreign body sensation in eyes, ocular discomfort. <b>Warning &amp; Precautions:</b> This drug may cause blurred vision, if affected, driving or operation of	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	পরবর্তী ঔষধ নিয়ন্ত্রণ কমিশনের সিদ্ধান্ত নিয়ে পরামর্শ করা হবে।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কারিটিং সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কারিটিং সিদ্ধান্ত
19.	The ACME Laboratories Ltd. Dharmal, Dhaka	Dydrogesterone 5 mg Tablet	Dydrogesterone BP 5 mg	Hormone Therapeutic Code: 056	1) Treats menstrual disorders like absent or irregular menstruation, painful menstruation, secondary amenorrhoea and premenstrual symptoms. 2) Prevents thickening of the uterine lining in the patient taking HRT. 3) Prevents miscarriage. 4) Relieves the endometriosis pain without inhibiting ovulation. 5) IVF treatment support	<b>Contra-indications:</b> Contraindicated in patients with undiagnosed abnormal vaginal bleeding, blood clot disorder, stroke, incomplete abortion, breast cancer, brain cancer, breastfeeding mothers, liver dysfunction, and hypersensitivity. <b>Side-effects:</b> Pulsating headache which can develop into a migraine, Pain in breast and breast tenderness, Occasional blood spotting, Pain during periods, Irregular period, Heavy bleeding during periods. <b>Warning &amp; Precautions:</b> Patients should be monitored for visual disturbances, migraine headache or embolic disorders. The duration and the frequency of the treatment should be decided by the treating physician.	Dydrogesterone 10 mg Tablet	PMDA	অনুমোদনের সুপারিশ করা হয়।	পরবর্তী ঔষধ নিয়ন্ত্রণ কারিটিং সভায় সক্রিয় বিশদায়ণ এর লক্ষ্যমত প্রবন্ধের সিদ্ধান্ত গৃহীত হয়।
20.	Ziska Pharmaceuticals Ltd. Advanced Chemical Industries Limited, 7 Hajeegoni, Godhni, Narayangoni	Ripasudil Hydrochloride Dihydrate 0.4% Eye Drop Solution	Ripasudil Hydrochloride Dihydrate INN 0.4%	Therapeutic class: A specific Rho-associated coiled-coil containing protein kinase (ROCK) inhibitor	Treatment of glaucoma and ocular hypertension	<b>Contraindications:</b> It is contraindicated in patients with history of hypersensitivity to any of the components of Ripasudil hydrochloride dihydrate. <b>Side effects:</b> Conjunctival hyperemia, conjunctivitis (including allergic blepharitis), eye irritation. Corneal epithelial disorder (such as corneal erosion and punctate keratitis), eye pruritus, abnormal sensation in eye, eye discharge, eye pain, conjunctival follicles, intraocular pressure increased. <b>Warnings and precautions:</b> Acute primary angle-closure glaucoma: Consider treatments other than	New	PMDA	অনুমোদনের সুপারিশ করা হয়।	পরবর্তী ঔষধ নিয়ন্ত্রণ কারিটিং সভায় সক্রিয় বিশদায়ণ এর লক্ষ্যমত প্রবন্ধের সিদ্ধান্ত গৃহীত হয়।

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	অনুমোদনের কার্যক্রম সত্তা	ক্রম নিয়ন্ত্রণ কার্যক্রম সত্তা
21.	Nuvista Pharma Ltd	Dienogest 1mg Tablet	Dienogest BP 1mg Tablet	Hormone Therapeutic Class: 056	A drug containing a new active ingredient indicated for the treatment of endometriosis.	<p>drug therapy, such as surgical therapy, when using GLANATEC for acute primary angle-closure glaucoma. Conjunctival hyperaemia: In clinical studies conducted prior to the time of approval in Japan, conjunctival hyperaemia in association with the use of ipasudil has been reported. The event usually occurs transiently at the time of instillation, but be cautious if it continues. Take any appropriate measures such as discontinuation of treatment if this event occurs. Conjunctivitis (including conjunctivitis allergic) and blepharitis (including allergic blepharitis): In clinical studies conducted prior to the time of approval in Japan, conjunctivitis (including conjunctivitis allergic) and blepharitis (including allergic blepharitis) have been reported in association with the use of ipasudil. The incidence of conjunctivitis allergic and blepharitis allergic tends to be high in patients with long-term instillation. Take any appropriate measures such as discontinuation of treatment if these events occur.</p> <p><b>Contraindication:</b></p> <ul style="list-style-type: none"> <li>• Known or suspected pregnancy</li> <li>• Active venous thromboembolic disorder</li> <li>• Arterial and cardiovascular disease, past or present (e.g., myocardial infarction, cerebrovascular accident, ischemic heart disease)</li> <li>• Diabetes mellitus with vascular involvement</li> <li>• Presence or history of severe hepatic disease as long as liver function values have not returned to normal.</li> <li>• Presence or history of liver tumors (benign or malignant)</li> <li>• Known or suspected sex hormone-dependent malignancies</li> <li>• Undiagnosed abnormal vaginal bleeding</li> <li>• Any ocular lesion arising from ophthalmic vascular disease, such as partial or complete loss of vision or defect in visual</li> </ul>	Dienogest 2mg Tablet	PMDA (Japan) FY 2007	অনুমোদনের কার্যক্রম সত্তা	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কনিট্রোল নম্বর ফিলাস	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
						<ul style="list-style-type: none"> <li>• Current or history of migraine with focal fields.</li> <li>• Hypersensitivity to dihydroergotamine or to any ingredient in the formulation or component of the container</li> </ul> <p><b>Side Effects:</b></p> <ul style="list-style-type: none"> <li>▪ Yellowing eyes/skin</li> <li>▪ Persistent nausea/vomiting</li> <li>▪ Dark urine</li> <li>▪ Severe stomach/abdominal pain</li> <li>▪ Unusual vaginal bleeding (such as spotting, breakthrough bleeding, prolonged/recurrent bleeding)</li> <li>▪ Mental/mood changes (such as depression)</li> <li>▪ Swelling hands/ankles/feet</li> </ul> <p>This medication may rarely cause serious problems from blood clots (such as heart attacks, strokes, deep vein thrombosis, pulmonary embolism). Get medical help right away if you have any serious side effects, including:</p> <ul style="list-style-type: none"> <li>▪ Chest/jaw/left arm pain</li> <li>▪ Unusual sweating</li> <li>▪ Sudden/severe headache</li> <li>▪ Weakness on one side of the body</li> <li>▪ Confusion</li> <li>▪ Trouble speaking</li> <li>▪ Sudden vision changes (such as partial/complete blindness)</li> </ul>				

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	উৎপাদনকারী প্রতিষ্ঠানের নাম	উৎপাদনকারী প্রতিষ্ঠানের ঠিকানা
22.	Healthcare Pharmaceuticals Ltd Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka Drug International Ltd., 31/11, Satrong, Tongi I/A, Gazipur Opsonin Pharma Limited, Rupatali, Barishal EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchipur, Narayanagnj Ziska Pharmaceuticals Ltd. Square Pharmaceuticals PLC, Kallakor, Gazipur Beacon	Vadadustat Tablet 150mg	Vadadustat INN 150 mg	Drug used in Anaemia and other Blood disorder  Therapeutic code: 045	This tablet is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.	<p><b>Contra-indication:</b> Hypersensitivity to the active substance or to any of the excipients of this product.</p> <p><b>Side-effect:</b> Thromboembolic events (problems due to the formation of blood clots in the blood vessels which may lead to heart attack, stroke, mini stroke) diarrrea, hypertension, headache, convulsions, constipation, feeling sick, vomiting, increased amount of bilirubin in blood.</p>	New	PMDA, EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	উৎপাদনের সর্বমুখ্য বিবরণ	উৎপাদন নিয়ন্ত্রণ বিবরণ
23.	Pharmaceuticals PLC, Kathali, Bhalka, Mymensingh The ACME Laboratories Ltd. Dhanrai, Dhaka	Vadadustat Tablet 300mg	Vadadustat 300 mg INN	Drug used in Anaemia and other Blood disorder  Therapeutic code: 045	This tablet is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.	<b>Contraindication:</b> Hypersensitivity to the active substance or to any of the excipients of this product.  <b>Side-effect:</b> Thromboembolic events (problems due to the formation of blood clots in the blood vessels which may lead to heart attack, stroke, mini stroke) diarrhea, hypertension, headache, convulsions, constipation, feeling sick, vomiting, increased amount of bilirubin in blood.	New	PMDA, EMA	উৎপাদনের সর্বমুখ্য বিবরণ	উৎপাদন নিয়ন্ত্রণ বিবরণ
	Opsonin Pharma Limited, Rupatali, Barisal EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kancharpur, Narayanagari Ziska Pharmaceuticals Ltd. Square Pharmaceuticals PLC, Kallakor, Gazipur Beacon Pharmaceuticals									

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অডিটিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কন্ট্রোল সত্তার বিচার	ঔষধ নিয়ন্ত্রণ কমিশনের সিদ্ধান্ত
24.	Beacon Pharmaceuticals PLC Kathali, Bhalka, Mymensingh Dhamrai, Dhaka	Calcifediol 10mcg Tablet	Calcifediol Monohydrate USP 104mcg eqv. to Calcifediol 10mcg	Vitamins and Combinations  Therapeutic Code: 078	It is a vitamin D3 analog which is used for Vitamin D deficiency.  It is also used for- Support bone mass and strength in post-menopausal women, Maintain healthy immune system function, Maintain healthy foetal development, Maintain bone health and strength, Support a healthy pregnancy, Support bone mineralization, Calcium absorption.	<b>Contraindications:</b> Hypersensitivity to the active substance or excipients.  <b>Side-Effect:</b> The most common adverse reactions > 3% and more frequent than placebo were anemia, nasopharyngitis, increased blood creatinine, dyspnea, congestive heart failure and constipation.	New	TGA	খরোজন সেই বিখ্যাত নামগুলোর সুপারিশ করা হয়।	বর্তমানে খরোজন সেই বিখ্যাত নামগুলোর সুপারিশ করা হয়।
25.	Ekayef Pharmaceuticals Limited, Saina, Gazipur  DBL Pharmaceuticals Ltd., Surabari, Kashimpur, Gazipur  Advanced Chemical Industries Limited, 7 Hajeegoni, Godnyl, Narayangoni	Methylprednisolone Acetonate 0.1% Cream	Methylprednisolone Acetonate INN 0.1gm/100gm	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, dystrophic, vulgar eczema, eczema in children.	<b>CONTRAINDICATIONS:</b> It is contraindicated in most viral diseases (e.g. vaccinia, varicella/herpes zoster) and when tuberculous or syphilitic processes and post-vaccination skin reactions are present in the area to be treated. If rosacea, acne vulgaris, ulcers, atrophic skin diseases, or perioral dermatitis are present, it must not be applied to the face.  <b>SIDE-EFFECT:</b> In clinical studies, most frequently observed side-effects included burning and pruritus at the application site.  <b>WARNINGS AND PRECAUTIONS:</b> • Care must be taken when using this drug to avoid contact with the eyes, deep open wounds and mucosa. Additional specific therapy is required in bacterially infected skin diseases and/or in fungal infections. Any spread of infection may require withdrawal of topical corticosteroid therapy.	New	TGA	অন্যদের মতো সুপারিশ করা হয়।	পূর্বের ঔষধ নিয়ন্ত্রণ কমিশনের সত্যের চর্চা যোগ্য বিশেষজ্ঞ এর মতামত গ্রহণের সিদ্ধান্ত গৃহীত হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHA/ EMA/PMDA/ TGA	টেকনিক্যাল সার্ভিসের সত্তা বিদ্যুত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
26.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagri Square Pharmaceuticals P.L.C, Kallakor, Gazipur	Zinc Glycinate 15 mg Capsule	Zinc Glycinate Enteric Coated Pellets Ph. Grade 260.00 mg Eqv. to Elemental Zinc 15 mg Capsule	Metals, Salts, Minerals and Calcium Preparations Therapeutic Code: 062	Zinc Bisglycinate is used as a dietary supplement to treat zinc deficiency. It is also used to treat zinc deficiency anemia. Zinc is essential for the proper functioning of the nervous system, the immune system, and the brain. It plays a vital role in immunity, wound healing, acne prevention, and digestion. Furthermore, it provides essential nutrients and plays a vital role in the formation of red blood cells, which carry oxygen throughout the body.	<b>Contraindication:</b> Zinc Bisglycinate, like other zinc supplements, is generally safe for most people when used as directed. However, it's important to note that taking too much zinc can lead to harmful side effects. These can include nausea, vomiting, diarrhea, metallic taste, kidney and stomach damage, and other adverse effects. <b>Side Effect:</b> No data available <b>Warnings and Precautions:</b> When taking Zinc Bisglycinate tablets, there are several precautions to keep in mind: Food Interactions: When zinc combines with certain foods, it may not be absorbed into your body and it will do you no good. If you are taking zinc, the following foods should be avoided or taken 2 hours after you take zinc: Bran, Fiber-containing foods, Phosphorus-containing foods such as milk or poultry, Whole-grain breads and cereals. Supplement Interactions: Do not take zinc supplements and copper, iron, or phosphorus supplements at the same time. It is best to space doses of these products 2 hours apart, to get the full benefit from each dietary supplement.	Zinc 10 mg Tablet, Zinc 20 mg Tablet	TGA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
27.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagri	Zinc Glycinate 25 mg Capsule	Zinc Glycinate Enteric Coated Pellets Ph. Grade 433.333 mg Eqv. to Elemental Zinc	Metals, Salts, Minerals and Calcium Preparations	Zinc Bisglycinate is used as a dietary supplement to treat zinc deficiency. It is also used to treat zinc deficiency anemia. Zinc is essential for the proper functioning of the nervous system, the immune	<b>Contraindication:</b> Zinc Bisglycinate, like other zinc supplements, is generally safe for most people when used as directed. However, it's important to note that taking too much zinc can lead to harmful side effects. These can include nausea, vomiting,	Zinc 10 mg Tablet, Zinc 20 mg Tablet	TGA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মোডিফিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKMHR/ EMA/PMDA/ TGA	ঔষধ নিয়ন্ত্রণ কর্তৃক কঠোর নিয়ন্ত্রণ	ঔষধ নিয়ন্ত্রণ কর্তৃক নিশ্চিত
28.	General Pharmaceutical Ltd., Gazipur	Multivitamin for Men (Each film coated tablet contains Ascorbic Acid 100 mg + Biotin 60 mcg + Calcium Folate 0.671 mg equivalent to Folic Acid .5 mg + Calcium Pantothenate 25.151 mg equivalent to Pantothenic Acid 22 mg + Colecalciferol 0.01 mg + Cyanocobalamin 20 mcg + Heavy Magnesium Oxide 186.133 mg equivalent to Magnesium 110 mg + Nicotinamide 9 mg + Piper Nigrum Fruit Extract Dry Concentrate (Pepper) 5 mg equivalent to Piper Nigrum (Dry)	Each film coated tablet contains Ascorbic Acid BP 100 mg + Biotin BP 60 mcg + Calcium Folate BP .671 mg equivalent to Folic Acid .5 mg + Calcium Pantothenate BP 25.151 mg equivalent to Pantothenic Acid BP 22 mg + Colecalciferol BP .01 mg + Cyanocobalamin BP 20 mcg + Heavy Magnesium Oxide BP 186.133	Vitamins & Combinations  Therapeutic code: 078	Antioxidant/Reduce free radicals formed in the body Helps reduce/decrease free radical damage to body cells Maintain/support body metabolism/metabolic rate Maintain/support energy production Relieve weariness/tiredness/fatigue/feeling of weakness Maintain/support immune system health Maintain/support healthy immune system function Aldassist/helps glucose/sugar/carbohydrate metabolism Aldassist/helps metabolism of (stare	<b>Contra-indication:</b> It is contraindicated in patients with a known hypersensitivity to any of the ingredients.  <b>Side Effect:</b> Generally, well tolerated.  <b>Warning and Precautions:</b> Long-term intake of high levels of vitamin A (excluding that sourced from b carotene) may increase the risk of osteoporosis in postmenopausal women.	NEW	TGA	ঔষধ নিয়ন্ত্রণ কর্তৃক কঠোর নিয়ন্ত্রণ করা হয়।	ঔষধ নিয়ন্ত্রণ কর্তৃক নিশ্চিত করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউয়ান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ IGA	টেকনিক্যাল সার ফর্মটির সত্যতা বিচার	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		250 mg + Pyridoxine Hydrochloride 11,106 mg equivalent to Pyridoxine 9 mg + Retinol Palmitate 550 mcg equivalent to Vitamin A 300 RE/mcg + Riboflavin 10 mg + Selenomethionine INN 154 mcg equivalent to Selenium 60 mcg + Thiamine Hydrochloride 12,288 mg equivalent to Thiamine 9 mg + Withania Somnifera Root Extract Dry Concentrate (Withania Somnifera Root) 250 mg equivalent to Withania Somnifera (Dry) 3,125 g + Zinc Oxide 38,488 mg equivalent to Zinc 30 mg.)	mg equivalent to Magnesium 110 mg + Nicotinamide BP 9 mg + Piper Nigrum Fruit Extract Dry Concentrate (Pepper) BP 5 mg equivalent to Piper Nigrum (Dry) 250 mg + Pyridoxine Hydrochloride BP 11,106 mg equivalent to Pyridoxine 9 mg + Retinol Palmitate 550 mcg equivalent to Vitamin A BP 300 RE/mcg + Riboflavin BP 10 mg + Selenomethionine INN 154 mcg equivalent to Selenium 60 mcg + Thiamine Hydrochloride BP 12,288 mg equivalent to Thiamine 9 mg + Withania Somnifera Root Extract Dry Concentrate (Withania Somnifera Root) BP 250 mg equivalent to Withania Somnifera (Dry) 3,125 g + Zinc Oxide BP 38,488 mg equivalent to Zinc 30 mg.		vitamin/mineral(nutrient) Traditionally used in Ayurvedic medicine to decrease/relieve symptoms of stress Maintain/support nervous system health Maintain/support reproductive system health Maintain/support sperm health Maintain/support sperm production					

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কপিটির সত্তর বিকল্প	ঔষধ নিয়ন্ত্রণ কর্তৃক বিকল্প
29.	General Pharmaceutical Ltd., Gazipur	Multivitamin for Women (Each film coated tablet contains Ascorbic Acid 100 mg + Betacarotene 2 mg + Biotin 55 mcg + Calcium Carbonate 61.111 mg equivalent to Calcium 22 mg + Calcium Folate 0.671 mg equivalent to Folic Acid .5 mg + Calcium Pantothenate 6.859 mg equivalent to Pantothenic Acid 6 mg + Colecalciferol .01 mg + Cyanocobalamin 30 mcg + D-Alpha-Tocopheryl Acid Succinate 28 mg + Heavy Magnesium Oxide 190.016 mg equivalent to Magnesium 110 mg + Iron (II) Glycinate INN 20 mg equivalent to Iron 4 mg + Nicotinamide 26 mg + Piper Nigrum Fruit Extract Dry Concentrate Standardised (Pepper) 5 mg equivalent to Piper Nigrum (Dry) 102.5 mg + Pyridoxine Hydrochloride 4.442 mg equivalent to Pyridoxine 3.6 mg + Resveratrol INN 5 mg + Riboflavin 3.6 mg + Sambucus Nigra Fruit Extract Dry Concentrate	Each film coated tablet contains Ascorbic Acid BP 100 mg + Betacarotene BP 2 mg + Biotin BP 55 mcg + Calcium Carbonate USP 61.111 mg equivalent to Calcium 22 mg + Calcium Folate BP 0.671 mg equivalent to Folic Acid .5 mg + Calcium Pantothenate BP 6.859 mg equivalent to Pantothenic Acid 6 mg + Colecalciferol BP .01 mg + Cyanocobalamin BP 30 mcg + D-Alpha-Tocopheryl Acid Succinate BP 28 mg + Heavy Magnesium Oxide BP 190.016 mg equivalent to Magnesium 110 mg + Iron (II) Glycinate INN 20 mg + Iron 4 mg + Nicotinamide BP 26 mg + Piper Nigrum Fruit Extract Dry Concentrate	Vitamins & Combinations Therapeutic code: 078	Antioxidant/Reduce free radicals formed in the body Helps reduce/decrease free radical damage to body cells Maintain/support body metabolism/metabolic rate Maintain/support energy production Relieve weariness/tiredness/fatigue/feeling of weakness Maintain/support immune system health Maintain/support healthy immune system function Aid/assist/helps glucose/sugar/carbohydrate metabolism Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) Traditionally used In Ayurvedic medicine to decrease/reduce/relieve symptoms of stress Maintain/support nervous system health Maintain/support reproductive system health Maintain/support sperm health Maintain/support sperm production	<b>Contraindication:</b> This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. <b>Side Effect:</b> No clinically significant side effects or toxicity are reported with such kind of preparation. <b>Warning and Precautions:</b> Excess vitamin A intake may be toxic and may increase the risk of birth defects. Women who are (or may become) pregnant are advised not to take this supplement except on the advice of a doctor or antenatal clinic.	NEW	TGA	প্রয়োজন সেই বিবরণ নামগুলোর সুপারিশ করা হয়।	প্রয়োজন সেই বিবরণ নামগুলোর সুপারিশ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউয়ান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কন্সিটার সজার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
30.	General Pharmaceutical Ltd, Gazipur	Multivitamin+ Iron Liquid for Kids (Each ml contains Ascorbic	Standardised (Pepper) BP 5 mg equivalent to Piper Nigrum (Dry) 102.5 mg + Pyridoxine Hydrochloride BP 4.442 mg equivalent to Pyridoxine 3.6 mg + Resveratrol INN 5 mg + Riboflavin BP 3.6 mg + Sambucus Nigra Fruit Extract Dry Concentrate (European Elder Berry Dry Extract) USP 75 mg equivalent to Sambucus Nigra (Fresh) 4.8 g + Selenomethionine INN 77 mcg equivalent to Selenium 30 mcg + Thiamine Hydrochloride BP 4.915 mg equivalent to Thiamine 3.6 mg + Zinc Oxide BP 18.708 mg equivalent to Zinc 15 mg.	Vitamins & Combinations	Maintain/support energy levels Maintain/support healthy growth and development	<b>Contraindication:</b> This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.	NEW	TGA	ধরোজন লেই বিধার নামস্থারের	ধরোজন লেই বিধার নামস্থার করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কমার্শিয়াল নাম ব্র্যান্ড	ইবম নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
		Acid 12.00 mg + Biotin 1.50 mcg + Calcium Pantothenate 0.572 mg Equivalent: Pantothenate Acid 0.524 mg + Cholecalciferol 0.0005 mg+ Ferric Pyrophosphate 1.7875 mg Equivalent: Iron 0.500 mg + Levomefolate Calcium 27.86 mcg Equivalent: Levomefolic Acid 22.50 mcg + Mecobalamin INN 0.138 mcg + Nicotinamide 0.90 mg+ Potassium Iodide 0.0059 mg Equivalent: Iodine 4.500 mcg + Pyridoxal 5-Phosphate Monohydrate 0.118 mg Equivalent: Pyridoxine 75.00 mcg + Retinol Palmitate 27.80 mcg Equivalent: Vitamin A 27.80 RE/ml + Riboflavin Sodium Phosphate 68.49 mcg Equivalent: Riboflavin 50.000 mcg+ Thiamine Hydrochloride 0.084 mg Equivalent: Thiamine 75.00 mcg+ Zinc Citrate Dihydrate 1.246 mg Equivalent: Zinc 0.400 mg.)	BP 1.50 mcg + Calcium Pantothenate BP 0.572 mg Equivalent: Pantothenate Acid 0.524 mg + Cholecalciferol BP 0.0005 mg+ Ferric Pyrophosphate USP 1.7875 mg Equivalent: Iron 0.500 mg + Levomefolate Calcium USP 27.86 mcg Equivalent: Levomefolic Acid 22.50 mcg + Mecobalamin INN 0.138 mcg + Nicotinamide BP 0.90 mg+ Potassium Iodide BP 0.0059 mg Equivalent: Iodine 4.500 mcg + Pyridoxal 5-Phosphate Monohydrate BP 0.118 mg Equivalent: Pyridoxine 75.00 mcg + Retinol Palmitate BP 27.80 mcg Equivalent: Vitamin A 27.80 RE/ml + Riboflavin Sodium Phosphate BP	Therapeutic code: 078	Maintain/support general health and wellbeing Maintain/support immune system health Maintain/support healthy immune system function Maintain/support (state vitamin/mineral/nutrient) levels in the body	<b>Side Effect:</b> No clinically significant side effects or toxicity are reported with such kind of preparation. <b>Warning and Precautions:</b> Accidental overdose if an iron-containing product is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. Do not use this product if safety seal bearing "Sealed for your protection" under cap is torn or missing.			নূরানি করা হয়।	হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	ঔষধনিয়ন্ত্রণ সার্বকমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
31.	Incepta Pharmaceuticals Ltd., Zhabo, Dhaka  Square Pharmaceuticals PLC, Kalkatol, Gazipur  Ziska Pharmaceuticals Ltd., Gazipur  Opsonin Pharma Ltd., Barishal	Zinc 30 mg + Vitamin D3 1000 IU + Ascorbic Acid 500 mg Tablet	68.49 mcg Equivalent: Riboflavin 50.000 mcg+ Thiamine Hydrochloride BP 0.084 mg Equivalent: Thiamine 75.00 mcg+ Zinc Citrate Dihydrate BP 1.246 mg Equivalent: Zinc 0.400 mg.)	Therapeutic Class: Vitamin & Combinations  Therapeutic Code: 078	Zinc tablet is used as a dietary supplement to treat zinc deficiency. It is also used to treat zinc deficiency anemia. Zinc is essential for the proper functioning of the nervous system, the immune system, and the brain. It plays a vital role in immunity, wound healing, acne prevention, and digestion. Furthermore, it provides essential nutrients and plays a vital role in the formation of red blood cells, which carry oxygen throughout the body.	<b>Contraindication:</b> Zinc tablet, like other zinc supplements, is generally safe for most people when used as directed. However, it's important to note that taking too much zinc can lead to harmful side effects. These can include nausea, vomiting, diarrhea, metallic taste, kidney and stomach damage, and other adverse effects.  Certain individuals should be cautious with zinc supplementation:  People with a zinc allergy should not take zinc supplements. Individuals with kidney disease should be cautious as they may have trouble excreting zinc, potentially leading to an accumulation of zinc in the body. Zinc can interact with certain medications, including certain antibiotics and diuretics. Therefore, individuals taking these medications should speak with a healthcare provider before starting zinc supplementation. <b>Side Effect:</b> Zinc tablet, like other zinc supplements, is generally well-tolerated. However, it can cause some side effects, especially when taken in large doses. Here are some potential side effects:	New	TGA	অনুরোধকারী সংশোধন করা হয়।	পরবর্তী ৩ মাস নিয়ন্ত্রণ কমিটির সভায় পুনর্মূল্যায়নের সিদ্ধান্ত গৃহীত হয়।

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## Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার্ব কনিটির সত্তার সিদ্ধান্ত	ইস্যে নিয়ন্ত্রণ কনিটির সিদ্ধান্ত
32.	Incepta Pharmaceuticals Ltd., Dharmrai Unit, Dhaka  Beacon Pharmaceuticals PLC, Kathal, Bhaluka, Mymensingh  Nuvista Pharma Ltd.  Oposon Pharma Limited, Rupatali, Barishal	Trolamine Salicylate 100mg/ym Cream	Trolamine Salicylate USP 100mg/ym	Skin and Mucous membrane preparations  Therapeutic Code: 071	Trolamine salicylate serves as an active ingredient in topical over-the-counter products for temporary management of mild to moderate muscular and joint pains.  Trolamine salicylate is indicated for the temporary relief of aches, and pains of muscles and joints associated with backache, lumbago, strains, bruises, sprains and arthritic or rheumatic pain, pain of tendons and ligaments.	Gastrointestinal issues: These can include nausea, vomiting, diarrhea, and stomach pain. Flu-like Symptoms: Exceeding 40 mg per day of elemental zinc can cause flu-like symptoms like fever, coughing, headache, and fatigue. Indigestion: Some people may experience indigestion. Headache: Zinc supplements can sometimes cause headaches. Copper Deficiency: When oral zinc is taken long-term and in high doses it can cause copper deficiency. People with low copper levels might experience neurological issues, such as numbness and weakness in the arms and legs.  <b>Warnings and Precautions:</b> No data available  <b>Contraindication:</b> Known hypersensitivity to Trolamine Salicylate or to any excipients in cream.  <b>Side-effects:</b> blistering/peeling/redness/irritation at the application site nausea/vomiting ringing in the ears  <b>Warnings and Precautions:</b> Wash hands before and after using this medicine. Do not apply this medicine to open wounds, burns, or broken or inflamed skin Be careful not to get any of the ointment in your eyes	New	TGA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
33.	Renata Limited Mirpur, Dhaka  EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kancharpur, Narayanagiri	Itraconazole 50mg Capsule	Itraconazole USP 50mg	Antifungal Therapeutic code: 020	It is an azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: Blastomycosis, pulmonary and extrapulmonary Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-	<b>CONTRAINDICATIONS:</b> Co-administration with certain drugs that either affect metabolism of Itraconazole or whose metabolism is affected by Itraconazole <b>Hypersensitivity</b> to Itraconazole <b>SIDE-EFFECT:</b> Nausea, rash, vomiting, edema, headache, diarrhea, fatigue, fever, pruritus, hypertension, abnormal hepatic function, abdominal	65mg Capsule 100mg Capsule 200mg Tablet	TGA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল শব্দ কারিটির নতুন বিক্রান্ত	উষধ নিয়ন্ত্রণ কমিটির বিক্রান্ত
	Incepta Pharmaceuticals Ltd., Zirabo, Dhaka Nwista Pharma Ltd.				meningeal histoplasmosis, and Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. Limitations of Use: It is not indicated for the treatment of onychomycosis. It is not interchangeable or substitutable with other itraconazole products	pain, dizziness, hypokalemia, anorexia, malaise, decreased libido, somnolence, albuminuria, impotence. <b>WARNINGS AND PRECAUTIONS:</b> Hepatotoxicity: Serious hepatotoxicity, including liver failure and death were reported with the use of itraconazole. Discontinue treatment if signs of liver dysfunction occur Cardiac Dysrhythmias: Life threatening cardiac dysrhythmias and/or sudden death have occurred in patients using certain drugs that are metabolized by human CYP450 enzymes concomitantly with oral itraconazole and/or other CYP3A4 inhibitors Peripheral Neuropathy: This has been reported in patients on long-term therapy with itraconazole. Monitor and promptly evaluate neurologic symptoms Hearing Loss: Reversible or permanent has been reported in patients. Discontinue treatment if hearing loss occurs.				
34.	Square Pharmaceuticals PLC, Salgaria, Patna Synovia Pharma PLC, Station Road, Tongi, Gazipur	Paracetamol 500 mg + Ibuprofen 150 mg Tablet	Paracetamol BP 500 mg + Ibuprofen BP 150mg	Analgasic and Antipyretic Therapeutic Code: 006	It is indicated for the treatment of temporary relief of pain associated with: headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, sore throat, arthritis, tennis elbow, period pain, muscular pain, rheumatic pain, aches and pains associated with colds and flu. Reduces fever.	<b>Warning:</b> Hepatotoxicity, cardiovascular and gastrointestinal risk. <b>Contraindications:</b> 1. patients with known hypersensitivity to acetylsalicylic acid, ibuprofen, other NSAIDs, or to any of the excipients in this product 2. patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients 3. the setting of coronary artery bypass graft (CABG) surgery <b>Adverse Reactions:</b> Common adverse reactions are nausea, vomiting, headache, dizziness, somnolence, post-procedural hemorrhage, and swelling of the face	New	TGA	খরোজন সেই বিষয় নামঞ্জুর করা যাবে।	খরোজন সেই বিষয় নামঞ্জুর করা যাবে।
35.	The ACME Laboratories Ltd. Dhamrai, Dhaka	Calcium (from Calcium carbonate) BP 800 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquione-7 (Vitamin K2) BP 180	Calcium (from Calcium carbonate) BP 800 mg + Colecalciferol USP (Vitamin D3 1000IU) 25	Metals, Salts, Minerals & Calcium Preparations Therapeutic Code: 062	*People at risk of Vitamin D, Vitamin K or Calcium insufficiency. *Those who identify as older adults/postmenopausal women. *People who want to support healthy bones.	<b>Contra-indications:</b> Contraindicated in patients with a known hypersensitivity to any of the ingredients. <b>Side effects:</b> Allergic sensitization has been reported following administration of folic acid	New	TGA	খরোজন সেই বিষয় নামঞ্জুর করা যাবে।	বর্তমানে খরোজন সেই বিষয় নামঞ্জুর করা যাবে।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কারিগরি সত্তার বিবরণ	ঔষধ নিয়ন্ত্রণ কার্যকরী পিনক্রাড
36.	The ACME Laboratories Ltd. Dharmrai, Dhaka	Calcium (from Calcium carbonate) BP 600 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquinone-7 (Vitamin K2) BP 180 micrograms Tablets	Calcium (from Calcium carbonate) BP 600 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquinone-7 (Vitamin K2) BP 180 micrograms	Metals, Salts, Minerals & Calcium Preparations Therapeutic Code: 062	*People at risk of Vitamin D, Vitamin K or Calcium insufficiency. *Those who identify as older adults/ postmenopausal women. *People who want to support healthy bones.	<b>Warning &amp; Precautions:</b> Always read the label and follow the directions for use. Do not take while on warfarin therapy without medical advice.  <b>Contra-indications:</b> Contraindicated in patients with a known hypersensitivity to any of the ingredients. <b>Side effects:</b> Allergic sensitization has been reported following administration of folic acid  <b>Warning &amp; Precautions:</b> Always read the label and follow the directions for use. Do not take while on warfarin therapy without medical advice.	New	TGA	ধরোজন লেই বিধায় নামজ্বরের সুপারিশ করা হয়।	নতুনকৈ ধরোজন লেই বিধায় নামজ্বরের সুপারিশ করা হয়।
37.	The ACME Laboratories Ltd. Dharmrai, Dhaka	Calcium (from Calcium carbonate (Oyster Shell Source)) BP 800 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquinone-7 (Vitamin K2) BP 180 micrograms Tablets	Calcium (from Calcium carbonate) BP 800 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquinone-7 (Vitamin K2) BP 180 micrograms	Metals, Salts, Minerals & Calcium Preparations Therapeutic Code: 062	*People at risk of Vitamin D, Vitamin K or Calcium insufficiency. *Those who identify as older adults/ postmenopausal women. *People who want to support healthy bones.	<b>Contra-indications:</b> Contraindicated in patients with a known hypersensitivity to any of the ingredients. <b>Side effects:</b> Allergic sensitization has been reported following administration of folic acid  <b>Warning &amp; Precautions:</b> Always read the label and follow the directions for use. Do not take while on warfarin therapy without medical advice.	New	TGA	ধরোজন লেই বিধায় নামজ্বরের সুপারিশ করা হয়।	ধরোজন লেই বিধায় নামজ্বরের সুপারিশ করা হয়।
38.	The ACME Laboratories Ltd. Dharmrai, Dhaka	Calcium (from Calcium carbonate (Oyster Shell Source)) BP 600 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquinone-7 (Vitamin K2) BP 180 micrograms Tablets	Calcium (from Calcium carbonate) BP 600 mg + Colecalciferol USP (Vitamin D3 1000IU) 25 micrograms + Menaquinone-7 (Vitamin K2) BP 180 micrograms	Metals, Salts, Minerals & Calcium Preparations Therapeutic Code: 062	*People at risk of Vitamin D, Vitamin K or Calcium insufficiency. *Those who identify as older adults/ postmenopausal women. *People who want to support healthy bones.	<b>Contra-indications:</b> Contraindicated in patients with a known hypersensitivity to any of the ingredients. <b>Side effects:</b> Allergic sensitization has been reported following administration of folic acid  <b>Warning &amp; Precautions:</b> Always read the label and follow the directions for use. Do not take while on warfarin therapy without medical advice.	New	TGA	ধরোজন লেই বিধায় নামজ্বরের সুপারিশ করা হয়।	ধরোজন লেই বিধায় নামজ্বরের সুপারিশ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য ডিউয়ান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কার্যকরী নামে পরিচিত	উর্ধ্ব নিয়ন্ত্রণ কার্যকরী নামে পরিচিত
39.	United Unl-health Pharmaceuticals Ltd., B.K Bari, Gazipur Sadar, Gazipur	Chlorhexidine Gluconate 0.30gm + Phenylephrine Hydrochloride 0.25gm/100gm Nasal Cream	(Chlorhexidine Gluconate Solution 20% BP 1.50gm eq. to Chlorhexidine Gluconate 0.30gm + Phenylephrine Hydrochloride BP 0.25gm/100gm	Antiseptic & Antihistamine	It is indicated for the post-operative care of nasal mucosa and as an aid in the treatment of nasal vestibulitis. It softens nasal crusts which helps to prevent drying and breakdown of the membranes. It also constricts blood vessels locally to prevent further bleeding.	<b>Contraindications:</b> Not for use by children less than 2 years of age. Not recommended for children 2 -6 years of ages except on medical advice. Nasalate should not be used for more than 7 consecutive days. If you have heart problems, high blood pressure or are taking anti-depressant medication see your doctor before using this product. Nasalate should not be used during pregnancy or lactation.	New	TGA	অনুসারনের সুপারিশ করা হয়।	অনুসারন করা হয়।
40.	Advanced Chemical Industries Limited, 7 Hajeagoni, Godnryl, Narayangonj	Benzyl Alcohol 6.50mg + Cetylpyridium Chloride 1.47mg Lozenge	Benzyl Alcohol BP 6.50mg + Cetylpyridium Chloride BP 1.47mg		It is used for rapidly numbs painful sore throats and helps to kill bacteria.	<b>Contraindications:</b> i. If you are pregnant or breast feeding it is recommended to consult a healthcare professional to ensure the lozenges are suitable for your needs. ii. Do not take hot food or drink soon after using this product because it may burn your mouth.	New	TGA	ধরোজন নেই বিধায় নামজ্ঞানের সুপারিশ করা হয়।	ধরোজন নেই বিধায় নামজ্ঞার করা হয়।
41.	Ziska Pharmaceuticals Ltd.	Ganirelix 250 µg (as acetate) /0.5 ml solution for injection pre-filled syringe	Ganirelix Acetate USP 259 mcg eq. to Ganirelix 250 µg/0.5ml	Therapeutic class: Anti-gonadotrophin releasing hormone	For the prevention of premature luteinization and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick up and assisted reproductive techniques.	<b>Contraindications:</b> Hypersensitivity to the active substance or to any of the components including natural rubber/latex - Hypersensitivity to GnRH or any other GnRH analogue - Pregnancy or lactation - Moderate to severe renal impairment and hepatic impairment. <b>Side effects:</b> General disorders and administrative site conditions Ganirelix may cause a skin reaction (in 10% - 15% of the patients moderate or severe redness with or without swelling was reported) at the site of injection, which normally disappears within 4 hours after administration. Malaise was reported in 0.3% of patients. Immune system disorders Very rarely, post-marketing cases of hypersensitivity reactions (including rash, facial swelling, dyspnea, anaphylaxis (including anaphylactic shock), angioedema, and urticaria) have been reported, as early as with the first dose, among patients administered ganirelix. Nervous system disorders Headache (0.4%) Gastrointestinal disorders Nausea	New	TGA	অনুসারনের সুপারিশ করা হয়।	অনুসারন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNEI / UKMHRA / EMA/PMDA / TGA	কোনকিভাবে সার করিষ্টিং সাক্ষর	ঔষধ নিয়ন্ত্রণ করিষ্টিং সাক্ষর
42.	Zsika Pharmaceuticals Ltd.	Dexchlorpheniramine Maleate 2 mg Tablet	Dexchlorpheniramine Maleate USP 2mg	Therapeutic Class: Histamine H1 antagonist	Indicated for the symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, mild manifestations of allergic skin, angioedema. It may relieve itching due to skin conditions such as allergic eczema, pruritus ani, pruritus vulvae, atopic dermatitis, contact dermatitis, insect bites, demographism and drug reactions, including serum sickness.	<p>(0.5%) Other reported adverse events are rather related to the controlled ovarian hyperstimulation treatment for assisted reproduction technique (ART) than to ganirelix (e.g., pelvic pain, abdominal distension, ovarian hyperstimulation syndrome (OHS), ectopic pregnancy and spontaneous abortion).</p> <p><b>Warnings and precautions:</b> Special care should be taken in women with signs and symptoms of active allergic conditions. Cases of hypersensitivity reactions (both generalized and local), have been reported with ganirelix, as early as with the first dose, during post-marketing surveillance. These events have included anaphylaxis (including anaphylactic shock), angioedema, and urticaria. Ovarian hyperstimulation syndrome (OHS) may occur during or following ovarian stimulation. OHS must be considered an intrinsic risk of gonadotropin stimulation. OHS should be treated symptomatically, e.g. with rest, intravenous infusion of electrolyte solutions or colloids and heparin. Since infertile women undergoing assisted reproduction, and particularly IVF, often have tubal abnormalities, the incidence of ectopic pregnancies might be increased. The safety and efficacy of ganirelix have not been established in women weighing less than 50 kg or more than 90 kg.</p> <p><b>Contraindications:</b> None.</p> <p><b>Side effects:</b> Stop taking this medicine and seek emergency medical attention if you experience an allergic reaction to dexchlorpheniramine:(difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives). Other, less common dexchlorpheniramine side effects may be more likely to occur. Continue to take this medicine and talk to your doctor if you experience</p> <ul style="list-style-type: none"> <li>• sleepiness, fatigue, or dizziness;</li> <li>• headache;</li> <li>• dry mouth; or</li> <li>• difficulty urinating or an enlarged</li> </ul>	New	TGA	ধরাজন লাই বিখার নামজ্ঞানের সুপারিশ করা হয়।	ধরাজন লাই বিখার নামজ্ঞান করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMHRA/EMA/PMDA/TGA	ক্রমিককরণ নাম কনিষ্ঠ নম্বর পিক্রাড	উষধ নিয়ন্ত্রণ কমিটির পিক্রাড
43.	Ziska Pharmaceuticals Ltd.	Phenylephrine Hydrochloride 5 mg + Paracetamol 500 mg Tablet	Phenylephrine Hydrochloride USP 5 mg + Paracetamol BP 500 mg	Therapeutic Class: Cough and cold medications	Temporary relief of the following cold & flu symptoms: nasal congestion, sinus pain, runny nose, headache, body aches & pains. Reduces fever. The night tablets also provide relief from sneezing and itchy or watery eyes, and assist rest by providing relief from these symptoms.	Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome. <b>Warnings and precautions:</b> Use caution when driving, operating machinery, or performing other hazardous activities. Dexchlorpheniramine may cause dizziness or drowsiness. If you experience dizziness or drowsiness, avoid these activities. <b>Contraindications:</b> None. <b>Side effects:</b> Not specified. <b>Warnings and precautions:</b> No Warnings included on Record.	New	TGA	প্রয়োজন নেই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
44.	Ziska Pharmaceuticals Ltd.	Paracetamol 500mg + Phenylephrine Hydrochloride 5mg + Chlorpheniramine maleate 2 mg Tablet	Paracetamol BP 500mg + Phenylephrine hydrochloride USP 5mg + Chlorpheniramine maleate BP 2 mg	Unclassified Agents Therapeutic code:075	Temporary relief of the following cold & flu symptoms: nasal congestion, sinus pain, runny nose, headache, body aches & pains. Reduces fever. The night tablets also provide relief from sneezing and itchy or watery eyes, and assist rest by providing relief from these symptoms.	<b>Contraindications:</b> Paracetamol: Paracetamol is contraindicated for use in patients with known hypersensitivity or idiosyncratic reaction to paracetamol (or any of the other ingredients in the product). Pseudoephedrine hydrochloride: Pseudoephedrine is contraindicated for use in patients with known hypersensitivity or idiosyncratic reaction to pseudoephedrine (or any of the other ingredients in the product), with severe hypertension or coronary artery disease; taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days. Chlorpheniramine maleate: Chlorpheniramine is contraindicated for use in patients with a history of hypersensitivity to the substance or substances of similar chemical structure (or any of the other ingredients in the product); narrow-angle glaucoma; stenosing peptic ulcer; symptomatic prostatic hypertrophy; bladder neck obstruction; pyloroduodenal obstruction. <b>Side effects:</b> Nausea, dyspepsia or vomiting • drowsiness or sleepiness • difficulty sleeping • nervousness • fatigue • headache • blurred vision • excitability • restlessness • dizziness • difficulty concentrating • lack of co-ordination • rapid heartbeat	New	TGA	প্রয়োজন নেই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার্ভিস কন্ট্রোল	তৃতীয় নিয়ন্ত্রণ কন্ট্রোল
45.	Zaska Pharmaceuticals Ltd.	Beta-carotene 1 mg + Docosahexaenoic acid (DHA) 100 mg + lutein 5 mg + Zeaxanthin 1 mg Capsule	Beta-carotene USP 1 mg + Docosahexaenoic acid (DHA) USP 100 mg + lutein USP 5 mg + Zeaxanthin USP 1mg	Therapeutic class: Vitamin & Minerals	Helps maintain/support healthy fetal CNS/brain development; Maintains/support healthy fetal development; Maintain / support healthy pregnancy; Maintain/support maternal health; Maintain/support preconception health.	<b>Contraindications:</b> Not found on report. <b>Side effects:</b> burping, changes in your sense of taste; loss of appetite, diarrhea, constipation, upset stomach; back pain; or dry mouth. <b>Warnings and precautions:</b> Contains soya bean products. Do not use it if the seal is broken or missing. Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.	New	TGA	প্রয়োজন নেই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
46.	Navana Pharmaceuticals Limited Incepta Pharmaceuticals Ltd.; Dharmal Unit.	Urea & Lactic Acid	Urea BP 10% & Lactic Acid BP 5% Cream	Skin and Mucous Membrane Preparations Therapeutic Code: 071	It is a moisturizing cream used for the supportive treatment of side effects on skin which arises due to chemotherapy by various neoplastic agents.	<b>Contraindications:</b> Hypersensitivity to the active substance or to any of the excipients. <b>Side Effects:</b> It may cause smarting or stinging pain, burning, itching that normally disappear upon discontinuing	New	UK MHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অডিটিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সাজসজ্জা	উৎস নিয়ন্ত্রণ কমিটির নিজস্ব
47.	Drug International Ltd. Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Treosulfan 250 mg Capsule	Treosulfan INN 250 mg	Anticancer Therapeutic Code No: 010	Treosulfan is indicated for the palliative treatment of epithelial ovarian cancer.	<p>the medication. If severe irritation occur, then it should be discontinued.</p> <p>Warnings and Precautions: It can cause smarting or stinging pain if applied to raw areas, fissures or mucous membranes. It should be avoided to contact with eyes, lips or mucous membranes.</p> <p><b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Treosulfan or any other components of this product.</p> <p><b>Precaution: Risk of infections:</b> The risk of infections (mycotic, viral, and bacterial) may be increased. <b>Haematological effects and monitoring of blood count:</b> The dose-limiting side effect of treosulfan is myelosuppression, which is usually reversible. It is manifested by a reduction in leukocytes and platelets and a decrease in haemoglobin. The leukocytes and platelets usually reach their baseline level after 28 days. <b>Risk of malignancy:</b> The risk is depending on the cumulative dose of treosulfan. Single cases of myeloma, myelodysplastic disorder and myelodysplastic syndrome have additionally been reported. <b>Pulmonary toxicity:</b> If allergic alveolitis or pulmonary fibrosis develop, treosulfan should be permanently discontinued. <b>Risk of cystitis:</b> Due to the possible development of a haemorrhagic cystitis, patients are advised to drink more fluids for up to 24 hours after intravenous infusion. <b>Renal impairment:</b> As Treosulfan is excreted renally, blood counts should be carefully monitored in patients with renal impairment and the dose adjusted accordingly. <b>Warning:</b> As per precaution.</p> <p><b>Side effects:</b> Most common side effects are viral, bacterial infections, myeloma, myeloproliferative disorder, leukocytopenia, thrombocytopenia, anaemia. Allergic reactions etc.</p>	New	UKMHRA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	উৎপাদনের ক্ষমতা নির্ধারণ করা হয়েছে	ক্রয় নিয়ন্ত্রণ করা হয়েছে
48.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Treosulfan 1.00gm/vial Injection	Treosulfan INN 1.00gm/vial	Anticancer Therapeutic Code No: 010	Treosulfan is indicated for the palliative treatment of epithelial ovarian cancer.	<b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Treosulfan or any other components of this product. <b>Precaution:</b> <b>Risk of infections:</b> The risk of infections (mycotic, viral, and bacterial) may be increased. <b>Haematological effects and monitoring of blood count:</b> The dose-limiting side effect of Treosulfan is myelosuppression, which is usually reversible. It is manifested by a reduction in leukocytes and platelets and a decrease in haemoglobin. The leukocytes and platelets usually reach their baseline level after 28 days. <b>Risk of malignancy:</b> The risk is depending on the cumulative dose of treosulfan. Single cases of myeloma, myeloproliferative disorder and myelodysplastic syndrome have additionally been reported. <b>Pulmonary toxicity:</b> If allergic alveolitis or pulmonary fibrosis develop, Treosulfan should be permanently discontinued. <b>Risk of cystitis:</b> Due to the possible development of a haemorrhagic cystitis, patients are advised to drink more fluids for up to 24 hours after intravenous infusion. <b>Renal impairment:</b> As Treosulfan is excreted renally, blood counts should be carefully monitored in patients with renal impairment and the dose adjusted accordingly. <b>Warning:</b> As per precaution. <b>Side effects:</b> Most common side effects are viral, bacterial infections, myeloma, myeloproliferative disorder, leukocytopenia, thrombocytopenia, anaemia, Allergic reactions etc.	New	UKMHRA	উৎপাদনের ক্ষমতা নির্ধারণ করা হয়েছে	ক্রয় নিয়ন্ত্রণ করা হয়েছে
49.	Drug International Ltd, 31/1, Sakrong, Tongi I/A, Gazipur	Buserelin as Buserelin Acetate 1.00mg/ml Injection	Buserelin INN as Buserelin Acetate 1.00mg/ml	Hormone Therapeutic Code: 056	The palliative treatment (initial and maintenance treatment) of patients with hormone-dependent advanced carcinoma of the prostate gland (Stage D)	<b>Contraindications:</b> It is Contraindicated in this drug is contraindicated in- Hypersensitivity, prostate cancer, women who are breast-feeding, females having undiagnosed abnormal vaginal bleeding etc. <b>Precaution:</b> It should not be administered in the following conditions: endometriosis and prostate cancer etc.	New	UKMHRA	উৎপাদনের ক্ষমতা নির্ধারণ করা হয়েছে	ক্রয় নিয়ন্ত্রণ করা হয়েছে

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিউজ্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/ UKMHRA/EMA/PMDA/TGA	টেকনিক্যাল সার কন্ট্রিবিউশন	ইংরেজি নিয়ন্ত্রণ কন্ট্রিবিউশন
50.	Drug International Ltd., 31/1, Satrong, Tongi IA, Gazipur  Incepta Pharmaceuticals Ltd.; Ztrabo, Dhaka  Opsonin Pharma Ltd., Barisal	Docusate Sodium 250mg/100ml Pediatric Drops	Docusate Sodium USP 250.00mg/100ml	Laxative Therapeutic Code: 060	It is indicated to prevent and treat chronic constipation and as an adjunct in abdominal radiological procedure.	<b>Warning:</b> As per precaution. <b>Side effects:</b> Certain adverse effects (e.g. dizziness) may impair the patient's ability to concentrate and react, and therefore, constitute a risk in situations where these abilities are of special importance (e.g. operating a vehicle or machinery). <b>Contraindication:</b> It is contraindicated in patients with known to have hypersensitivity to the active ingredient or any other component of this drug. This is also contraindicated in the presence of abdominal pain, intestinal obstruction, nausea or if vomiting occurs. <b>Precaution:</b> Docusate Sodium should not give to infants under six months. Prolonged use can precipitate the onset of an atonic non-functioning colon and hypokalemia. <b>Warning:</b> As with all laxatives, do not give Docusate Sodium Paediatric every day for a long time <b>Side effects:</b> Stimulant laxatives increase intestinal motility and often cause abdominal cramp. There have been spontaneous reports of burning sensation in mouth and throat following the use of Typharm Docusate Sodium Pediatric patients are advised to drink plenty of water of flavored drink after taking the solution.	Docusate Sodium 100mg Capsule	UKMHRA	অনুরোধের সুপারিশ করা হয়।	অনুরোধের সুপারিশ করা হয়।
51.	Eskayel Pharmaceuticals Limited, Tongi, Gazipur  General Pharmaceutical Ltd., (Unit-2) Gazipur	Xylometazoline Hydrochloride 0.1mg + Dexpanthanol 5mg Nasal Spray	Xylometazoline Hydrochloride USP 0.1mg + Dexpanthanol BP 5mg/100µL	Ear & Nose Preparations Therapeutic Code: 050	It is used for reducing the swelling of the inflamed nasal mucous membrane (rhinitis) and relieving the symptoms of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis (vasomotor rhinitis) or other respiratory tract allergies. This medicine is intended for use in adults and children aged 12 years or over.	<b>CONTRAINDICATIONS:</b> <ul style="list-style-type: none"> <li>Hypersensitivity to the active substances or to any of the excipients</li> <li>Contraindicated in children under 12 years of age</li> <li>Contraindicated in individuals with dry inflammation of the nasal mucosa (rhinitis sicca)</li> <li>Contraindicated in individuals who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks</li> <li>Contraindicated in individuals with a history of transsphenoidal hypophysectomy or other surgical interventions which expose the dura mater.</li> </ul>	Xylometazolin e Hydrochloride 0.05%, 0.1% Nasal Drops/ Nasal Spray Sodium Chromoglycate 2% + Xylometazolin e Hydrochloride 0.025% Nasal Drops	UKMHRA	প্রয়োজন নেই বিষয় নামগুলোর সুপারিশ করা হয়।	প্রয়োজন নেই বিষয় নামগুলোর সুপারিশ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	উৎপাদনকারী/ কনিষ্ঠার নাম/ ঠিকানা	উৎপাদনকারী/ কনিষ্ঠার ঠিকানা
52.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Xylometazoline Hydrochloride 70mcg + Ipratropium Bromide 84mcg Nasal Spray	Xylometazoline Hydrochloride USP 70mcg + Ipratropium Bromide 84mcg /140µL BP	Ear & Nose Preparations Therapeutic Code: 050	This Nasal spray is a combination medicinal product consisting of two different substances (xylometazoline hydrochloride and ipratropium bromide). One of the active ingredients (ipratropium bromide) helps with the runny nose; the other (xylometazoline hydrochloride) has a decongesting effect. This Nasal spray is used for the treatment of nasal congestion with runny nose (rhinorrhoea) in connection with common colds.	<p><b>CONTRA-INDICATIONS:</b></p> <ul style="list-style-type: none"> <li>It should not be given to children under the age of 18 due to lack of sufficient documentation.</li> <li>Hypersensitivity to the active substances or to any of the excipients</li> <li>Hypersensitivity to atropine or atropine like substances such as, hyoscyamine and scopolamine.</li> <li>After surgical operations where dura mater may have been penetrated, e.g. trans-sphenoidal hypophysectomy or other trans-nasal operations.</li> <li>Glaucoma.</li> <li>Rhinitis sicca or atrophic rhinitis</li> </ul> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <p>This medicinal product may be used only after a careful assessment of the risks and benefits in cases of:</p> <ul style="list-style-type: none"> <li>increased intraocular pressure, especially narrow-angle glaucoma,</li> <li>serious heart and circulatory diseases (e.g. coronary heart disease, hypertension),</li> <li>phaeochromocytoma,</li> <li>metabolic disorders (e.g. hyperthyroidism, diabetes),</li> <li>porphyria,</li> <li>prostate hyperplasia.</li> </ul> <p><b>WARNING AND PRECAUTIONS:</b></p> <p>This medicinal product may be used only after a careful assessment of the risks and benefits in cases of:</p> <ul style="list-style-type: none"> <li>increased intraocular pressure, especially narrow-angle glaucoma,</li> <li>serious heart and circulatory diseases (e.g. coronary heart disease, hypertension),</li> <li>phaeochromocytoma,</li> <li>metabolic disorders (e.g. hyperthyroidism, diabetes),</li> <li>porphyria,</li> <li>prostate hyperplasia.</li> </ul>	<p>Sodium Cromoglycate 0.003% + Xylometazolin e Hydrochloride 0.033% Nasal Spray</p>	UKMHRA ??	এসকায়ফ লিমিটেড বিখ্যাত নামগুলোর মুখাবলি করা হয়।	এসকায়ফ লিমিটেড বিখ্যাত নামগুলোর মুখাবলি করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার্ভিস কন্ট্রোল সার্ভিস	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
53.	Square Lifesciences Ltd., Hemayetpur,	Sinethicone 300mg + Alverine Citrate 60mg	Sinethicone BP 300mg + Alverine	Anticholinergic	It is indicated for the relief of abdominal pain in irritable bowel syndrome	<p>using this Nasal spray and seek medical help immediately if you have any of the following:</p> <ul style="list-style-type: none"> <li>• Palpitations and increased heart rate (affects less than 1 in 100 people)</li> <li>• Signs of an allergic reaction as difficulty breathing, speaking or swallowing; swelling of the face, lips, tongue or throat; severe itching of the skin, with a red rash or raised bumps (frequency not known cannot be estimated from available data)</li> <li>• disturbances of vision (including blurred vision, worsening of glaucoma or increased pressure in the eye), rainbow-coloured circles/halos around bright lights and/or eye pain (frequency not known cannot be estimated from available data)</li> </ul> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <p>The medicinal product must be used with caution in patients who are sensitive to adrenergic substances, which may give symptoms such as sleeping disturbances, dizziness, tremor, cardiac arrhythmias or elevated blood pressure. The medicinal product must be administered with caution to patients with:</p> <ul style="list-style-type: none"> <li>• Heart disease (e.g. long QT syndrome)</li> <li>• Raised blood pressure</li> <li>• Diabetes</li> <li>• An overactive thyroid gland (hyperthyroidism)</li> <li>• Difficulty in urinating and/or an enlarged prostate gland</li> <li>• Narrow-angle glaucoma (sudden build-up of pressure in the eye)</li> <li>• A tendency to have nosebleeds</li> <li>• Obstruction of the intestine (paralytic ileus).</li> <li>• Cystic fibrosis</li> <li>• Benign tumour of the adrenal gland that produces high amounts of adrenaline and nor-adrenaline (phaeochromocytoma) or a particular sensitivity to adrenaline and nor-adrenaline</li> </ul> <p><b>Contraindication:</b> It should not be used in Paralytic ileus condition and if there is intestinal obstruction.</p>	<p>0.003% + Xylometazolin e Hydrochloride 0.033% Nasal Spray</p> <p>Ipratropium Bromide 20 mcg/Spray Spray</p> <p>Ipratropium Bromide 250 mcg/ml Solution</p> <p>Ipratropium Bromide 0.04% + Salbutamol 0.12% Nebuliser Solution</p> <p>Ipratropium Bromide 20 mcg + Salbutamol 100 mcg/Metered Inhalation Aerosol Inhalation</p>	UKMHRA	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেজিনিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কার্ভার সভার সিদ্ধান্ত	উপর নিয়ন্ত্রণ কার্ভার সিদ্ধান্ত
54.	Square Pharmaceuticals PLC, Salgara, Palna  Opsonin Pharma Limited, Rupatali, Barishal	Xylometazoline Hydrochloride 0.50mg + Ipratropium Bromide 0.60 mg / ml Nasal Spray	Xylometazoline Hydrochloride USP 0.500 mg + Ipratropium Bromide BP 0.600 mg / ml	Ear and Nose preparations Therapeutic Code: 050	Symptomatic treatment of nasal congestion and rhinorrhea in connection with common colds.	<b>Contraindications:</b> It should not be given to children under the age of 18 due to lack of sufficient documentation. Hypersensitivity to the active substances. Hypersensitivity to atropine or atropine like substances such as, hyoscyamine and scopolamine. After surgical operations where dura mater may have been penetrated, e.g. trans-sphenoidal hypophysectomy or other trans-nasal operations. Glaucoma. Rhinitis sicca or atrophic rhinitis. <b>Side effects:</b> Nasal discomfort, congestion of the nose, dry nose, pain in the nose, altered taste sensation, headache, dizziness, local burning sensation.	Sodium Cromoglycate 0.003% + Xylometazolin e Hydrochloride 0.033% Nasal Spray	UKMHRA	ধরোজন তর্ক বিখ্য নামস্থর বিখ্য নামস্থর করা হয়।	ধরোজন তর্ক বিখ্য নামস্থর করা হয়।
55.	Navana Pharmaceuticals Limited  EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagol, BANGLADESH	Orphenadrine 25 mg + Aspirin 385 mg + Caffeine 30 mg Tablet	Orphenadrine USP 25 mg + Aspirin BP 385 mg + Caffeine BP 30 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	<b>Contraindications:</b> Because of the mild anti-cholinergic effect of Orphenadrine, Norgescic Forte Tablets should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy, or obstructions at the bladder neck. Norgescic 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. <b>Side Effects:</b> Dry mouth, blurred vision, dilatation of the pupil, increased intracocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, and rarely, urticaria and other dermatoses.	New	US FDA	ধরোজন তর্ক বিখ্য নামস্থর বিখ্য নামস্থর করা হয়।	ধরোজন তর্ক বিখ্য নামস্থর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিউয়ান রেজিস্ট্রেশন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMERA/ EMA/ PMDA/ TGA	টেকনিক্যাল সার্ভিস কর্তৃক সার্ভিস	ড্রাগ নিয়ন্ত্রণ কর্তৃক সার্ভিস
56.	ACI HealthCare Limited, Sonargaon Museum Gate-1 Road, Teepondi, Sonargaon, Narayanganj  EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kancharpur, Narayanagnj  Opsonin Pharma Ltd., Barishal	Bupropion Hydrochloride 300 mg Extended Release Tablet	Bupropion Hydrochloride USP 300 mg	Therapeutic class: Anti-depressant Therapeutic Code: 014	It is indicated in -Major Depressive Disorder (MDD) - Seasonal Affective Disorder (SAD).	<p>Warnings and Precautions: Reye's Syndrome may develop in individuals who have chicken pox, influenza, or flu symptoms. Some studies suggest possible association between the development of Reye's Syndrome and the use of medicines containing salicylate or aspirin. Orphenadrine Citrate, Aspirin and Caffeine Tablets 25 mg/ 385 mg/ 30 mg contain aspirin and therefore are not recommended for use in patients with chicken pox, influenza, or flu symptoms. Orphenadrine Citrate, Aspirin and Caffeine Tablets may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly. Aspirin should be used with extreme caution in the presence of peptic ulcers and coagulation abnormalities.</p> <p>Contraindication: • seizure disorder. • In patients with a current or prior diagnosis of bulimia or anorexia nervosa as a higher incidence of seizures was observed in such patients treated with Bupropion Hydrochloride Extended Release (XL) Tablets. • in patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs. • Increased risk of hypertensive reactions when Bupropion Hydrochloride Extended Release (XL) Tablets are used concomitantly with MAOIs. • The use of Bupropion Hydrochloride Extended Release (XL) Tablets within 14 days of discontinuing treatment with an MAOI is also contraindicated.</p>	150mg SR Tablet	USFDA	অনুরোধের মাধ্যমে করা হবে।	অনুরোধের মাধ্যমে করা হবে।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMBA/ EMA/PMDA/ TGA	উৎপাদনকারী শার কনিষ্ঠার সত্তার চিহ্ন	উৎপাদনকারী শার কনিষ্ঠার চিহ্ন
57.	Advanced Chemical Industries Limited, 7 Hajeeganj, Godnyl, Narayangonj.	Fluticasone Furoate 50mcg + Vilanterol 25 mcg Dry Powder Inhaler	Fluticasone Furoate INN 50mcg + Vilanterol Trifenatate INN 39.80 mcg eqv. to Vilanterol 25mcg	Drug used in Bronchial Asthma. Chronic obstructive pulmonary disease (COPD) Therapeutic Code: 044	This combination is indicated for- 1) The maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), 2) The maintenance treatment of asthma in patients aged 5 years and older. <b>Important limitation of use:</b> This combination is not indicated for the relief of acute bronchospasm.	<ul style="list-style-type: none"> <li>patient treated with reversible MAOIs such as linezolid or intravenous methylene blue is contraindicated.</li> </ul> <b>Side effects:</b> dry mouth, sore throat, stuffy nose, ringing in the ears, insomnia, confusion, agitation, hostility, nausea, vomiting, stomach pain, loss of appetite, constipation etc.	1) Fluticasone Furoate 100 µg + Vilanterol 25 µg Dry Powder Inhaler 2) Fluticasone Furoate 200 µg + Vilanterol 25 µg Dry Powder Inhaler Capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
58.	Beacon Pharmaceuticals PLC Kathali, Bhatuka, Mymensingh	Gemcitabine 2.0gm/52.6 ml Solution for Injection	Gemcitabine Hydrochloride USP 2.0gm/52.6 ml (38 mg/ml)	Anti-cancer Therapeutic Code:010	Gemcitabine Injection is a nucleoside metabolic inhibitor indicated: <ul style="list-style-type: none"> <li>in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.</li> <li>in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines</li> </ul>	<b>Contraindications:</b> Patients with a known hypersensitivity to gemcitabine.  <b>Side-Effect:</b> The most common adverse reactions for the single agent (≥20%) are nausea/vomiting, anemia, hepatic transaminitis, neutropenia, increased alkaline phosphatase, proteinuria, fever, hematuria, rash, thrombocytopenia, dyspnea, and peripheral edema	200mg, 1.0gm Capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	ঔষধ নিয়ন্ত্রণ সচিবালয় সচিবের কার্যালয়	ঔষধ নিয়ন্ত্রণ কর্তৃক সনাক্ত
59.	Beacon Pharmaceuticals PLC Kathail, Bhaluka, Mymensingh	Sodium Nitroprusside 50mg Solution	Sodium Nitroprusside USP 50mg/100ml	Cerebral Vasodilator Therapeutic Code:036	<p>Sodium nitroprusside is a direct acting vasodilator indicated for:</p> <ul style="list-style-type: none"> <li>• Immediate reduction of blood pressure</li> <li>• Producing controlled hypotension to reduce bleeding during surgery</li> <li>• Treatment of acute heart failure to reduce left ventricular end-diastolic pressure, pulmonary capillary wedge pressure, peripheral vascular resistance and mean arterial blood pressure</li> </ul>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Diseases with compensatory hypertension (e.g. coarctation of the aorta, arteriovenous shunting) (4).</li> <li>• Inadequate cerebral circulation or moribund patients (A.S.A. Class 5E) coming to emergency surgery</li> <li>(4), • Congenital (Leber's) optic atrophy or tobacco amblyopia (4).</li> <li>• Acute heart failure with reduced peripheral vascular resistance (4).</li> <li>• Concomitant use with sildenafil, tadalafil, vardenafil or riociguat (4)</li> </ul> <p><b>Side-Effect:</b> Most common adverse reactions are hypotension and cyanide toxicity (6).</p>	New	USFDA	ঔষধ নিয়ন্ত্রণ সচিবালয় সচিবের কার্যালয় করা হয়।	ঔষধ নিয়ন্ত্রণ কর্তৃক সনাক্ত করা হয়।
60.	Beacon Pharmaceuticals PLC Kathail, Bhaluka, Mymensingh	Ibrutinib 280mg Tablet	Ibrutinib INN 280mg	Anti-cancer Therapeutic Code:010	<p>It is a kinase inhibitor indicated for the treatment of adult patients with:</p> <ul style="list-style-type: none"> <li>• Mantle cell lymphoma (MCL) who have received at least one prior therapy (1, 1). Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</li> <li>• Chronic lymphocytic leukemia (CLL)</li> <li>• Small lymphocytic lymphoma (SLL)</li> <li>• Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion</li> </ul>	<p><b>Contraindication</b> None</p> <p><b>Side-effects:</b> The most common adverse reactions (<math>\geq 20\%</math>) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia, thrombocytopenia, diarrhea, anemia, musculoskeletal pain, rash, nausea, bruising, fatigue, hemorrhage, and pyrexia (6). The most common adverse reactions (<math>\geq 20\%</math>) in patients with cGVHD were fatigue, bruising, diarrhea, thrombocytopenia, muscle spasms, stomatitis, nausea, hemorrhage, anemia, and pneumonia.</p> <p><b>WARNING AND PRECAUTIONS</b> Hemorrhage: Monitor for bleeding and manage</p> <ul style="list-style-type: none"> <li>• Infections: Monitor patients for fever and infections, evaluate promptly, and treat (5,2).</li> <li>• Cytopenias: Check complete blood counts monthly</li> </ul>	140mg capsule	USFDA	ঔষধ নিয়ন্ত্রণ সচিবালয় সচিবের কার্যালয় করা হয়।	ঔষধ নিয়ন্ত্রণ কর্তৃক সনাক্ত করা হয়।

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	ডাক্তারিকাল শর্ত কারিটির সত্তার সিদ্ধান্ত	ড্রাগ নিয়ন্ত্রণ কারিটির সিদ্ধান্ত
61.	Beacon Pharmaceuticals PLC, Kathal, Bhalka, Mymensingh EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kancharpur, Narayanagari	Ibuprofen 420mg Tablet	Ibuprofen INN 420mg	Anti-cancer Therapeutic Code:010	<p>It is a kinase inhibitor indicated for the treatment of adult patients with:</p> <ul style="list-style-type: none"> <li>• Mantle cell lymphoma (MCL) who have received at least one prior therapy (1.1). Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</li> <li>• Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)</li> <li>• Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)</li> <li>• Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy (1.5). Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication</li> </ul>	<p><b>Contraindication Note</b></p> <p><b>Side-effects:</b> The most common adverse reactions (<math>\geq 20\%</math>) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia, thrombocytopenia, diarrhea, anemia, musculoskeletal pain, rash, nausea, bruising, fatigue, hemorrhage, and pyrexia (6). The most common adverse reactions (<math>\geq 20\%</math>) in patients with cGVHD were fatigue, bruising, diarrhea, thrombocytopenia, muscle spasms, stomatitis, nausea, hemorrhage, anemia, and pneumonia.</p> <p><b>WARNING AND PRECAUTIONS Hemorrhage:</b></p> <p>Monitor for bleeding and manage</p> <ul style="list-style-type: none"> <li>• Infections: Monitor patients for fever and infections, evaluate promptly, and treat (5.2).</li> <li>• Cytopenias: Check complete blood counts monthly</li> <li>• Cardiac arrhythmias: Monitor for symptoms of arrhythmias and manage</li> <li>• Hypertension: Monitor blood pressure and treat</li> <li>• Second Primary Malignancies: Other malignancies have occurred in patients, including skin cancers, and other carcinomas</li> <li>• Tumor Lysis Syndrome (TLS): Assess baseline risk and take precautions. Monitor and treat for TLS</li> <li>• Embryo-Fetal Toxicity: Can cause fetal harm.</li> </ul>	140mg capsule	USFDA	ডাক্তারিকাল শর্ত সূপারিশ করা হয়।	ড্রাগ নিয়ন্ত্রণ করা হয়।



**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কন্ট্রোল সত্তার বিস্তার	ঔষধ নিয়ন্ত্রণ কমিটির বিস্তার
62	Beacon Pharmaceuticals PLC Kathal, Bhalka, Mymensingh	Ibrutinib 560mg Tablet	Ibrutinib INN 560mg	Anti-cancer Therapeutic Code:010	<p>It is a kinase inhibitor indicated for the treatment of adult patients with:</p> <ul style="list-style-type: none"> <li>• Mantle cell lymphoma (MCL) who have received at least one prior therapy (1.1). Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</li> <li>• Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)</li> <li>• Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)</li> <li>• Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy (1.5). Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</li> <li>• Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy</li> </ul>	<p>Advise women of the potential risk to a fetus and to avoid pregnancy while taking the drug and for 1 month after cessation of therapy. Advise men to avoid fathering a child during the same time period (5.8, 8.3)</p> <p><b>Contraindication</b> None</p> <p><b>Side-effects:</b> The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia, thrombocytopenia, diarrhea, anemia, musculoskeletal pain, rash, nausea, bruising, fatigue, hemorrhage, and pyrexia (6). The most common adverse reactions (≥20%) in patients with cGVHD were fatigue, bruising, diarrhea, thrombocytopenia, muscle spasms, stomatitis, nausea, hemorrhage, anemia, and pneumonia.</p> <p><b>WARNING AND PRECAUTIONS</b> Hemorrhage:</p> <ul style="list-style-type: none"> <li>• Monitor for bleeding and manage</li> <li>• Infections: Monitor patients for fever and infections, evaluate promptly, and treat (5.2).</li> <li>• Cytopenias: Check complete blood counts monthly</li> <li>• Cardiac arrhythmias: Monitor for symptoms of arrhythmias and manage</li> <li>• Hypertension: Monitor blood pressure and treat</li> <li>• Second Primary Malignancies: Other malignancies have occurred in patients, including skin cancers, and other carcinomas</li> <li>• Tumor Lysis Syndrome (TLS): Assess baseline risk and take precautions. Monitor and treat for TLS</li> <li>• Embryo-Fetal Toxicity: Can cause fetal harm. Advise women of the potential risk to a fetus and to avoid pregnancy while taking the drug and for 1 month after cessation of therapy. Advise men to avoid fathering a child during the same time period (5.8, 8.3)</li> </ul>	140mg capsule	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

**Annex-A: স্থানীয়ভাবে উপাদানের জন্য বিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম করণের শর্তাদি ফিলাজ	ড্রাগ নিয়ন্ত্রণ করণের শর্তাদি ফিলাজ
63.	Beacon Pharmaceuticals PLC, Kathali, Bhaluka, Mymensingh  Ziska Pharmaceuticals Ltd. Gazipur	Anacaulase-bocb 8.8% Gel	Anacaulase-bocb INN 8.8%	Skin and Mucous Membrane Preparations  Therapeutic Code:071	It contains proteolytic enzymes and is indicated for eschar removal in adults with deep partial thickness and/or full thickness thermal burns • Limitations of Use The safety and effectiveness of NEXOBRID have not been established for treatment of: • Chemical or electrical burns • Burns on the face, perineum, or genitalia • Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease • Circumferential burns • Burns in patients with significant cardiopulmonary disease, including inhalation injury (1). NEXOBRID is not recommended for wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance (1)	<b>Contraindication</b> Known hypersensitivity to anacaulase-bocb, bromelain, pineapples, or to any of the other components (4). • Known hypersensitivity to papayas or papain because of the risk of cross-sensitivity  <b>Side-effects:</b> The most common adverse reactions (>10%) were pruritus and pyrexia <b>WARNING AND PRECAUTIONS</b> Hypersensitivity reactions: Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulasebocb. If a hypersensitivity reaction occurs, remove NEXOBRID (if applicable) and initiate appropriate therapy (5.1). • Pain: Manage pain as appropriate for an extensive dressing change of burn wounds. At least 15 minutes prior to NEXOBRID-related procedures ensure adequate pain control measures are in place	New	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।
64.	Beacon Pharmaceuticals PLC  Kathali, Bhaluka, Mymensingh	Anacaulase-bocb 1.940gm/20mL Gel	Anacaulase-bocb INN 1.940gm/20mL	Skin and Mucous Membrane Preparations  Therapeutic Code:071	It contains proteolytic enzymes and is indicated for eschar removal in adults with deep partial thickness and/or full thickness thermal burns • Limitations of Use The safety and effectiveness of NEXOBRID have not been established for treatment of: • Chemical or electrical burns • Burns on the face, perineum, or genitalia • Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease • Circumferential burns • Burns in patients with significant cardiopulmonary disease, including inhalation injury (1). NEXOBRID is not recommended for wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the	<b>Contraindication</b> Known hypersensitivity to anacaulase-bocb, bromelain, pineapples, or to any of the other components (4). • Known hypersensitivity to papayas or papain because of the risk of cross-sensitivity  <b>Side-effects:</b> The most common adverse reactions (>10%) were pruritus and pyrexia <b>WARNING AND PRECAUTIONS</b> Hypersensitivity reactions: Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulasebocb. If a hypersensitivity reaction occurs, remove NEXOBRID (if applicable) and initiate appropriate therapy (5.1). • Pain: Manage pain as appropriate for an extensive dressing change of burn wounds. At least 15 minutes prior to NEXOBRID-related procedures ensure adequate pain control measures are in place	New	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মোডিফিন এর তালিকা**

Sl. No.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class and Code	Indication	Contraindication, Side-effects, Warnings and Precautions	Status (New / Existing Molecule)	USFDA / BNF / UKMHRRA / EMA/PMDA / TGA	উৎপাদনের সব কর্মটির সত্যতা নিশ্চিত	উৎপাদন নিয়ন্ত্রণ কর্মটির সত্যতা নিশ্চিত
65.	Beacon Pharmaceuticals PLC, Kathail, Bhaluka, Mynenshgh	Zuranolone 25 mg Capsule	Zuranolone INN/in-house 25mg	Therapeutic Class: Antidepressants Therapeutic Code: 014	product and an increased risk of spreading the noxious substance. Zuranolone is in pre-registration for major depressive disorder and postpartum depression, phase II clinical trials for insomnia, and phase II clinical studies for bipolar depression, essential tremor, and Parkinson's disease. Zuranolone is being evaluated as a short-course, rapid-acting, oral medication for major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone has been granted Fast Track and Breakthrough Therapy Designation for MDD and Fast Track Designation for PPD by the U.S. Food & Drug Administration. It is also being studied for other indications, such as insomnia, bipolar depression, essential tremor, and Parkinson's disease.	<b>Contraindication:</b> Do not use if you are allergic to zuranolone or any of the ingredients. Zuranolone may cause allergic reactions, such as rash, itching, swelling, or trouble breathing. <b>Side-effects:</b> Zuranolone is an investigational medication that is under development for the treatment of depressive disorders and other conditions. It is a neurosteroid that acts on the GABA A receptor in the brain. Some of the possible side effects of zuranolone include: Drowsiness, Headache, Dizziness, Upper respiratory tract infection, Diarrhea, Sedation & Confusion <b>Warnings and Precautions:</b> Zuranolone is an investigational medication that is being developed for the treatment of depressive disorders and other conditions. It is a neuroactive steroid that acts as a positive allosteric modulator of the GABA A receptor, which is the major inhibitory signaling pathway of the brain and central nervous system. According to the web sources, some of the possible precautions of zuranolone are: It may cause drowsiness, dizziness, or impaired coordination. Do not drive or operate machinery until you know how it affects you. It may interact with other medications that affect the GABA system, such as benzodiazepines, barbiturates, opioids, or alcohol. Consult your doctor before taking zuranolone with any of these substances. It may cause hormonal changes, such as decreased progesterone levels or menstrual irregularities. Women who are pregnant, breastfeeding, or planning to become pregnant should not take zuranolone without medical supervision. It may cause allergic reactions, such as rash, itching, swelling, or trouble breathing. Seek immediate medical attention if you experience any of these symptoms. It may cause withdrawal symptoms if stopped	New	USFDA	অন্যোপদানের সুপারিশ করা হয়।	অন্যোপদান করা হয়।
	Healthcare Pharmaceuticals Ltd									
	Eskayef Pharmaceuticals Limited, Rugganj, Narayanganj									
	The ACME Laboratories Ltd. Dhamrai, Dhaka									
	General Pharmaceutical Ltd., Gazipur									
	One Pharma Ltd., Plot No. C23-24, BSCIC, Bogura									
	Opsonin Pharma Limited, Rupatali, Barishal									

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ IGA	টেকনিক্যাল নাম কিভাবে	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
65.	Beacon Pharmaceuticals PLC, Kathail, Bhairuka, Mymensingh Incepta Pharmaceuticals Ltd., Dharmrai Unit, Dhaka Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtail I/A, Dhaka Nuvisia Pharma Ltd., Tongi, Gazipur Ziska	Clindamycin Phosphate 1.2gm + Adapalene 0.15gm + Benzoyl Peroxide 3.1gm/100gm Tropical Gel	Clindamycin Phosphate BP 1.2gm + Adapalene BP 0.15gm + Benzoyl Peroxide USP 3.1gm/100gm	Skin and Mucous Membrane Preparations Therapeutic Code:071	It is a combination of clindamycin phosphate (a lincosamide antibacterial), adapalene (a retinoid), and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older.	abruptly after long-term use. Follow your doctor's instructions on how to taper off zuranone gradually.	New	USFDA	ধরোজন লাই বিধায় নামঞ্জুর করা মুণ্ডাশিল করা হ্যাঁ।	ধরোজন লাই বিধায় নামঞ্জুর করা হ্যাঁ।

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কার্ভার সভার সিদ্ধান্ত	উপর নিয়ন্ত্রণ কার্ভার সিদ্ধান্ত
67.	Beacon Pharmaceuticals PLC, Kathail, Bhaluka, Mymensingh	Baclofen 20mg Tablet	Baclofen BP 20mg	Skeleton Muscle Relaxan Therapeutic Code:070	It is useful for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Patients should have reversible spasticity so that treatment with baclofen will aid in restoring residual function. Baclofen may also be of some value in patients with spinal cord injuries and other spinal cord diseases. Baclofen is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. The efficacy of Baclofen in stroke, cerebral palsy, and Parkinson's disease has not been established and, therefore, it is not recommended for these conditions.	<b>Contraindications:</b> It is contraindicated in patients who are hypersensitive to any component of this product. <b>Side effect:</b> The most common adverse reaction during treatment with baclofen is transient drowsiness (10-63%). In one controlled study of 175 patients, transient drowsiness was observed in 63% of those receiving baclofen tablets compared to 36% of those in the placebo group. Other common adverse reactions are dizziness (5-15%), weakness (5-15%) and fatigue (2-4%). Others reported: <b>Warning and Precautions:</b> Hallucinations and seizures have occurred on abrupt withdrawal of baclofen. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued. Impaired Renal Function Because baclofen is primarily excreted unchanged by the kidneys, it should be given with caution and it may be necessary to reduce the dosage in patients with impaired renal function.	5mg, 10mg, 25mg Tablet & 0.1gm/100ml Syrup	USFDA	অন্যোক্তিক নৈ বিধায় নাথাকলেও মর্গারিগ করা হয়।	অন্যোক্তিক নৈ বিধায় নাথাকলেও মর্গারিগ করা হয়।
68.	Beximco Pharmaceuticals Ltd, Tongi, Gazipur	Ivacaftor 37.5 mg + Tezacaftor 25 mg + Elezacaftor 50 mg	Ivacaftor INN 37.5mg + Tezacaftor INN	Therapeutic Class: Antiviral	Indicated in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 6 years	<b>Contraindication:</b> Hypersensitivity to the active substance(s) or to any of the excipients. <b>Side-effect:</b> The most common adverse reactions	New	USFDA	অন্যোক্তিক নৈ মর্গারিগ করা হয়।	অন্যোক্তিক নৈ মর্গারিগ করা হয়।

*DR. DCC-255 Meeting*

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/ PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার বিবরণ	ঔষধ নিয়ন্ত্রণ কমিটির বিবরণ
69.	Beximco Pharmaceuticals Ltd, Tongi, Gazipur	Ivacaftor 75 mg + Tezacaftor 50 mg + Elexacaftor 100 mg Tablet	Ivacaftor INN 75 mg + Tezacaftor INN 50 mg + Elexacaftor INN 100 mg	Antiviral Therapeutic Code: 032	It is indicated in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	<p>experienced by patients aged 12 years and older who received IVATEZELX in combination with IVA were headache (17.3%), diarrhoea (12.9%) and upper respiratory tract infection (11.9%). Serious adverse reactions of rash were reported in 3 (1.5%) patients treated with IVATEZELX in combination with IVA compared to 1 (0.5%) in placebo.</p> <p><b>Warnings and Precautions: Hepatic impairment</b> Treatment of patients with moderate hepatic impairment is not recommended. For patients with moderate hepatic impairment, the use of IVATEZELX should only be considered when there is a clear medical need, and the benefits are expected to outweigh the risks. If used, it should be used with caution at a reduced dose (see Table 3). Patients with severe hepatic impairment should not be treated with IVATEZELX.</p> <p><b>Renal impairment</b> There is no experience in patients with severe renal impairment/ end-stage renal disease therefore caution is recommended in this population.</p> <p><b>Patients after organ transplantation</b> IVATEZELX in combination with IVA has not been studied in patients with CF who have undergone organ transplantation. Therefore, use in transplanted patients is not recommended.</p> <p><b>Contraindication:</b> Hypersensitivity to the active substance(s) or to any of the excipients.</p> <p><b>Side-effect:</b> The most common adverse reactions experienced by patients aged 12 years and older who received IVATEZELX in combination with IVA were headache (17.3%), diarrhoea (12.9%) and upper respiratory tract infection (11.9%). Serious adverse reactions of rash were reported in 3 (1.5%) patients treated with IVATEZELX in combination with IVA compared to 1 (0.5%) in placebo.</p> <p><b>Warnings and Precautions: Hepatic impairment</b> Treatment of patients with moderate hepatic impairment is not recommended. For patients with moderate hepatic impairment, the use of IVATEZELX should only be considered when there</p>	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	চলকিলাস শার কনিষ্ঠ শতর সিকাত	ঔষধ নিয়ন্ত্রণ কমিটির সিকাত
70.	Bexinco Pharmaceuticals Ltd., Tongi, Gazipur Drug International Ltd 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh	Ivacaftor 150 mg Tablet	Ivacaftor INN 150mg	Therapeutic Class: Unclassified Agent Therapeutic Code: 075	It is classified as a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and it is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D mutation.	<b>Contraindication:</b> None known <b>Side-effect:</b> The most common adverse drug reactions are headache, oropharyngeal pain, upper respiratory tract infection, nasal congestion, abdominal pain, nasopharyngitis, diarrhea, rash, nausea, and dizziness. <b>Warnings and Precautions:</b> Elevated transaminases (ALT or AST); Transaminases (ALT and AST) should be assessed prior to initiating KALYDECO, every 3 months during the first year of treatment, and annually thereafter. Patients who develop increased transaminase levels should be closely monitored until the abnormalities resolve. Dosing should be interrupted in patients with ALT or AST of greater than 5 times the upper limit of normal (ULN). Following resolution of transaminase elevations, consider the benefits and risks of resuming KALYDECO dosing.	New	USFDA	অনুসন্ধানের সূচনা করা করা	অনুসন্ধান করা করা
71.	Bexinco Pharmaceuticals Ltd., Tongi, Gazipur	Dalbavancin 500 mg Powder for concentrate for solution for Infusion	Dalbavancin hydrochloride INN lyophilized powder	Therapeutic Class: Anti-infective	Dalbavancin is indicated for Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by	<b>Contraindications:</b> Dalbavancin is contraindicated in patients with known hypersensitivity to Dalbavancin. No data are	New	USFDA	অনুসন্ধানের সূচনা করা করা	অনুসন্ধান করা করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMIRA / EMA/PMDA / TGA	টেকনিক্যাল নাম কবির সভার ফিক্সড	ঔষধ নিয়ন্ত্রণ কবির ফিক্সড
72.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur General Pharmaceutical Ltd., Gazipur Square	Ibuprofen 97.5 mg + Paracetamol 325 mg Tablet	Ibuprofen BP 97.5mg + Paracetamol BP 325mg	Therapeutic Class: Nonsteroidal antiinflammatory Therapeutic Code: 064	Combination of acetaminophen and Ibuprofen, a nonsteroidal anti-inflammatory drug (NSAID), and is indicated in adults for the short-term management of mild to moderate acute pain	available on cross-reactivity between Dalbavancin and other glycopeptides, including vancomycin. <b>Side Effects:</b> The most common adverse reactions in patients treated with Dalbavancin includes: nausea, headache, diarrhea. Other side effects included vomiting, rash, and itching. Serious allergic reactions, reactions related to the injection of Dalbavancin, and an elevation of liver enzymes can also occur. <b>Warning &amp; precautions:</b> Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents; including Dalbavancin; exercise caution in patients with known hypersensitivity to glycopeptides. Rapid intravenous infusion of glycopeptide antibacterial agents can cause reactions. ALT elevations with Dalbavancin treatment were reported in clinical trials. Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including Dalbavancin. Evaluate if diarrhea occurs.	Ibuprofen 200mg, 300mg 400mg Tab, 100mg/5ml Susp.	USFDA	ধারাজন নাই বিধায় নামজ্বরের সংশোধন করা হয়।	ধারাজন নাই বিধায় নামজ্বরের করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল শব্দ কবিতার সত্তার বিচার	উৎস নিয়ন্ত্রণ কবিতার বিচার
73.	Beaxico Pharmaceuticals Ltd., Tongi, Gazipur  Square Pharmaceuticals PLC, Kailakoir, Gazipur  Eskayer Pharmaceuticals	Paracetamol 1000 mg + Ibuprofen 300 mg IV infusion	Paracetamol BP 1000 mg + Ibuprofen sodium dihydrate BP eqv. to Ibuprofen 300 mg	Therapeutic Class: Nonsteroidal antiinflammatory  Therapeutic Code: 064	Indicated in adults where an intravenous route of administration is considered clinically necessary for: • the relief of mild to moderate pain • the management of moderate to severe pain as an adjunct to opioid analgesics	<p><b>Contraindication:</b></p> <ul style="list-style-type: none"> <li>Patients with a known hypersensitivity (e.g., anaphylactic reactions, serious skin reactions) to acetylsalicylic acid, ibuprofen, other NSAIDs, or to any of the excipients in this product.</li> <li>Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.</li> <li>The setting of coronary artery bypass graft (CABG) surgery. Side-effect: The most common adverse reactions (greater than or equal to 2%) are nausea</li> </ul> <p><b>Side-effects:</b> The most common adverse reactions (greater than or equal to 2%) are nausea, vomiting, headache, dizziness, somnolence, post-procedural hemorrhage, and swelling of the face</p> <p><b>Warnings and Precautions:</b> Hypertension: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.</p> <ul style="list-style-type: none"> <li>Heart Failure and Edema: Avoid use of COMBINATION in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure.</li> <li>Renal Toxicity: Long-term administration of NSAIDs, including the ibuprofen component of COMBINATION, has resulted in renal papillary necrosis and other renal injury.</li> <li>Anaphylactic Reactions: Seek emergency help if an anaphylactic react. This combination is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).</li> <li>Serious Skin Reactions: Discontinue COMBINATION at first appearance of skin rash or other signs of hypersensitivity.</li> <li>Drug Rash with Eosinophilia and Systemic Symptoms (DRESS): Discontinue and evaluate clinically.</li> </ul>	Ibuprofen 200mg, 300mg, 400mg Tab, 100mg/5ml Susp.	USFDA	বর্তমানে এই ঔষধ নামটির বিচার করা হয়।	এরাজন এই বিচার নামটির করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সত্তর নিষ্পত্ত	উৎপাদন নিয়ন্ত্রণ কমিটির নিষ্পত্ত
74.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur  The ACME Laboratories Ltd., Dharmal, Dhaka  Opsonin Pharma Ltd., Barishal	Esomeprazole 2.5mg delayed release suspension (Sachet)	Esomeprazole Magnesium Trihydrate Ph. Eur eqv. to Esomeprazole 2.5mg	Therapeutic Class: Proton Pump Inhibitor Therapeutic Code: 067	Indicated in - 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	Contra-indication: Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred) Side-effect: -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.	Esomeprazole 20 & 40 mg capsule/Tablet	USFDA	ধরোজন নৈরি বিধায় সাহায্যের আবেদন করা হয়।	ধরোজন নৈরি বিধায় সাহায্যের আবেদন করা হয়।

## Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMRA/EMA/PMDA/TGA	টেকনিক্যাল সার কமிটির সভায় নিম্নলিখিত	ওষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
75.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur  The ACME Laboratories Ltd, Dharmai, Dhaka	Esomeprazole 5mg delayed release suspension (Sachet)	Esomeprazole Magnesium Trihydrate Ph. Eur eqv. to Esomeprazole 5mg	Therapeutic Class: Proton Pump Inhibitor Code: 067	<ul style="list-style-type: none"> <li>- Treatment of gastroesophageal reflux disease (GERD)</li> <li>- Risk reduction of NSAID-associated gastric ulcer</li> <li>- H. pylori eradication to reduce the risk of duodenal ulcer recurrence</li> <li>- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome</li> </ul>	<p><b>Contra-Indication:</b> Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred)</p> <p><b>Side-effect:</b> -Adults (≥ 18 years) (incidence &gt; 1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth -Pediatric (1 to 17 years) (incidence &gt; 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.</p> <p><b>Warnings and Precautions:</b> Symptomatic response does not preclude the</p>	Esomeprazole 20 & 40 mg capsule/ Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	পরবর্তী টেকনিক্যাল সার কমিটির সভায় পুনর্লক্ষ্যমতের সিদ্ধান্ত গৃহীত হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMRA/EMA/PMDA/TGA	টেকনিক্যাল সাইট কপিটির সত্যতা নিশ্চিত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
76.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur Healthcare Pharmaceuticals Ltd., Rajendrapur, Gazipur	Esomeprazole 10mg delayed release suspension (Sachet)	Esomeprazole Magnesium Trihydrate Ph. Eur eqv. to Esomeprazole 10mg	Therapeutic Class: Proton Pump Inhibitor Therapeutic Code: 067	Indicated in - 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	Contra-indication: Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred) Side-effect: -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. Warnings and Precautions: Symptomatic response does not preclude the presence of gastric Malignancy	Esomeprazole e 20 & 40 mg capsule/Tablet	USFDA	ধরাজন নেই বিধায় নামঞ্জুর সুপারিশ করা হয়।	পরবর্তী টেকনিক্যাল সাইট কপিটির সত্যতা নিশ্চিত করার পুনঃপর্যালোচনার নিশ্চিত্য গৃহীত হয়।

**Annex-A: স্থানীয়ভাবে উপাদানের জন্য বিউয়ান মোডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	উপাদানের নাম কবিত্ব শতাংশ নিশ্চিত	উপর নিয়ন্ত্রণ কবিত্ব নিশ্চিত
77.	Delta Pharma Ltd. Advanced Chemical Industries Limited, 7 Hajeegani, Godryl, Narayangoni.	Sotagliflozin 400 mg Tablet.	Sotagliflozin INN 400 mg	Antihyperglycemics  <b>Therapeutic Code: 015</b>	Sotagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors.	<b>Contra-indications:</b> History of serious hypersensitivity reaction to Sotagliflozin. <b>Side-effects:</b> Most common adverse reactions (incidence $\geq$ 5%) are urinary tract infection, volume depletion, diarrhea, and hypoglycemia. <b>Warning and Precautions:</b> Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis: Consider ketone monitoring in patients with type 1 diabetes mellitus and consider ketone monitoring in others at risk for ketoacidosis, as indicated. Assess for ketoacidosis regardless of presenting blood glucose levels and discontinue sotagliflozin if ketoacidosis is suspected. Monitor patients for resolution of ketoacidosis before restarting.  • Volume Depletion: Before initiating, correct volume status. Monitor for signs and symptoms	Sotagliflozin INN 200 mg.	USFDA	উপাদানের নাম কবিত্ব শতাংশ নিশ্চিত	উপর নিয়ন্ত্রণ কবিত্ব নিশ্চিত

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান যৌক্তিকতা এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কনিষ্টার সভার নিকট	ইসখ নিয়ন্ত্রণ কনিষ্টার নিকট
78.	Delta Pharma Ltd. Popular Pharmaceuticals Ltd., 164, Tongi Industrial Area, Monmunagar, Gazipur	Fezolinetant 200 mg Tablet	Fezolinetant INN 200 mg	Other Classifications Therapeutic Code: 075	Fezolinetant is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.	<b>Contra-indications:</b> Known cirrhosis, Severe renal impairment or end-stage renal disease, Concomitant use with CYP1A2 inhibitors. <b>Warning and Precautions:</b> Hepatic transaminase elevation: Elevations in serum transaminase concentrations greater than three times the upper limit of normal (ULN) occurred in the clinical trials. Perform bloodwork prior to initiation of fezolinetant to evaluate for hepatic function and injury. Do not start therapy if serum transaminase concentration is equal to or exceeds two times the ULN. Perform follow-up evaluations of hepatic transaminase concentration at 3 months, 6 months, and 9 months after initiation of therapy. <b>Contraindications:</b> This tablet is contraindicated in patients with known hypersensitivity to any component of the formulation. <b>Precautions:</b> Anaphylactoid and Possibly Related Reactions: Presumably because angiotensin-	New	USFDA	অনুরোধের সুপারিশ করা করা	অনুরোধ করা করা
79.	Drug International Ltd 31/1, Satrong, Tongi I/A, Gazipur	Lisinopril 10.00mg & Hydrochlorothiazide 12.50mg Tablet	Lisinopril USP 10.00mg & Hydrochlorothiazide USP 12.50mg	Antihypertensive Therapeutic Code: 022	It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure lowers the risk of fatal and non-fatal cardiovascular events, primarily strokes and	<b>Contraindications:</b> This tablet is contraindicated in patients with known hypersensitivity to any component of the formulation. <b>Precautions:</b> Anaphylactoid and Possibly Related Reactions: Presumably because angiotensin-	New	USFDA	অনুরোধের সুপারিশ করা করা	অনুরোধের সুপারিশ করা করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	প্রকরণকার শর কারিটির সঙ্গর বিজ্ঞাঙ্	ঔষধ নিয়ন্ত্রণ কারিটির বিজ্ঞাঙ্
80.	Drug International Ltd, 31/1 Satrong, Tongi I/A, Gazipur	Lisinopril 20.00mg & Hydrochlorothiazide 12.50mg Tablet.	Lisinopril USP 20.00mg & Hydrochlorothiazide USP 12.50mg	Antihypertensive e Therapeutic Code:022	It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure lowers the risk of fatal and non-fatal 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 Lisinopril and hydrochlorothiazide.	Contraindications: This tablet is contraindicated in patients with known hypersensitivity to any component of the formulation. Precautions: Anaphylactoid and Possibly Related Reactions: Presumably because angiotensin-converting enzyme inhibitors affect the metabolism of eicosanoids and polypeptides, including endogenous bradykinin, patients receiving ACE inhibitors (including may be subject to a variety of adverse reactions, some of them serious: Head and Neck Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported rarely in patients treated with angiotensin-converting enzyme inhibitors, including lisinopril. Intestinal Angioedema: Intestinal angioedema has been reported in patients treated with ACE inhibitors. Anaphylactoid Reactions during	New	USFDA	ধরাজ্ঞন করই বিধর নামঙ্রর সুপারিণ করা হয়।	ধরাজ্ঞন বিধর নামঙ্রর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য রিউম্যান রেজিস্ট্রেশন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার বিজ্ঞপ্তি	ঔষধ নিয়ন্ত্রণ কমিটির বিজ্ঞপ্তি
81.	Drug International Ltd (252, Tongi Industrial Area, Gazipur, Bangladesh).	Olopatadine Hydrochloride 665 mcg + Mometasone Furoate Monohydrate 25.86 mcg Nasal Spray	Olopatadine Hydrochloride USP 665 mcg (Eqv. To 600 mcg of Olopatadine) + Mometasone Furoate Monohydrate USP 25.86 mcg (Eqv. To 25.0 mcg Mometasone Furoate)	Ear & Nose Preparations  Therapeutic Code: 050	It is a combination of olopatadine, a histamine-1 (H1) receptor inhibitor, and mometasone furoate, a corticosteroid, indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older.	<b>Contraindication:</b> It is contraindicated in patients with hypersensitivity to any of the ingredients. <b>Precaution:</b> It should be used with caution in patients with Epistaxis, nasal ulcerations, nasal septal perforations, impaired wound healing, and Candida albicans infection. Monitor patients periodically for signs of adverse reactions On the nasal mucosa, Glaucoma and cataracts, Hypersensitivity Reactions, Immunosuppression and Risk of Infections etc. <b>Warning:</b> As per precaution. <b>Side effects:</b> The most common adverse reactions ( $\geq 1\%$ incidence) are dysgeusia, epistaxis, and nasal discomfort.	New	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।
82.	Drug International Ltd, 31/1, Satrong, Tongi I/A, Gazipur	Norgestrel 0.075mg Tablet	Norgestrel INN 0.075mg	Contraceptive Code: 039	It is indicated for use by females of reproductive potential to prevent pregnancy.	<b>Contraindication:</b> It is contraindicated in patients with Known or suspected pregnancy, Known or suspected carcinoma of the breast, or other progestin-sensitive cancer, now or in the past, Undiagnosed abnormal uterine bleeding, Hypersensitivity to any component of this product, Benign or malignant liver tumors, Acute liver disease. <b>Precaution:</b> The onset or exacerbation of migraine.	New	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান মতামতের এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHR/ EMA/ PMDA/ TGA	টেকনিক্যাল সার কমান্ডির মতামত	উৎপাদন নিয়ন্ত্রণ কমান্ডির মতামত
83.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Talazoparib 0.1mg Capsule	Talazoparib Tosylate INN 0.145mg (Eqv. to 0.1mg Talazoparib)	Anticancer Therapeutic Code: 010	BRCA-mutated (gBRCAm) HER2-negative Locally Advanced or Metastatic Breast Cancer. It is indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. HRR Gene-mutated mCRPC. It is indicated in combination with Enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).	Contraindications: It is contraindicated in patients with known hypersensitivity to Talazoparib or any other components of this product.  Precautions: •Myelodysplastic Syndrome/ Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to Talazoparib, and some cases were fatal. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed. •Myelosuppression: It may affect hematopoiesis and can cause anemia, neutropenia, and/or thrombocytopenia. •Embryo-Fetal Toxicity: It can cause fetal harm. Advise of the potential risk to the fetus and to use effective contraception.  Warning: As per precaution. Side effects: Myelodysplastic Syndrome/Acute Myeloid, yelosuppression	New	USFDA	অনুমোদনের সুপারিশ করা হবে।	অনুমোদন করা হবে।
84.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur  Ziska Pharmaceuticals Ltd, Gazipur	Talazoparib 0.25mg Capsule	Talazoparib Tosylate INN 0.363mg (Eqv. to 0.25mg Talazoparib)	Anticancer Therapeutic Code: 010	BRCA-mutated (gBRCAm) HER2-negative Locally Advanced or Metastatic Breast Cancer. It is indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor	Contraindications: It is contraindicated in patients with known hypersensitivity to Talazoparib or any other components of this product.  Precautions: •Myelodysplastic Syndrome/ Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to Talazoparib, and some cases were fatal. Monitor patients for	New	USFDA	অনুমোদনের সুপারিশ করা হবে।	অনুমোদন করা হবে।

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	ঔষধিকাল শরৎ ক্রমিক সত্তার শিলাভ	উপর নিয়ন্ত্রণ ক্রমিক শিলাভ
85.	Drug International Ltd. Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Talazoparib 0.35mg Capsule	Talazoparib Tosylate INN 0.509mg (Eqv. to 0.35mg Talazoparib)	Anticancer Therapeutic Code: 010	<b>BRCA-mutated (gBRCAm) HER2-negative Locally Advanced or Metastatic Breast Cancer:</b> It is indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. <b>HRR Gene-mutated mCRPC:</b> It is indicated in combination with Enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).	<b>Contraindications:</b> It is contraindicated in patients with known hypersensitivity to Talazoparib or any other components of this product. <b>Precautions:</b> •Myelodysplastic Syndrome/ Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to Talazoparib, and some cases were fatal. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed. •Myelosuppression: It may affect hematopoiesis and can cause anemia, neutropenia, and/or thrombocytopenia. •Embryo-Fetal Toxicity: It can cause fetal harm. Advise of the potential risk to the fetus and to use effective contraception. <b>Warning:</b> As per precaution. <b>Side effects:</b> • Myelodysplastic Syndrome/Acute Myeloid • Myelosuppression	New	USFDA	অনুসন্ধানের সুপারিশ করা করা	অনুসন্ধান করা করা
86.	Drug International Ltd. Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Talazoparib 0.75mg Capsule	Talazoparib Tosylate INN 1.09mg (Eqv. to 0.75mg Talazoparib)	Anticancer Therapeutic Code No: 010	BRCA-mutated (gBRCAm) HER2-negative Locally Advanced or Metastatic Breast Cancer. It is indicated as a single agent for the treatment of adult patients with	<b>Contraindications:</b> It is contraindicated in patients with known hypersensitivity to Talazoparib or any other components of this product. <b>Precautions:</b> •Myelodysplastic Syndrome/ Acute	New	USFDA	অনুসন্ধানের সুপারিশ করা করা	অনুসন্ধান করা করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অতিসিনি এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কமிটির সভার বিবরণ	উপর নিরীক্ষণ কமிটির বিবরণ
87.	Drug International Ltd. Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Selumetinib Capsule	Selumetinib Sulfate INN 12.1mg (Eqv. to 10.00mg Selumetinib)	Anticancer Therapeutic Code No: 010	It is indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas.	<p><b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Selumetinib or any other components of this product.</p> <p><b>Precaution:</b> Caution should be exercised when use Selumetinib in the patients with Cardiomyopathy, Ocular toxicity, Gastrointestinal toxicity, Skin toxicity, Increased creatine phosphokinase &amp; embryo fetal toxicity.</p> <p><b>Warning:</b> As per precaution.</p> <p><b>Side effects:</b></p> <ul style="list-style-type: none"> <li>• Cardiomyopathy</li> <li>• Ocular toxicity</li> <li>• Gastrointestinal toxicity</li> <li>• Skin toxicity</li> <li>• Increased creatine phosphokinase.</li> </ul> <p><b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Selumetinib or any other components of this product.</p> <p><b>Precaution:</b> Caution should be exercised when use Selumetinib in the patients with Cardiomyopathy.</p>	New	USFDA	অনুরোধের সুপারিশ করা হবে।	অনুরোধ করা হবে।
88.	Drug International Ltd. Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Selumetinib Capsule	Selumetinib Sulfate INN 30.25mg (Eqv. to 25.00mg Selumetinib)	Anticancer Therapeutic Code No: 010	It is indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas.	<p><b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Selumetinib or any other components of this product.</p> <p><b>Precaution:</b> Caution should be exercised when use Selumetinib in the patients with Cardiomyopathy.</p>	New	USFDA	অনুরোধের সুপারিশ করা হবে।	অনুরোধ করা হবে।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান ভিত্তিক এবং তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/ PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	উৎপাদন নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
89.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Futibatinib 4.0 mg Tablet	Futibatinib INN 4.00mg	Anticancer Therapeutic Code No: 010	Futibatinib is indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.	<b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Tirabrutinib or any other components of this product. <b>Warning:</b> As per precaution. <b>Side effects:</b> The most common side effects are infection, severe skin disorder, bone marrow depression, hypersensitivity, interstitial lung disease, hepatic dysfunction, and hemorrhage. <b>Contraindication:</b> It is contraindicated in this drug is contraindicated in- Acute critical illness, Hypersensitivity to somatogon-ghia or excipients, Closed epiphyses, Active malignancy, Active proliferative or severe non-proliferative diabetic retinopathy, Prader-Willi syndrome who are severely obese or have severe respiratory impairment.	New	USFDA	অনুমোদনের সুপারিশ করা করা।	অনুমোদন করা করা।
90.	Drug International Ltd., 31/1, Satrong, Tongi I/A, Gazipur Ziska Pharmaceuticals Ltd.	Somatogon-ghia 24mg/1.2ml Pre-Filled Syringe Injection	Somatogon-ghia INN 24.00mg/1.2ml	Hormone Therapeutic Code: 056	It is a human growth hormone analog indicated for treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.	<b>Precaution:</b> It should not be administered in the following conditions: Severe Hypersensitivity, Increased Risk of Neoplasms, Glucose Intolerance and Diabetes Mellitus, Intracranial Hypertension, Fluid Retention, Hypoadrenalism, Hypothyroidism	New	USFDA	অনুমোদনের সুপারিশ করা করা।	অনুমোদন করা করা।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান যেডিসিএন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHR/ EMA/ PMDA/ TGA	টেকনিক্যাল শার কনিটর সত্তর নিসাত	উসখ নিসরণ কনিটর নিসাত
91.	Drug International Ltd. 31/1, Satrong, Tongi I/A, Gazipur Ziska Pharmaceuticals Ltd.	Somatogon-ghla 60.00mg/1.2ml Pre-Filled Syringe Injection	Somatogon-ghla INN 60.00mg/1.2ml	Hormone Therapeutic Code: 056	It is a human growth hormone analog indicated for treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.	<p><b>Warning:</b> As per precaution</p> <p><b>Side effects:</b> Adverse reactions reported in ≥5% of patients treated with these are: injection site reactions, nasopharyngitis, headache, pyrexia, anemia, cough, vomiting, hypothyroidism, abdominal pain, rash, and oropharyngeal pain.</p> <p><b>Contraindication:</b> It is Contraindicated in this drug is contraindicated in- Acute critical illness, Hypersensitivity to somatogon-ghla or excipients, Closed epiphyses, Active malignancy, Active proliferative or severe non-proliferative diabetic retinopathy, Prader-Willi syndrome who are severely obese or have severe respiratory impairment.</p> <p><b>Precaution:</b> It should not be administered in the following conditions: Severe Hypersensitivity, Increased Risk of Neoplasms, Glucose Intolerance and Diabetes Mellitus, Intracranial Hypertension, Fluid Retention, Hypoadrenalism, Hypothyroidism etc.</p> <p><b>Warning:</b> As per precaution</p> <p><b>Side effects:</b> Adverse reactions reported in ≥5% of patients treated with these are: Injection site reactions, nasopharyngitis, headache, pyrexia, anemia, cough, vomiting, hypothyroidism, abdominal pain, rash, and oropharyngeal pain.</p>	New	USFDA	অন্যোদনের সুরাণিগ করা হয়।	অন্যোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান মৌলিকতা এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/ PMDA/ TGA	উৎপাদনের সব কার্যটির নিজস্ব বিকাশ	উৎপাদন কার্যটির নিজস্ব বিকাশ
92.	Drug International Ltd., 31/1, Satrong, Tongi I/A, Gazipur	Mirvetuximab Soravansine-GYNX 100 mg /20 ml Injection	Mirvetuximab Soravansine-GYNX INN 100 mg / 20 ml (single) in a single dose vial	Anticancer Therapeutic Code: 010	It is indicated for the treatment of adult patients with folate receptor-alpha (FR $\alpha$ ) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.	<b>Contraindications:</b> No data available. <b>Precautions:</b> <b>Ocular Disorders:</b> It can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis so it should be avoided. <b>Pneumonitis:</b> Withhold Mirvetuximab for persistent or recurrent Grade 2 pneumonitis and consider dose reduction. Permanently discontinue it for Grade 3 or 4 pneumonitis. <b>Peripheral Neuropathy:</b> Monitor patients for new or worsening peripheral neuropathy. Withhold dosage, dose reduce, or permanently discontinue Mirvetuximab based on the severity of peripheral neuropathy. <b>Embryo-Fetal Toxicity:</b> It can cause fetal harm. Advise of the potential risk to a fetus and to use effective contraception. <b>Warning:</b> As per precaution. <b>Side effects:</b> Ocular Disorders, Pneumonitis, Peripheral Neuropathy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
93.	Drug International Ltd., Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Capivasertib 160.00mg Tablet	Capivasertib INN 160.00mg	Anticancer Therapeutic Code No: 010	Capivasertib, in combination with Fulvestrant, is indicated for the treatment of adult patients with hormone (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alteration as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.	<b>Contraindication:</b> Capivasertib is contraindicated in patients with severe hypersensitivity to Capivasertib or any of its components. <b>Precaution:</b> Caution should be exercised when Capivasertib is used in patients with Hypoglycemia, Diarrhea, Cutaneous Adverse Reactions, Embryo-Fetal Toxicity. <b>Warning:</b> As per precaution. <b>Side effects:</b> The most common side effects are - •Hypoglycemia •Diarrhea •Cutaneous Adverse Reactions.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
94.	Drug International Ltd., Plot # 13A &	Capivasertib 200.00mg Tablet	Capivasertib INN 200.00mg	Anticancer	Capivasertib, in combination with Fulvestrant, is indicated for the	<b>Contraindication:</b> Capivasertib is contraindicated in patients with severe hypersensitivity to Capivasertib	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান অভিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	ঔষধিকাল নাম কনিটর সভার বিস্তার	ঔষধ নিয়ন্ত্রণ কনিটর বিস্তার
95.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Fruquintinib 1.00mg Capsule	Fruquintinib 1.00mg	Anticancer Therapeutic Code No: 010	It is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with Fluoropyrimidine, Oxaliplatin, and Irinotecan based chemotherapy, an anti-VEGF therapy, and if RAS wild type and medically appropriate, an anti-EGFR therapy.	<b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Fruquintinib or any other components of this product. <b>Precaution:</b> Caution should be exercised when Fruquintinib is used in patients with Hypertension, Hemorrhagic Events, Infections, Gastrointestinal Perforation, Hepatotoxicity, Proteinuria, Palmar-Plantar Erythrodysesthesia (PPE), Posterior Reversible Encephalopathy Syndrome (PRES), Impaired Wound Healing, Arterial Thromboembolic Events, Allergic Reactions to FD&C Yellow No. 5 (Tartrazine) and No. 6 (Sunset Yellow FCF), Embryo-Fetal Toxicity. <b>Warning:</b> As per precaution.	New	USFDA	অন্যদেশের যুগান্তিত করা হয়।	অন্যদেশে করা হয়।
96.	Drug International Ltd, Plot # 13A & 14A, Tongi I/A,	Fruquintinib 5.00mg Capsule	Fruquintinib INN 5.00mg	Anticancer Therapeutic	It is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been	<b>Side effects:</b> The most common side effects are- Hypertension • Hemorrhagic Events • Infections • Gastrointestinal Perforation • Hepatotoxicity • Proteinuria • Palmar Plantar Erythrodysesthesia (PPE) • Posterior Reversible Encephalopathy Syndrome (PRES). <b>Contraindication:</b> It is contraindicated in patients with known hypersensitivity to Fruquintinib or any other components of this product.	New	USFDA	অন্যদেশের যুগান্তিত করা হয়।	অন্যদেশে করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিউয়ান যেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিকাল সার কপিটির সংগ্রহ পিছাতে	উপর নিয়ন্ত্রণ কপিটির পিছাতে
97.	Drug International Ltd.; Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur  EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchipur, Narayanagñi	Talazoparib 0.5mg Capsule	Talazoparib Tosylate INN 0.727mg (Eqv. to 0.5mg Talazoparib)	Anticancer Therapeutic Code: 010	BRCA-mutated (gBRCAm) HER2-negative Locally Advanced or Metastatic Breast Cancer. It is indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. HRR Gene-mutated mCRPC. It is indicated in combination with Enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).	<b>Contraindications:</b> It is contraindicated in patients with known hypersensitivity to Talazoparib or any other components of this product. <b>Precautions:</b> *Myelodysplastic Syndrome/ Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to Talazoparib, and some cases were fatal. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed. *Myelosuppression: It may affect hematopoiesis and can cause anemia, neutropenia, and/or thrombocytopenia. *Embryo-Fetal Toxicity: It can cause fetal harm. Advise of the potential risk to the fetus and to use effective contraception. <b>Warning:</b> As per precaution. <b>Side effects:</b> Myelodysplastic Syndrome/Acute Myeloid, Myelosuppression	New	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।
98.	Drug International Ltd.; Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur  EVEREST	Belzutifan 40 mg Tablet	Belzutifan INN 40mg	Anticancer Therapeutic Code No. 010	<b>von Hippel-Lindau (VHL) disease:</b> It is indicated for treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS)	<b>Contraindications:</b> It is contraindicated in patients with severe hypersensitivity to Belzutifan or any of its components. <b>Precaution:</b> Caution should be exercised when Belzutifan is used in patients with Anemia: von	New	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞাপন যেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMHR/A/EMA/PMDA/TGA	ডেইক্লারেশন সত্তা ককিটিং সত্তা নিস্কৃত	উৎস নিরূপণ ককিটিং নিস্কৃত
99.	Pharmaceuticals Ltd, BSCIC I/A, Kanchpur, Narayanganj Beacon Pharmaceuticals PLC, Kathali, Bhuluka, Mymensingh	Ubituximab-xivy 150mg/6ml (25mg/ml) Injection For IV Infusion	Ubituximab-xivy 150mg/Vial		hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery. <b>Advanced Renal Cell Carcinoma (RCC):</b> It is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). It is a CD20-directed cytolytic antibody 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	Hippei-Lindau (VHL) disease & Advanced Renal Cell Carcinoma (RCC), Hypoxia, Embryo-Fetal Toxicity. <b>Warning:</b> As per precaution. <b>Side effects:</b> The most common side effects are- • Anemia • Hypoxia.	New	USFDA	অনুমোদনের সুগারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান রেডিপিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNP/UKMIRA/EMA/PMDA/TGA	ঔষধ নিয়ন্ত্রণ কর্তৃক কঠোর পর্যালোচনা করা হয়েছে	ঔষধ নিয়ন্ত্রণ কর্তৃক সীমিত পর্যালোচনা করা হয়েছে
100.	Eskayef Pharmaceuticals Limited, Rujganj, Narayanganj	Leuprolide Acetate Lyophilized Powder For Depot Injection	Leuprolide Acetate USP 11.25mg/Vial	Therapeutic Class: <b>Hormone</b> Therapeutic code: 056	It is a gonadotropin-releasing hormone (GnRH) agonist indicated for: <u>Endometriosis:</u> • Management of endometriosis, including pain relief and reduction of endometriotic lesions. • In combination with a norethindrone acetate for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. <u>Limitations of Use:</u> • The total duration of therapy with this drug plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density. <u>Uterine Leiomyomata (Fibroids)</u> • Concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. <u>Limitations of Use:</u> This drug is not indicated for combination use with norethindrone acetate add-back therapy for the	when recurrent serious infections are suspected. Consider discontinuing THIS DRUG in patients with serious opportunistic or recurrent serious infections, and if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulin. Fetal Risk: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least 6 months after stopping THIS DRUG. <b>CONTRAINDICATIONS:</b> • Hypersensitivity to GnRH, GnRH agonist analogs, including Leuprolide acetate, or any of the excipients • Undiagnosed abnormal uterine bleeding. • Pregnancy. <b>SIDE-EFFECT:</b> Most common adverse reactions (>10%) in clinical trials were hot flashes/sweats, headache/migraine, vaginitis, depression/emotional lability, general pain, weight gain/loss, nausea/vomiting, decreased libido, and dizziness. <b>WARNINGS AND PRECAUTIONS:</b> • Loss of bone mineral density (BMD): Duration of treatment is limited by risk of bone mineral density. When using for management of endometriosis: combination use with norethindrone acetate is effective in reducing loss of BMD; do not retreat without combination norethindrone acetate. Assess BMD before retreatment. • Embryo-Fetal Toxicity: May cause fetal harm. Exclude pregnancy before initiating treatment if clinically indicated and discontinue use if pregnancy occurs. Use non-hormonal methods of contraception only. • Hypersensitivity reactions, including	Leuprolide Mesylate 42mg ready to use subcutaneous depot injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	উৎস নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
101.	Eskayef Pharmaceuticals Limited, Ruppani, Narayangani	Leuprolide Acetate Lyophilized Powder For Depot Injection	Leuprolide Acetate USP 3.75mg/Vial	Therapeutic Class: <b>Hormone</b> Therapeutic code: 036	<p>It is a gonadotropin-releasing hormone (GnRH) agonist indicated for:</p> <p><b>Endometriosis:</b></p> <ul style="list-style-type: none"> <li>Management of endometriosis, including pain relief and reduction of endometrial lesions.</li> <li>In combination with a norethindrone acetate for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.</li> </ul> <p><b>Limitations of Use:</b></p> <ul style="list-style-type: none"> <li>The total duration of therapy with this drug plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.</li> </ul> <p><i>Uterine Leiomyomata (Fibroids)</i></p> <ul style="list-style-type: none"> <li>Concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary.</li> </ul> <p><b>Limitations of Use:</b></p> <p>This drug is not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.</p>	<p>anaphylaxis, have been reported</p> <p>If this drug is administered with norethindrone acetate, the warnings and precautions for norethindrone acetate apply to the combination regimen.</p> <p><b>CONTRAINDICATIONS:</b></p> <ul style="list-style-type: none"> <li>Hypersensitivity to GnRH, GnRH agonist analogs, including Leuprolide acetate, or any of the excipients</li> <li>Undiagnosed abnormal uterine bleeding.</li> <li>Pregnancy.</li> </ul> <p><b>SIDE-EFFECT:</b></p> <p>Most common adverse reactions (&gt;10%) in clinical trials were hot flashes/sweats, headache/migraine, vaginitis, depression/emotional lability, general pain, weight gain/floss, nausea/vomiting, decreased libido, and dizziness.</p> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <ul style="list-style-type: none"> <li>Loss of bone mineral density (BMD): Duration of treatment is limited by risk of bone mineral density. When using for management of endometriosis: combination use with norethindrone acetate is effective in reducing loss of BMD; do not retreat without combination norethindrone acetate. Assess BMD before retreatment.</li> <li>Embryo-Fetal Toxicity: May cause fetal harm. Exclude pregnancy before initiating treatment if clinically indicated and discontinue use if pregnancy occurs. Use non-hormonal methods of contraception only.</li> <li>Hypersensitivity reactions, including anaphylaxis, have been reported</li> </ul> <p>If this drug is administered with norethindrone acetate, the warnings and precautions for norethindrone acetate apply to the combination regimen.</p>	Leuprolide Mesylate 42mg ready to use subcutaneous depot injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRRA/ EMA/PMDA/ TGA	উৎপাদনকারী শাখা কর্মটির সত্তার সিদ্ধান্ত	উৎস নিয়ন্ত্রণ কর্মটির সিদ্ধান্ত
102.	Eskayef Pharmaceuticals Limited, Rupganj, Narayanganj	Ofatumumab 20mg/0.4ml Injection	Ofatumumab INN 20mg/Prefilled Syringe	Anticancer Therapeutic code: 010	Ofatumumab is a CD20-directed cytolytic monoclonal antibody indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab. The effectiveness of Ofatumumab is based on the demonstration of durable objective responses. No data demonstrate an improvement in disease related symptoms or increased survival with Ofatumumab.	<p><b>CONTRAINDICATIONS:</b> Active HBV infection.</p> <p><b>SIDE-EFFECT:</b> Most common adverse reactions (incidence greater than 10%) are upper respiratory tract infection, headache, injection-related reactions, and local injection site reactions.</p> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <ul style="list-style-type: none"> <li><b>Infections:</b> Delay KESIMPTA administration in patients with an active infection until the infection is resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment with this and after discontinuation, until B-cell repletion.</li> <li><b>Injection-Related Reactions:</b> Management for injection-related reactions depends on the type and severity of the reaction.</li> <li><b>Reduction in Immunoglobulin's:</b> Monitor the level of immunoglobulin's at the beginning, during, and after discontinuation of treatment with this drug until B-cell repletion. Consider discontinuing this drug if a patient develops a serious opportunistic infection or recurrent infections if immunoglobulin levels indicate immune compromise.</li> </ul> <p><b>Fetal Risk:</b> May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping this.</p>	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
103.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Benazepril Hydrochloride 5mg Tablet	Benazepril Hydrochloride USP 5mg	Antihypertensive	It is an angiotensin-converting enzyme (ACE) inhibitor 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.	<p><b>CONTRAINDICATIONS:</b></p> <ul style="list-style-type: none"> <li>Hypersensitivity</li> <li>Angioedema or history of hereditary or idiopathic angioedema</li> <li>Co-administration with alicikren in patients with diabetes</li> </ul> <p><b>SIDE-EFFECT:</b> The most common adverse reactions leading to</p>	Amlodipine 2.5mg + Benazepril 10mg Capsule	USFDA	অনুমোদন নেই বিস্তারিত নাথাকলে সুপারিশ করা হয়।	অনুমোদন নেই বিস্তারিত নাথাকলে করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	ঔষধ নিয়ন্ত্রণ সর্ব কাঠামির সত্তর নিয়ন্ত্র	ঔষধ নিয়ন্ত্রণ সর্ব কাঠামির নিয়ন্ত্র
104.	Eskeyef Pharmaceuticals Limited, Tongi, Gazipur	Benzapril Hydrochloride 10mg Tablet	Benzapril Hydrochloride USP 10mg	Antihypertensive e Therapeutic code:022	It is an angiotensin-converting enzyme (ACE) inhibitor 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.	discontinuation were headache (0.5%) and cough (0.5%)  <b>WARNINGS AND PRECAUTIONS:</b> <ul style="list-style-type: none"> <li>When pregnancy is detected, discontinue this drug as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.</li> <li>Angioedema: Discontinue and treat appropriately.</li> <li>Monitor renal function periodically.</li> <li>Monitor blood pressure after initiation.</li> <li>Hyperkalemia: Monitor serum potassium periodically.</li> <li>Hepatic toxicity: Monitor for jaundice or signs of liver failure.</li> </ul> <b>CONTRAINDICATIONS:</b> <ul style="list-style-type: none"> <li>Hypersensitivity</li> <li>Angioedema or history of hereditary or idiopathic angioedema</li> <li>Co-administration with alicisiren in patients with diabetes</li> </ul> <b>SIDE-EFFECT:</b> The most common adverse reactions leading to discontinuation were headache (0.5%) and cough (0.5%)  <b>WARNINGS AND PRECAUTIONS:</b> <ul style="list-style-type: none"> <li>When pregnancy is detected, discontinue this drug as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.</li> <li>Angioedema: Discontinue and treat appropriately.</li> <li>Monitor renal function periodically.</li> <li>Monitor blood pressure after initiation.</li> <li>Hyperkalemia: Monitor serum potassium periodically.</li> <li>Hepatic toxicity: Monitor for jaundice or signs of liver failure.</li> </ul>	Amlodipine 2.5mg + Benzapril 10mg Capsule  Amlodipine 5mg + Benzapril 10mg Capsule	USFDA	প্রয়োজন নেই বিধায় নামমাত্র করা সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামমাত্র করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMRA/EMA/PMDA/TGA	টেকনিক্যাল শব্দ কমিটির সভার সিদ্ধান্ত	ড্রাগ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
105.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Benazepril Hydrochloride 20mg Tablet	Benazepril Hydrochloride USP 20mg	Antihypertensive e Therapeutic code:022	It is an angiotensin-converting enzyme (ACE) inhibitor 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.	<p><b>CONTRAINDICATIONS:</b></p> <ul style="list-style-type: none"> <li>Hypersensitivity</li> <li>Angioedema or history of hereditary or idiopathic angioedema</li> <li>Co-administration with aliskiren in patients with diabetes</li> </ul> <p><b>SIDE-EFFECT:</b> The most common adverse reactions leading to discontinuation were headache (0.6%) and cough (0.5%)</p> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <ul style="list-style-type: none"> <li>When pregnancy is detected, discontinue this drug as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.</li> <li>Angioedema: Discontinue and treat appropriately.</li> <li>Monitor renal function periodically.</li> <li>Monitor blood pressure after initiation.</li> <li>Hypertakemia: Monitor serum potassium periodically.</li> <li>Hepatic toxicity: Monitor for jaundice or signs of liver failure.</li> </ul>	Amiodipine 2.5mg + Benazepril 10mg Capsule	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।
106.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Benazepril Hydrochloride 40mg Tablet	Benazepril Hydrochloride USP 40mg	Antihypertensive e Therapeutic code:022	It is an angiotensin-converting enzyme (ACE) inhibitor 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.	<p><b>CONTRAINDICATIONS:</b></p> <ul style="list-style-type: none"> <li>Hypersensitivity</li> <li>Angioedema or history of hereditary or idiopathic angioedema</li> <li>Co-administration with aliskiren in patients with diabetes</li> </ul> <p><b>SIDE-EFFECT:</b> The most common adverse reactions leading to discontinuation were headache (0.6%) and cough (0.5%)</p>	Amiodipine 2.5mg + Benazepril 10mg Capsule	USFDA	প্রয়োজন নেই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান রেডিফিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	উৎপাদনের শর্ত কর্তৃপক্ষের সত্তায় নির্ধারিত	উৎপাদন নিয়ন্ত্রণ কর্তৃপক্ষ
107.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur  Square Pharmaceuticals PLC, Salgaria, Pabna  Opsonin Pharma Ltd.	Fluticasone Propionate 93.00mcg/100µL Nasal Spray	Fluticasone BP 0.093mg/100µL	Drug used in Bronchial Asthma, Chronic obstructive pulmonary disease (COPD)  Therapeutic Code: 044	It is a corticosteroid indicated for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age or older.	<p><b>CONTRAINDICATIONS:</b> Hypersensitivity</p> <p><b>SIDE-EFFECT:</b> The most common adverse reactions (incidence ≥ 3%) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.</p> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <ul style="list-style-type: none"> <li>Local Nasal Adverse Reactions</li> <li>Close monitoring for glaucoma and cataracts is warranted</li> <li>Hypersensitivity reactions</li> <li>Immunosuppression and Risk of Infections</li> <li>Hypertoricism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals.</li> </ul> <p>Assess for decrease in bone mineral density initially and periodically thereafter.</p>	Amiodipine 5mg + Benzepriil 20mg Capsule  Amlodipine 10mg + Benzepriil 20mg Capsule		উৎপাদনের শর্ত সুপারিশ করা হয়।	উৎপাদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	উৎপাদনকারী শিল্পের নাম	উৎপাদনকারী শিল্পের ঠিকানা
							Inhalation Capsule Fluticasone Propionate 500mcg Inhalation Capsule Fluticasone Propionate 0.05% Cream Fluticasone Propionate 0.005% Ointment Fluticasone Propionate 2mg/2ml Respirator Suspension Fluticasone Propionate 500mcg/2ml Respirator Suspension Fluticasone Propionate 250mcg/Metered Inhalation Aerosol Fluticasone Propionate 500mcg/Metered Inhalation			

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHR/ EMA/PMDA/ TGA	ঐকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঐষ নিরঞ্জন কমিটির সিদ্ধান্ত	
108.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur  Opsonin Pharma Limited, Rupatali, Barishal	Nizatidine 150mg/ml Oral Solution	Nizatidine USP 1.5gm/100ml	H <sub>2</sub> -Receptor Blocker  Therapeutic code: 055	Nizatidine oral solution is indicated for up to 8 weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within 4 weeks. Nizatidine oral solution is indicated for maintenance therapy for duodenal ulcer patients at a reduced dosage of 150 mg h.s. after healing of an active duodenal ulcer. The consequences of continuous therapy with nizatidine for longer than 1 year are not known. Nizatidine oral solution is indicated for up to 12 weeks for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis, and associated heartburn due to GERD. Nizatidine oral solution is indicated for up to 8 weeks for the treatment of active benign gastric ulcer. Before initiating therapy, care should be taken to exclude the possibility of malignant gastric ulceration. In pediatric patients, nizatidine oral solution is indicated for ages 12 years and older. Nizatidine oral solution is indicated for up to 8 weeks for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis, and associated heartburn due to GERD.	<b>CONTRAINDICATIONS:</b> Nizatidine oral solution is contraindicated in patients with known hypersensitivity to the drug. Because cross sensitivity in this class of compounds has been observed, H <sub>2</sub> receptor antagonists, including nizatidine, should not be administered to patients with a history of hypersensitivity to other H <sub>2</sub> receptor antagonists.  <b>SIDE-EFFECT:</b> In controlled clinical trials in pediatric patients (age 2 to 18 years), nizatidine was found to be generally safe and well tolerated. The principal adverse experiences (> 5%) were pyrexia, nasopharyngitis, diarrhea, vomiting, irritability, nasal congestion and cough. Most adverse events were mild or moderate in severity. Mild elevations in serum transaminase (12 x ULN) were noted in some patients. One subject experienced a seizure by EEG diagnosis after taking nizatidine oral solution 2.5mg/kg b.i.d. for 23 days. The adverse reactions reported for nizatidine may also occur with nizatidine oral solution.	<b>CONTRAINDICATIONS:</b> • allergic to Nizatidine or any of the other ingredients of this medicine • if taken a similar anti-ulcer medicine before and suffered an unusual or allergic reaction. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.	Nizatidine 150mg Capsule  Aerosol Inhalation	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	পরবর্তী ঐকনিক্যাল সাব কমিটির পুনর্বিবেচনার সিদ্ধান্ত গৃহীত হয়।
109.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur  Opsonin Pharma Ltd.	Nizatidine 300mg Capsule	Nizatidine USP 300mg	H <sub>2</sub> -Receptor Blocker  Therapeutic code: 055	Nizatidine belongs to a group of medicines called H <sub>2</sub> -receptor antagonists (anti-ulcer medicines), which reduce the amount of acid in stomach.  This medicine is used to: • heal and stop ulcers in the stomach, or the part where it empties into the small intestine (duodenum)	<b>CONTRAINDICATIONS:</b> • allergic to Nizatidine or any of the other ingredients of this medicine • if taken a similar anti-ulcer medicine before and suffered an unusual or allergic reaction. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.	Nizatidine 150mg Capsule	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।	

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/ PMDA/ TGA	টেকনিক্যাল ন্যাব ক্যাটগরি সত্তা নিৰ্দ্ধাৰ	উপৰ নিৰ্দ্ধাৰ ক্যাটগরি নিৰ্দ্ধাৰ
110.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur  Incepta Pharmaceuticals Ltd.; Zirabo, Dhaka  Ziska Pharmaceuticals Ltd. Gazipur	Polidocanol 0.01gm/2ml ampoule IV Injection (0.5%, 2ml)	Polidocanol INN 0.01gm/2ml	Other Classification  Therapeutic code: 075	It is a sclerosing agent indicated to sclerose uncomplicated spider veins (varicose veins $\leq 1$ mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3mm in diameter) in the lower extremity. Asclera has not been studied in varicose veins more than 3mm in diameter.	<p><b>Contra-indication, Side-effects, Warnings and Precautions</b></p> <ul style="list-style-type: none"> <li>Known allergies to polidocanol</li> <li>Patients with acute thromboembolic diseases</li> </ul> <p><b>WARNINGS AND PRECAUTIONS:</b></p> <ul style="list-style-type: none"> <li>Talk to your doctor or pharmacist before taking Nizalidine if you have liver or kidney problems.</li> <li>Other medicines and Nizalidine: a medicine called a salicylate (i.e. aspirin), normally used to relieve minor aches and pains.</li> <li>Pregnancy and breast-feeding.</li> </ul> <p><b>CONTRAINDICATIONS:</b></p> <ul style="list-style-type: none"> <li>Known allergies to polidocanol</li> <li>Patients with acute thromboembolic diseases</li> </ul> <p><b>SIDE-EFFECT:</b></p> <ul style="list-style-type: none"> <li>Be prepared to treat anaphylaxis</li> <li>Venous Thrombosis and Pulmonary Embolism.</li> <li>Arterial Embolism</li> <li>Tissue ischemia and necrosis: Do not inject intra-arterially.</li> </ul>	New	USFDA	অন্যোপাধেৰ নূৰ্ণাৰিণ করা ২২।	অন্যোপাধেৰ করা ২২।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউমাণ মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKMHIRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কারিগরি শব্দে লিখতে	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
111.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Ziska Pharmaceuticals Ltd. Gazipur	Polidocanol 0.02gm/2ml ampoule IV Injection (1.0%, 2ml)	Polidocanol INN 0.02gm/2ml	Other Classification Therapeutic code: 075	It is a sclerosing agent indicated to sclerose uncomplicated spider veins (Varicose veins $\leq 1$ mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3mm in diameter) in the lower extremity. Asclera has not been studied in varicose veins more than 3mm in diameter.	<b>CONTRAINDICATIONS:</b> <ul style="list-style-type: none"> <li>Known allergies to polidocanol</li> <li>Pallents with acute thromboembolic diseases</li> </ul> <b>SIDE-EFFECT:</b> <ul style="list-style-type: none"> <li>Be prepared to treat anaphylaxis</li> <li>Venous Thrombosis and Pulmonary Embolism.</li> <li>Arterial Embolism</li> </ul> Tissue ischemia and necrosis: Do not inject intra-arterially.	New	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।
112.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur Advanced Chemical Industries Limited 7, Hafeegonj, Godhly, Narayangonj	Avacincaptad Pegol 2mg/0.1ml Intravitreal Injection	Avacincaptad Pegol Sodium INN 2mg/Vial	Eye Preparations Therapeutic code: 052	It is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).	<b>CONTRAINDICATIONS:</b> <ul style="list-style-type: none"> <li>Ocular or perocular infections</li> <li>Active intraocular inflammation</li> </ul> <b>SIDE-EFFECT:</b> The most common adverse reactions were conjunctival hemorrhage (13%), increased IOP (9%), blurred vision (8%) and neovascular age-related macular degeneration (7%).	New	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	পরবর্তী ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত প্রস্তুত করার বিষয়ে সিদ্ধান্ত গৃহীত হয়
113.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchnur, Narayanagnj, BANGLADESH Healthcare Pharmaceuticals Ltd Gazalapar, Rajendrapur, Gazipu	Budesonide Delayed Release Capsule	Budesonide 4mg BP 4mg	Drug used in Bronchial Asthma Therapeutic Code: 044	It is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) $\geq 1.5$ g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether it slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.	<b>CONTRAINDICATIONS:</b> Hypersensitivity to budesonide or any of the ingredients	Budesonide 9mg Extended Release Tablet	USFDA	ধারাবাহিক তালিকাভুক্ত করার সুপারিশ করা হয়।	পরবর্তী ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত প্রস্তুত করার বিষয়ে সিদ্ধান্ত গৃহীত হয়

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/ PMDA/ TGA	টেকনিক্যাল শার কবিত্বের সত্তা নিশ্চিত	উৎপাদন নিশ্চিত কবিত্ব নিশ্চিত
114.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchipur, Narayanagiri  Beacon Pharmaceuticals Pl.C, Kathail, Bhaluka, Myrmeningh  DBL Pharmaceuticals Ltd. Surabari, Kashimpur,	Tenapanor 30mg Tablet	Tenapanor HCl INN 31,900 mg Eqv. to Tenapanor 30 mg Tablet	Others Classification Therapeutic Code: 075	Tenapanor is a sodium hydrogen exchanger 3 (NHE3) inhibitor indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy	<b>Contraindication:</b> •Pediatric patients less than 6 years of age. •Patients with known or suspected mechanical gastrointestinal obstruction. <b>Side effects:</b> Most common adverse reactions (≥2%) are diarrhea, abdominal distension, flatulence and dizziness. <b>warnings and precautions</b> Patients may experience severe diarrhea	1mg/2ml, 250mcg/2ml, 500mcg/2ml Nebuliser Suspension  Budesonide 100, 200, 250, 400mcg Powder for inhalation/aqueous suspension for inhalation/Metered Inhalation Aerosol Inhalation/Inhalation/Capsule/	USFDA	অনুসন্ধানের সুপারিশ করা করা।	অনুসন্ধান করা।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অতিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNE/ UKMHRA/ EMA/PMDA/ TGA	উৎস নিয়ন্ত্রণকারী কর্তৃক নির্ধারিত নাম	উৎস নিয়ন্ত্রণকারী কর্তৃক নির্ধারিত নাম
	Gazipur The ACME Laboratories Ltd. Dhamrai, Dhaka									
	Incepta Pharmaceuticals Ltd. Savar, Dhaka									
	Eskayel Pharmaceuticals Limited, Tongi, Gazipur									
	Opsonin Pharma Limited, Rupatali, Barishal									
115.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kancharpur, Narayanagiri, BANGLADESH	Dextromethorphan Hydrobromide BP 20 mg + Quinidine Sulfate BP 10 mg Capsule	Dextromethorphan Hydrobromide BP 20 mg + Quinidine Sulfate BP 10 mg Capsule	Others Classification Therapeutic Code: 075	For the treatment of pseudobulbar affect (PBA) characterized by involuntary, sudden, and frequent episodes of laughing and/or crying.	<b>CONTRAINDICATION:</b> • Concomitant use with quinidine, quinine, or mefloquine. • Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. • Patients with known hypersensitivity to dextromethorphan. • Use with an MAOI or within 14 days of stopping an MAOI. Allow 14 days after stopping the drugs before starting an MAOI. • Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. • Complete atrioventricular (AV) block without implanted pacemaker or patients at high risk of complete AV block. • Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pinozide).	New	USFDA	এডোজন নতুন বিধায় নামঞ্জুর করা হয়।	এডোজন নতুন বিধায় নামঞ্জুর করা হয়।

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMIRA / EMA/PMDA / TGA	চর্চাকালীন শব্দ কমিটির সভার নিকাল	ত্বরিত বিবেচনা কমিটির নিকাল
116.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Karolpur, Narayanganj, BANGLADESH	Mobocertinib Succinate 40 mg Capsule	Mobocertinib Succinate INN 48,060 mg Eqv. to Mobocertinib 40 mg Capsule	Anticancer drug Therapeutic Code: 070	Mobocertinib is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy	<p><b>Side effects:</b> Diarrhea, nausea, vomiting, loss of appetite, stomach/abdominal pain, heartburn, mouth sores, weight loss, dry skin, runny nose, muscle/joint pain, tiredness, or headache may occur</p> <p><b>Warnings &amp; Precautions:</b> Interstitial Lung Disease (ILD)/Pneumonitis: Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold Mobocertinib in patients with suspected</p> <p><b>Contraindication:</b> None</p> <p><b>Side effects:</b> Diarrhea, nausea, vomiting, loss of appetite, stomach/abdominal pain, heartburn, mouth sores, weight loss, dry skin, runny nose, muscle/joint pain, tiredness, or headache may occur</p> <p><b>Warnings &amp; Precautions:</b> Interstitial Lung Disease (ILD)/Pneumonitis: Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold Mobocertinib in patients with suspected</p> <p><b>Contra-indication:</b> None</p> <p><b>Side effects:</b> Diarrhea, nausea, vomiting, loss of appetite, stomach/abdominal pain, heartburn, mouth sores, weight loss, dry skin, runny nose, muscle/joint pain, tiredness, or headache may occur</p> <p><b>Warnings &amp; Precautions:</b> Interstitial Lung Disease (ILD)/Pneumonitis: Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold Mobocertinib in patients with suspected</p>	New	USFDA	অনুমোদনের সংশোধন করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMRA/EMA/PMDA/TGA	টেকনিক্যাল সাপোর্টের কপিটির সভার নিকাশ	ড্রাগ নিয়ন্ত্রণ কমিটির নিকাশ
117.	EVEREST Pharmaceuticals Ltd. BSCIC IA, Kanchnpur, Narayanagni, BANGLADESH	Enasidenib INN 50mg Tablet	Enasidenib Mesylate INN 60,000 mg Eqv. to Enasidenib 50 mg Tablet	Anticancer drug Therapeutic Code: 010	It is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocytaric dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.	<b>Contraindication:</b> None <b>Side effects:</b> The most common adverse reactions included nausea, vomiting, diarrhea, elevated bilirubin, decreased appetite, respiratory, thoracic and mediastinal disorder. Serious adverse reactions are reported such as leukocytosis and differentiating syndrome. <b>Warnings &amp; Precautions:</b> Embryo-Fetal Toxicity: IDH1/2A can cause fetal harm when administered to a pregnant woman. Advise of the potential risk to a fetus	DCC 249 Enasidenib 100 mg Tablet	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।
118.	General Pharmaceutical Ltd., Gazipur	Lisdexamfetamine Dimethylate Capsule 30mg	Lisdexamfetamine Dimethylate INN 30,000 mg equivalent to Lisdexamfetamine 17,300 mg	Antidepressants Therapeutic code: 014	Lisdexamfetamine dimethylate is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) & Moderate to Severe Binge Eating Disorder (BED) in adultz	<b>Contraindications:</b> Lisdexamfetamine dimethylate is contraindicated in patients with: Known hypersensitivity to amphetamine products; Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have been observed in postmarketing reports. Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an	New	USFDA	ধরাজ্ঞান নাই বিষয়ঃ নামঞ্জুরের সুপারিশ করা হয়।	ধরাজ্ঞান নাই বিষয়ঃ নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNE/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
119.	General Pharmaceutical	Lisdexamfetamine dimesyate 60 mg	Lisdexamfetamine Dimesyate INN	Antidepressants	Lisdexamfetamine dimesyate is a central nervous system (CNS)	<p>Increased risk of hypertensive crisis.</p> <p><b>Warning &amp; Precautions:</b>            Serious Cardiovascular Events: Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Stimulant products generally should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems.            Increase in Blood Pressure: Monitor blood pressure and pulse at appropriate intervals in patients taking Lisdexamfetamine Dimesyate. Use with caution in patients for whom blood pressure increases may be problematic.            Psychiatric Adverse Events: Use of stimulants may cause treatment-emergent psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychosis. Clinical evaluation for bipolar disorder is recommended prior to stimulant use. Monitor for aggressive behavior.            Seizures: may lower the convulsive threshold, and in the presence of seizures, should be discontinued.            Visual Disturbance: difficulties with accommodation and blurring of vision have been reported with stimulant treatment.            Tics: may exacerbate tics. Clinical evaluation for tics and Tourette's syndrome is recommended prior to stimulant administration.            Long-Term Suppression of Growth: monitor height and weight at appropriate intervals in pediatric patients taking Lisdexamfetamine Dimesyate.</p> <p><b>Contraindications:</b>            Lisdexamfetamine dimesyate is contraindicated in</p>	New	USFDA	ধরোজন নেই	ধরোজন নেই

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMRA / EMA/PMDA / TGA	টেকনিক্যাল সাব কমিটির সভার বিধায় নামঞ্জুর করা হইবে।	উচ্চ নিয়ন্ত্রণ কমিটির বিধায় নামঞ্জুর করা হইবে।		
	Ltd., Gazipur	Capsule	60,000 mg equivalent to Lisdexamfetamine 34,700 mg	Therapeutic code: 014	stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) & Moderate to Severe Binge Eating Disorder (BED) in adults	<p>patients with: Known hypersensitivity to amphetamine products. Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have been observed in postmarketing reports. Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.</p> <p><b>Warning &amp; Precautions:</b></p> <p><b>Serious Cardiovascular Events:</b> Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD.</p> <p>Stimulant products generally should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems.</p> <p>Increase in Blood Pressure: Monitor blood pressure and pulse at appropriate intervals in patients taking Lisdexamfetamine Dimesylate. Use with caution in patients for whom blood pressure increases may be problematic.</p> <p><b>Psychiatric Adverse Events:</b> Use of stimulants may cause treatment-emergent psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychosis. Clinical evaluation for bipolar disorder is recommended prior to stimulant use. Monitor for aggressive behavior.</p> <p><b>Seizures:</b> may lower the convulsive threshold, and in the presence of seizures, should be discontinued.</p> <p><b>Visual Disturbance:</b> difficulties with accommodation and blurring of vision have been reported with stimulant treatment.</p> <p><b>Tics:</b> may exacerbate tics. Clinical evaluation for tics</p>						

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অ্যেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	টেকনিক্যাল সাব কবিতার সত্তার বিজ্ঞপ্তি	উৎস নিয়ন্ত্রণ কবিতার বিজ্ঞপ্তি
120.	Healthicare Pharmaceuticals Ltd EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj, BANGLADESH Advanced Chemical Industries Limited, 7 Hajeegonj, Godhyl, Narayanagnj Opsonin Pharma Limited, Rupatali, Barishal	Gepirone 54.5mg Extended-release Tablet	Gepirone INN 54.50mg	Antidepressant Therapeutic Code: 014	Gepirone is indicated for the treatment of major depressive disorder (MDD) in adults	<p>and Tourette's syndrome is recommended prior to stimulant administration.  <u>Long-Term Suppression of Growth:</u> monitor height and weight at appropriate intervals in pediatric patients taking Lisdexamfetamine Dimesylate.</p> <p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Known hypersensitivity to gepirone.</li> <li>• Prolonged QTc interval &gt; 450 msec at baseline</li> <li>• Congenital long QT syndrome.</li> <li>• Concomitant use of strong CYP3A4 inhibitors.</li> <li>• Severe hepatic impairment.</li> <li>• Use with an MAOI or within 14 days of stopping treatment with gepirone.</li> </ul> <p>Do not use gepirone within 14 days of discontinuing an MAOI</p> <p><b>Side effects:</b> Most common adverse reactions (incidence of ≥5% and at least twice incidence of placebo) were dizziness, nausea, insomnia, abdominal pain, and dyspepsia</p> <p><b>Warnings and Precautions:</b></p> <ul style="list-style-type: none"> <li>• QT Interval Prolongation: gepirone prolongs the QTc. Correct electrolyte abnormalities. Perform ECGs prior to initiation, during dose titration, and periodically during treatment with gepirone. Monitor ECGs more frequently when gepirone is used concomitantly with drugs known to prolong the QT interval in patients who develop QTc ≥ 450 msec during treatment or are at significant risk of developing torsade de pointes. Do not escalate dosage if QTc &gt; 450 msec.</li> <li>• Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents. If serotonin syndrome occurs, discontinue gepirone and initiate supportive measures.</li> <li>• Activation of Mania/Hypomania: Screen patients for</li> </ul>		USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল শব্দ কবিতার সমস্ত সিক্সাভ	ঔষধ নিয়ন্ত্রণ কবিতার সিক্সাভ
121.	Healthcare Pharmaceuticals Ltd  The Acme Laboratories Lt., Savar	Gepirone 72.6 mg Extended-Release Tablet	Gepirone INN 72.60mg	Antidepressant Therapeutic Code: 074	Gepirone is indicated for the treatment of major depressive disorder (MDD) in adults	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Known hypersensitivity to gepirone.</li> <li>• Prolonged QTc interval &gt; 450 msec at baseline</li> <li>• Congenital long QT syndrome.</li> <li>• Concomitant use of strong CYP3A4 inhibitors.</li> <li>• Severe hepatic impairment.</li> </ul> <p>• Use with an MAOI or within 14 days of stopping treatment with gepirone.</p> <p>Do not use gepirone within 14 days of discontinuing an MAOI.</p> <p><b>Side effects:</b></p> <p>Most common adverse reactions (incidence of ≥5% and at least twice incidence of placebo) were dizziness, nausea, insomnia, abdominal pain, and dyspepsia</p> <p><b>Warnings and Precautions:</b></p> <ul style="list-style-type: none"> <li>• QT Interval Prolongation: gepirone prolongs the QTc. Correct electrolyte abnormalities. Perform ECGs prior to initiation, during dose titration, and periodically during treatment with gepirone. Monitor ECGs more frequently when gepirone is used concomitantly with drugs known to prolong the QT interval. In patients who develop QTc ≥ 450 msec during treatment or are at significant risk of developing torsade de pointes. Do not escalate dosage if QTc &gt; 450 msec.</li> <li>• Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents. If serotonin syndrome occurs, discontinue gepirone and initiate supportive measures.</li> <li>• Activation of Mania/Hypomania: Screen patients for bipolar disorder.</li> </ul> <p><b>Contraindications:</b> None</p> <p><b>Side effects:</b> The most common adverse reactions</p>	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
122.	Healthcare Pharmaceuticals Ltd	Trofinetide 200 mg /mL Oral Solution	Trofinetide INN 200mg/mL	Other Classifications	Trofinetide is indicated for the treatment of Rett syndrome in adults		New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNE/ UKMIRA/ EMA/PMDA/ TGA	ঐকনিকাল শার কনিটির স্তর সিফাড	ঐকনিকাল শার কনিটির স্তর সিফাড
123.	Incepta Pharmaceuticals Ltd, Ziraib, Dhaka  Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka  Eskayel Pharmaceuticals Limited, Tongi, Gazipur  Advanced Chemical Industries Limited, 7 Hajeeganj, Goddnyl, Narayangoni  NIPRO JMI Pharma Ltd Drug International	Empagliflozin 5 mg + Linagliptin 2.5 mg + Metformin Hydrochloride 1000 mg Extended-release Tablet	Empagliflozin INN/in-house 5mg + Linagliptin INN/in-house 2.5mg + Metformine Hydrochloride BP 1000mg	Therapeutic Class Antidiabetic Therapeutic Code: 015	A combination of empagliflozin, a sodium-glucose cotransporter 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. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease	(that occurred in at least 10% of Trofinetide-treated patients and at least 2% greater than in placebo) were diarrhea and vomiting <b>Warnings and Precautions:</b> Diarrhea: Most patients experience diarrhea during treatment with Trofinetide. Advise patients to stop laxatives before starting Trofinetide. If diarrhea occurs, patients should start antidiarrheal treatment, increase oral fluids, and notify their healthcare provider. Interrupt, reduce dose, or discontinue Trofinetide if severe diarrhea occurs or if dehydration is suspected. • Weight Loss: Weight loss may occur in patients treated with Trofinetide. Monitor weight and interrupt, reduce dose, or discontinue Trofinetide if significant weight loss occurs.	Empagliflozin 25mg + Linagliptin 5mg Tablet, Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet	USFDA	ধরাজন সেই বিধায় নামজ্ঞের সুশাসিন করা হয়।	ধরাজন সেই বিধায় নামজ্ঞের করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কবিতার সত্যতা নিশ্চিত	ঔষধ নিয়ন্ত্রণ কমিশনের নিশ্চিত
124.	Incepta Pharmaceuticals Ltd, Zirabo, Dhaka  The IBN SINA Pharmaceutical Industries Ltd.  Healthcare Pharmaceuticals Ltd  Eskayef Pharmaceuticals Limited, Rupganj, Natayanganj	Zuranolone 20 mg Capsule	Zuranolone INN 20mg	Therapeutic Class: Antidepressants Therapeutic Code: 014	Zuranolone is in pre-registration for major depressive disorder and postpartum depression, phase III clinical trials for insomnia, and phase II clinical studies for bipolar depression, essential tremor, and Parkinson's disease. Zuranolone is being evaluated as a short-course, rapid-acting, oral medication for major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone has been granted Fast Track and Breakthrough Therapy Designation for MDD and Fast Track Designation for PPD by the U.S. Food	<b>Contraindication:</b> Do not use it if you are allergic to zuranolone or any of the ingredients. Zuranolone may cause allergic reactions, such as rash, itching, swelling, or trouble breathing. <b>Side-effects:</b> Zuranolone is an investigational medication that is under development for the treatment of depressive disorders and other conditions. It is a neurosteroid that acts on the GABA A receptor in the brain. Some of the possible side effects of zuranolone include: Drowsiness, Headache, Dizziness, Upper respiratory tract infection, Diarrhea, Sedation & Confusion <b>Warnings and Precautions:</b> Zuranolone is an investigational medication that is being developed for the treatment of depressive	New	USFDA	অনুসন্ধানের সুপারিশ করা করা।	অনুসন্ধান করা করা।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান সোর্জিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMRA/EMA/PMDA/TGA	টেকনিক্যাল সর্ব কবিত্বের সত্তার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
	The ACME Laboratories Ltd. Dharmrai, Dhaka				& Drug Administration. It is also being studied for other indications, such as insomnia, bipolar depression, essential tremor, and Parkinson's disease.	disorders and other conditions. It is a neuroactive steroid that acts as a positive allosteric modulator of the GABA A receptor, which is the major inhibitory signaling pathway of the brain and central nervous system. According to the web sources, some of the possible precautions of zuranolone are: It may cause drowsiness, dizziness, or impaired coordination. Do not drive or operate machinery until you know how it affects you. It may interact with other medications that affect the GABA system, such as benzodiazepines, barbiturates, opioids, or alcohol. Consult your doctor before taking zuranolone with any of these substances. It may cause hormonal changes, such as decreased progesterone levels or menstrual irregularities. Women who are pregnant, breastfeeding, or planning to become pregnant should not take zuranolone without medical supervision. It may cause allergic reactions, such as rash, itching, swelling, or trouble breathing. Seek immediate medical attention if you experience any of these symptoms. It may cause withdrawal symptoms if stopped abruptly after long-term use. Follow your doctor's instructions on how to taper off zuranolone gradually..				
	General Pharmaceutical Ltd, Gazipur									
	One Pharma Ltd., Plot No. C23-24, BSC/C, Bogura									
	Oposonin Pharma Limited, Rupatali, Barishal									
	Pharmasia Limited, Bhawal, Mirzapur, Gazipur									
	Renata Limited Mirpur, Dhaka									
	Square Pharmaceuticals PLC., Salgaria, Pabna									
	Ziska Pharmaceuticals Ltd.									
	Advanced Chemical Industries Limited, 7 Heleegoni, Godnri, Narayanganj									

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	অনুরোধকার সাব কেমিষ্ট্রি নম্বর সিদ্ধান্ত	ঐচ্ছিক নিয়ন্ত্রণ কেমিষ্ট্রি সিদ্ধান্ত
125.	Inceptia Pharmaceuticals Ltd. Zirabo, Dhaka Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtail I/A, Dhaka-1204, Dhaka Opsonin Pharma Limited, Rupatali, Barishal Ziska Pharmaceuticals Ltd. Drug International Ltd Tongi I/A, Gazipur	Zavegepant 10mg/Spray Nasal Spray	Zavegepant Hydrochloride INN 10.6 mg eqv. to Zavegepant 10mg/Spray	Therapeutic Class: Drug used in Migraine Therapeutic Code: 047	Zavegepant is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults.	<b>Contraindication:</b> Patients with a history of hypersensitivity reaction to zavegepant or to any of the components of Zavegepant. <b>Side-effects:</b> Most common adverse reactions (at least 2% of patients treated with Zavegepant and greater than placebo) were taste disorders, nausea, nasal discomfort, and vomiting. <b>Warnings and Precautions:</b> Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue Zavegepant and initiate appropriate therapy. Hypersensitivity Reactions including facial swelling and urticaria have occurred with Zavegepant	New	USFDA	অনুরোধকার সাব কেমিষ্ট্রি নম্বর সিদ্ধান্ত হ্যাঁ।	অনুরোধ করা হ্যাঁ।
126.	Inceptia Pharmaceuticals Ltd, Savar, Dhaka Eskayef Pharmaceuticals Limited, Tongi, Gazipur Beacon Pharmaceuticals PLC Kathail, Bhaluka, Mymensingh Drug International Ltd, 31/1, Satrong, Tongi I/A, Gazipur	Ritlecitinib 50 mg Capsule	Ritlecitinib Tosylate INN 80.13 mg eq. to Ritlecitinib 50 mg	Therapeutic Class: Immuno-suppressant Therapeutic Code: 058	Ritlecitinib is a kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older. Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.	<b>Contraindication:</b> Ritlecitinib is contraindicated in patients with known hypersensitivity to ritlecitinib or any of its excipients <b>Side-effects:</b> Headache, diarrhea, acne, rash, hives, inflamed hair pores (folliculitis) fever, eczema, dizziness, shingles, decreased red blood cell counts, mouth sores, redness and swelling of the lining of your mouth. <b>Warnings and Precautions:</b> Serious infections have been reported in patients receiving RITLECITINIB. The most frequent serious infections have been appendicitis, COVID-19 infection (including pneumonia), and sepsis. Among opportunistic infections, multi-dermatomal herpes zoster was reported with RITLECITINIB. Avoid use of RITLECITINIB in patients with an active, serious infection. Consider the risks and benefits of treatment prior to	New	USFDA	অনুরোধকার সাব কেমিষ্ট্রি নম্বর সিদ্ধান্ত হ্যাঁ।	অনুরোধ করা হ্যাঁ।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKMHR/ EMA/PMDA/ TGA	উৎপাদনকারী নাম কারিগরি শর্তাবলি	উপর নিয়ন্ত্রণ কারিগরি শিকার
127.	Inceptia Pharmaceuticals Ltd., Zirabo, Dhaka  Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kademtal/IA, Dhaka-1204, Dhaka  Eskayef Pharmaceuticals Limited, Tongji, Gazipur  Advanced Chemical Industries Limited, 7 Hajeeganj, Godnvi, Narayanganj, NIPRO JMI Pharma Ltd  Drug International Ltd 3/1/1, Satong,	Empagliflozin 10mg + Linagliptin 5mg + Metformine Hydrochloride 1000mg Extended-release Tablet	Empagliflozin INN/In-house 10mg + Linagliptin INN/In-house 5mg + Metformine Hydrochloride BP 1000mg	Therapeutic Class Antidiabetic Therapeutic Code: 015	A combination of empagliflozin, a sodium-glucose cotransporter 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 glycaemic 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	<b>Contraindication:</b> Severe renal impairment (eGFR below 30 mL/min/1.73 m <sup>2</sup> ), end-stage renal disease, or dialysis  • Metabolic acidosis, including diabetic ketoacidosis Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients in it. <b>Side Effect:</b> Leucopenia, thrombocytopenia, eosinophilia, Dizziness, headache, Phlebitis, diarrhoea, vomiting, nausea <b>Warnings and Precautions:</b> Lactic Acidosis: See boxed warning • Pancreatitis: There have been reports of acute pancreatitis, including fatal pancreatitis, if pancreatitis is suspected, promptly discontinue • Heart Failure: Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of it in patients who have known risk factors for heart failure. Monitor for signs and symptoms • Hypotension: Before initiating it, assess and correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy. • Ketoacidosis: Assess patients who present with	Empagliflozin 25 mg + Linagliptin 5mg Tablet, Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet	USFDA	ধারাজন নাই বিধার নামস্বরের স্বাক্ষরিত করা করা।	ধারাজন বিধার নামস্বর করা করা।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	ঔষধ নিয়ন্ত্রণকারী কর্তৃক নির্ধারিত শর্তাবলি	ঔষধ নিয়ন্ত্রণকারী কর্তৃক নির্ধারিত শর্তাবলি
128.	Incepta Pharmaceuticals Ltd., Zirabo, Dhaka Aristopharma Ltd.	Empagliflozin 12.5mg + Linagliptin 2.5mg + Metformine Hydrochloride 1000mg Extended-release	Empagliflozin INN/In-house 12.5mg + Linagliptin INN/In-house 2.5mg +	Therapeutic Class Antidiabetic Therapeutic Code: 015	A combination of empagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride	<b>Contraindication:</b> Severe renal impairment (eGFR below 30 mL/min/1.73 m <sup>2</sup> ), end-stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis	Empagliflozin 25 mg + Linagliptin 5mg Tablet, Empagliflozin	USFDA	ঔষধ নিয়ন্ত্রণকারী কর্তৃক নির্ধারিত শর্তাবলি	ঔষধ নিয়ন্ত্রণকারী কর্তৃক নির্ধারিত শর্তাবলি
	Tongl U/A, Gazipur General Pharmaceutical Ltd., Gazipur									
	Opsonin Pharma Limited, Rupatali, Barisal Beacon Pharmaceuticals PLC, Kathail, Bhaluka, Mynensingh Popular Pharmaceuticals Ltd., 164, Tongi Industrial Area, Mornunagar, Gazipur, Square Pharmaceuticals PLC, Kalakoir, Gazipur Ziska Pharmaceuticals Ltd., Gazipur									

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান অডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	টেকনিক্যাল শার কনিটর সভার সিদ্ধান্ত	ড্রাগ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত	
	Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Tablet	Metformine Hydrochloride BP 1000mg		(HCl), a biguanide, indicated as an adjunct to diet and exercise to improve glycaemic 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	<p>Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients in it.</p> <p>Side Effect: Leucopenia, thrombocytopenia, eosinophilia, Dizziness, headache, Phlebitis, Diarrhoea, vomiting, nausea</p> <p><b>Warnings and Precautions:</b> Lactic Acidosis: See boxed warning</p> <ul style="list-style-type: none"> <li>• Pancreatitis: There have been reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue.</li> <li>• Heart Failure: Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of it in patients who have known risk factors for heart failure. Monitor for signs and symptoms</li> <li>• Hypotension: Before initiating it, assess and correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy.</li> <li>• Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue it, evaluate and treat promptly. Before initiating it, consider risk factors for ketoacidosis. Patients on it may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.</li> <li>• 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.</li> </ul>	5 mg + Metformin HCl 1000 mg XR Tablet				
	Eskayef Pharmaceuticals Limited, Tongi, Gazipur										
	Beacon Pharmaceuticals PLC, Kathail, Bhaluka, Mymensingh										
	Advanced Chemical Industries Limited, 7 Hafeegari, Godnyl, Narayangoni.										
	NIPRO JMI Pharma Ltd										
	General Pharmaceutical Ltd, Gazipur										
	Opsonin Pharma Limited, Rupatali, Bansal										
	Popular Pharmaceuticals Ltd, 164, Tongi Industrial Area, Moinunagar, Gazipur										
	Square										

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান মোড়িনি এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কাঠিওর সত্তর নিদ্রাঙ্ক	ইসখ নিমন্ত্রণ কারিওর নিদ্রাঙ্ক
129.	Incepta Pharmaceuticals Ltd., Zirabo, Dhaka Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtai I/A, Dhaka-1204, Dhaka Eskayef Pharmaceuticals Limited, Tongi, Gazipur Advanced Chemical Industries Limited, 7 Hajeegani, Godny, Narayanganj. NIPRO JM Pharma Ltd Drug International Ltd., 31/1, Sarrong, Tongi I/A, Gazipur General Pharmaceutical Ltd., Gazipur Opsonin Pharma Limited, Rupatali,	Empagliflozin 25mg + Linagliptin 5mg + Metformine Hydrochloride 1000mg Extended-release Tablet	Empagliflozin INN/In-house 25mg + Linagliptin INN/In-house 5mg + Metformine Hydrochloride BP 1000mg	Antidiabetic Therapeutic Code: 015	A combination of empagliflozin, a sodium-glucose cotransporter 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 glycaemic 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	<b>Contraindication:</b> Severe renal impairment (eGFR below 30 mL/min/1.73 m <sup>2</sup> ), end-stage renal disease, or dialysis • Metabolic acidosis, including diabetic ketoacidosis Hypersensitivity to empagliflozin, linagliptin, metformin, or any of the excipients in it. <b>Side Effect:</b> Leucopenia, thrombocytopenia, eosinophilia Dizziness, headache, Phlebitis, Diarrhoea, vomiting, nausea <b>Warnings and Precautions:</b> Lactic Acidosis: See boxed warning • Pancreatitis: There have been reports of acute pancreatitis, including fatal pancreatitis. If pancreatitis is suspected, promptly discontinue • Heart Failure: Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of it in patients who have known risk factors for heart failure. Monitor for signs and symptoms • Hypotension: Before initiating it, assess and correct volume status in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. 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 it, evaluate and treat promptly. Before initiating it, consider risk factors for ketoacidosis. Patients on it may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.	Empagliflozin 25 mg + Linagliptin 5mg Tablet, Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet	USFDA	ঔষধ নিমন্ত্রণ কৰাৰ নিদ্রাঙ্ক বিসয় নামস্বত্ৰ কৰা হয়।	ঔষধ নিমন্ত্রণ কৰাৰ নিদ্রাঙ্ক বিসয় নামস্বত্ৰ কৰা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান যেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	চিকিৎসকাল শার কাগজের নম্বর সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কাগজের সিদ্ধান্ত
130.	Incepta Pharmaceuticals Ltd, Zirabo, Zirabo, Dhaka  The IBN SINA Pharmaceutical Industries Ltd  Healthcare Pharmaceuticals Ltd	Fezolinetant 45 mg Tablet	Fezolinetant INN 45 mg	Therapeutic Class: Unclassified Agents Therapeutic Code: 075	Fezolinetant is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.	<b>Contraindication:</b> Severe renal impairment, Concomitant use with CYP1A2  <b>Side-effects:</b> The most common adverse reactions with Fezolinetant [at least 2% in Fezolinetant and greater than placebo] are: abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.  <b>Warnings and Precautions:</b> Hepatic transaminase elevation: Elevations in serum transaminase concentrations greater than three times the upper	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
	Beaisal  Beacon Pharmaceuticals PLC, Kathali, Bhaluka, Mymensingh  Popular Pharmaceuticals Ltd., 164, Tongl Industrial Area, Mominagar, Gazipur  Square Pharmaceuticals PLC, Kailakoir, Gazipur  Ziska Pharmaceuticals Ltd., Gazipur					* 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.				




**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কপিটির সত্যতা নিশ্চিত	উৎপাদন নিয়ন্ত্রণ কপিটির নিশ্চিত
	Eskayel Pharmaceuticals Limited, Tongi, Gazipur					limit of normal (ULN) occurred in the clinical trials. Perform bloodwork prior to initiation of Fezolinetant to evaluate for hepatic function and injury. Do not start therapy if serum transaminase concentration is equal to or exceeds two times the ULN. Perform follow-up evaluations of hepatic transaminase concentration at 3 months, 6 months, and 9 months after initiation of therapy.				
	Novartis Pharmaceuticals Ltd									
	The ACME Laboratories Ltd, Dharmaj, Dhaka									
	Navana Pharmaceuticals Limited									
	Beacon Pharmaceuticals PLC									
	Kathali, Bhajuka, Mymensingh									
	Drug International Ltd., 31/1, Satrong, Tongi I/A, Gazipur									
	DBL Pharmaceuticals Ltd. Surabari, Kashimpur, Gazipur									
	EVEREST Pharmaceuticals Ltd. BSC/C I/A, Kerchpur, Narayanagi, BANGLADESH									
	General									

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNE/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল শব্দ ক্যাটাগরি সত্তাৰ পিছাত্ত	ঔষধ নিয়ন্ত্রণ ক্যাটাগরি পিছাত্ত
	Pharmaceutical Ltd., Gazipur									
	One Pharma Ltd., Plot No. C23-24, BSCIC, Bogura									
	Opsonin Pharma Limited, Rupatali, Barishal									
	Popular Pharmaceuticals Ltd., 164, Tongi I/A, Monmunagar, Gazipur									
	Renata Limited Mirpur, Dhaka									
	Square Pharmaceuticals PLC, Kallakoir, Gazipur									
	Sharif Pharmaceuticals Ltd., Rubgani I, Narayanganj									
	UniMed & Uni-Health Pharmaceuticals Ltd. B,K Bari, Gazipur									
	Ziska Pharmaceuticals Ltd.;									
	Pharmasia Limited,									

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অডিটিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMRA/ EMA/PMDA/ TGA	ঔষধ নিয়ন্ত্রণ সার্বিক কার্যক্রমের নিয়ন্ত্রণ	ঔষধ নিয়ন্ত্রণ কার্যক্রমের নিয়ন্ত্রণ
131.	Incepta Pharmaceuticals Ltd, Zirabo, Dhaka Gazipur	Sodium Oxypate INN 50g/100ml (0.5g/ml) Oral Solution	Sodium Oxibate INN 50g/100ml (0.5g/ml)	Therapeutic Class: Antidepressants Therapeutic Code: 014	<b>Cataplexy in Narcolepsy</b> Sodium oxibate (sodium oxypate) oral solution is indicated for the treatment of cataplexy in narcolepsy. <b>Excessive Daytime Sleepiness in Narcolepsy</b> Sodium oxibate (sodium oxypate) oral solution is indicated for the treatment of excessive daytime sleepiness (EDS) in narcolepsy.	<b>Contraindication:</b> Sodium oxibate is contraindicated in patients being treated with sedative hypnotic agents. Patients should not drink alcohol when using Sodium oxibate. Sodium oxibate is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency. This is a rare disorder of inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia. <b>Side-effects:</b> The following adverse reactions appear in other sections of the labeling: CNS depression, Abuse and Misuse, Respiratory Depression and Sleep-disordered Breathing, Depression and Suicidality <b>Warnings and Precautions:</b> <b>Central Nervous System Depression</b> Sodium oxibate is a central nervous system (CNS) depressant. Alcohol and sedative hypnotics are contraindicated in patients who are using Sodium oxibate. The concurrent use of Sodium oxibate with other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating anti-epileptic drugs, general anesthetics, muscle relaxants, and/or illicit CNS depressants, may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death. If use of these CNS depressants in combination with Sodium oxibate is required, dose reduction or discontinuation of one or more CNS depressants (including Sodium oxibate) should be considered. In addition, if short-term use of an opioid (e.g. post-or peroperative) is required, interruption of treatment with Sodium oxibate should be considered. Healthcare providers should caution patients about operating hazardous machinery, including automobiles or airplanes, until they are reasonably certain that Sodium oxibate does not affect them adversely (e.g., impair judgment, thinking, or motor skills). Patients should not engage in hazardous occupations or activities requiring complete mental alertness or motor	New	USFDA	ধারাজন নই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	ধারাজন নই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান অভিপিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	টেকনিক্যাল শার কপিটির সভার সিদ্ধান্ত	উৎপাদন নিষেধণ কপিটির সিদ্ধান্ত
132.	Incepta Pharmaceuticals Ltd., Dharmal Unit, Dhaka	Canttharidin 0.7g/100ml Topical Solution	Canttharidin INN 0.7g/100ml	Antiviral Therapeutic Code: 032	CANTHARIDIN is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older	<p><b>CONTRAINDICATIONS:</b> None</p> <p><b>WARNINGS AND PRECAUTIONS:</b> Toxicities Associated with Inappropriate Administration: Life threatening or fatal toxicities can occur if administered orally. Avoid contact with the treatment area, including oral contact, after treatment. Ocular toxicity can occur if CANTHARIDIN comes in contact with eyes. If CANTHARIDIN gets in eyes, flush eyes with water for at least 15 minutes. <b>Local Skin Reactions:</b> Reactions at the application site have included vesiculation, pruritus, pain, discoloration, and erythema. Avoid application near eyes and mucosal tissue, and to healthy skin. If CANTHARIDIN contacts any unintended surface, or healthy skin, immediately remove. If severe local skin reactions occur, remove prior to 24 hours after treatment.</p> <p><b>Flammability:</b> CANTHARIDIN is flammable, even after drying. Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.</p>	New	USFDA	ঔষধোপাদানের বিধায় নামসমূহের সুশীলিত করা করা।	বর্তমান ঔষধোপাদানের বিধায় নামসমূহের করা করা।
133.	Incepta Pharmaceuticals Ltd.; Dharmal Unit, Dhaka	[Antihemophilic factor (recombinant), PEGylated-auc] Factor VIII concentrated 1000IU/ml ready to fill bulk* 1ml/Vial eqv. to Factor VIII concentrated 1000 IU/Vial Injection	[Antihemophilic factor (recombinant), PEGylated-auc] Factor VIII concentrated 1000IU/ml ready to fill bulk* INN/In-house 1ml/Vial	Therapeutic Class: Unclassified Agents Therapeutic Code: 075	antihemophilic factor (recombinant), PEGylated-auc, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: • On-demand treatment and control of bleeding episodes	<p><b>CONTRAINDICATIONS</b> Do not use in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product</p> <p><b>Side-effects:</b> No data available.</p>	New	USFDA	ঔষধোপাদানের সুশীলিত করা করা।	ঔষধোপাদন করা করা।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHR/ EMA/PMDA/ TGA	টেকনিক্যাল সার কமிটির সভার সিদ্ধান্ত	উপর নিরূপণ কমিটির সিদ্ধান্ত
134.	Incepta Pharmaceuticals Ltd., Dharmrai Unit, Dhaka	[Antihemophilic factor (recombinant), PEGylated-auc] Factor VIII concentrated 500U/ml ready to fill bulk* 1ml/Vial eqv. to Factor VIII concentrated 500 IU/Vial injection lyophilized powder for solution, for intravenous	[Antihemophilic factor (recombinant), PEGylated-auc] Factor VIII concentrated 500U/ml ready to fill bulk* INN/In-house 1ml/Vial eqv. to Factor VIII concentrated 500 IU/Vial	Therapeutic Class: Unclassified Agents Therapeutic Code: 075	antihemophilic factor (recombinant, PEGylated-auc) is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (Congenital Factor VIII deficiency) for: <ul style="list-style-type: none"> <li>• On-demand treatment and control of bleeding episodes</li> <li>• Perioperative management of bleeding</li> <li>• Routine prophylaxis to reduce the frequency of bleeding episodes</li> </ul>	<p><b>WARNINGS AND PRECAUTIONS</b></p> <p>Hypersensitivity reactions, including severe allergic reactions, have occurred. Monitor patients for hypersensitivity symptoms. Should hypersensitivity symptoms occur, discontinue treatment with Antihemophilic and administer appropriate treatment. Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG)</p> <p>Development of Factor VIII neutralizing antibodies can occur. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled as expected with the administered dose, then perform an assay that measures Factor VIII inhibitor concentration.</p> <p>Immune response to PEG, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in subjects &lt; 6 years of age. Evaluate patients experiencing symptoms of hypersensitivity reactions in the absence of detectable Factor VIII inhibitors for possible bleeding or reduced recovery</p> <p><b>CONTRAINDICATIONS</b></p> <p>Do not use in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product</p> <p><b>Side-effects:</b></p> <p>No data available.</p> <p><b>WARNINGS AND PRECAUTIONS</b></p> <p>Hypersensitivity reactions, including severe allergic reactions, have occurred. Monitor patients for</p>	New	USFDA	অনুমোদনের সুপারিশ করা করা	অনুমোদন করা করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অ্যান্টিবডি এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	ক্রমিকভাবে নাম ক্রমিকভাবে নাম	ঔষধ নিয়ন্ত্রণ কমিশনের সিদ্ধান্ত
135.	Incepta Pharmaceuticals Ltd.; Saver, Dhaka Beacon Pharmaceuticals PLC, Kathail, Bhailuka, Mymensingh	Niraparib 100 mg + Abiraterone Acetate 500mg Tablet	Niraparib Tosylate INN/In-house 159.30 mg eq. to Niraparib 100 mg + Abiraterone Acetate USP 500 mg	Anticancer Therapeutic Code: 010	Niraparib and Abiraterone acetate is a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved test for Niraparib and Abiraterone acetate	<p>Development of Factor VIII neutralizing antibodies can occur. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled as expected with the administered dose, then perform an assay that measures Factor VIII inhibitor concentration.</p> <p>Immune response to PEG, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in subjects &lt; 6 years of age. Evaluate patients experiencing symptoms of hypersensitivity reactions in the absence of detectable Factor VIII inhibitors for possible bleeding or reduced recovery.</p> <p><b>Contraindication:</b> No data available  <b>Side Effect:</b> The most common adverse reactions (≥10%), including laboratory abnormalities, are decreased hemoglobin, decreased lymphocytes, decreased white blood cells, musculoskeletal pain, fatigue, decreased platelets, increased alkaline phosphatase, constipation, hypertension, nausea, decreased neutrophils, increased creatinine, increased potassium, decreased creatinine, increased AST, increased ALT, edema, dyspnea, decreased appetite, vomiting, dizziness, COVID-19, headache, abdominal pain, hemorrhage, urinary tract infection, cough, insomnia, increased bilirubin, weight decreased, arrhythmia, fall, and pyrexia  <b>Warnings and Precautions:</b>                      Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML); MDS/AML, including cases with fatal</p>	New	USFDA	অনুমোদনের সুপারিশ করা করা	অনুমোদন করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অ্যুজিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/ PMDA/ TGA	টেকনিক্যাল শব্দ কারিটির স্বাক্ষর নিশ্চিত	ঔষধ নিয়ন্ত্রণ কারিটির নিশ্চিত
136.	Incepta Pharmaceuticals Ltd.; Ztrabo, Dhaka The IBN SINA Pharmaceutical Industries Ltd. Healthcare Pharmaceuticals Ltd Eskayel Pharmaceuticals Limited, Ruppargi, Narayanganj The ACME Laboratories Ltd. Dharmal, Dhaka General Pharmaceutical Ltd., Gazipur One Pharma Ltd., Plot No. C23-24, BSCIC, Bogura Oposonin	Zuranolone 30 mg Capsule	Zuranolone INN/in-house 30mg	Therapeutic Class: Antidepressants Code: 014	Zuranolone is in pre-registration for major depressive disorder, phase III clinical trials for insomnia, and phase II clinical studies for bipolar depression, essential tremor, and Parkinson's disease.  Zuranolone is being evaluated as a short-course, rapid-acting, oral medication for major depressive disorder (MDD) and postpartum depression (PPD).  Zuranolone has been granted Fast Track and Breakthrough Therapy Designation for MDD and Fast Track Designation for PPD by the U.S. Food & Drug Administration. It is also being studied for other indications, such as insomnia, bipolar depression, essential tremor, and Parkinson's disease.	outcome, has been observed in patients treated with niraparib, a component of Niraparib and Abiraterone acetate 50/500mg Tablet. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed.  • Myelosuppression: Test complete blood counts weekly for the first month, every two weeks for the next two months, monthly for the remainder of the first year, then every other month, and as clinically indicated. • Hypokalemia, Fluid Retention, and Cardiovascular Adverse Reactions: Monitor patients for hypertension, hypokalemia, and fluid retention at least weekly for the first two months, then once a month. Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia, or fluid retention. Control hypertension and correct hypokalemia before and during treatment with Niraparib and Abiraterone acetate 50/500mg Tablet.  <b>Contraindications:</b> Do not use it if you are allergic to zuranolone or any of the ingredients. Zuranolone may cause allergic reactions, such as rash, itching, swelling, or trouble breathing.  <b>Side-effects:</b> Zuranolone is an investigational medication that is under development for the treatment of depressive disorders and other conditions. It is a neurosteroid that acts on the GABA A receptor in the brain. Some of the possible side effects of zuranolone include: Drowsiness, Headache, Dizziness, Upper respiratory tract infection, Diarrhea, Sedation & Confusion  <b>Warnings and Precautions:</b> Zuranolone is an investigational medication that is being developed for the treatment of depressive disorders and other conditions. It is a neuroactive steroid that acts as a positive allosteric modulator of the GABA A receptor, which is the major inhibitory signaling pathway of the brain and central nervous system. According to the web sources, some of the possible precautions of zuranolone are:	New	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অ্যুভিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHR/ EMA/PPMDA/ TGA	উৎপাদনের স্থানীয়তা	নিষেধক
137.	Pharma Rupatali, Barishal Pharmasia Limited, Bhawal, Mirzapur, Gazipur Renata Limited Mirpur, Dhaka Square Pharmaceuticals PLC, Salgaria, Pabna Ziska Pharmaceuticals Ltd. Opsonin Pharma	Rezafungin 200mg/Vial lyophilized cake or Powder for injection	Rezafungin 200mg/vial as Rezafungin Acetate INN/In-House	Therapeutic Class: Antifungal Agents Therapeutic code: 020	Rezafungin is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for Rezafungin	It may cause drowsiness, dizziness, or impaired coordination. Do not drive or operate machinery until you know how it affects you. It may interact with other medications that affect the GABA system, such as benzodiazepines, barbiturates, opioids, or alcohol. Consult your doctor before taking zuranolone with any of these substances. It may cause hormonal changes, such as decreased progesterone levels or menstrual irregularities. Women who are pregnant, breastfeeding, or planning to become pregnant should not take zuranolone without medical supervision. It may cause allergic reactions, such as rash, itching, swelling, or trouble breathing. Seek immediate medical attention if you experience any of these symptoms. It may cause withdrawal symptoms if stopped abruptly after long-term use. Follow your doctor's instructions on how to taper off zuranolone gradually.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
	Inceptia Pharmaceuticals Ltd.; Zrabo, Dhaka Eskayel Pharmaceuticals Limited, Tongi, Gazipur Square Pharmaceuticals PLC, Salgaria, Pabna Ziska Pharmaceuticals Ltd. Opsonin Pharma	Rezafungin 200mg/Vial lyophilized cake or Powder for injection	Rezafungin 200mg/vial as Rezafungin Acetate INN/In-House	Therapeutic Class: Antifungal Agents Therapeutic code: 020	Rezafungin is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for Rezafungin	<b>Contraindication:</b> Known hypersensitivity to rezafungin or other echinocandins <b>WARNINGS AND PRECAUTIONS:</b> 1. Infusion-related Reactions: rezafungin may cause infusion-related reactions, including flushing, sensation of warmth, urticaria, nausea, or chest tightness. If these reactions occur, slow or pause the infusion. Photosensitivity: rezafungin may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation. 3. Hepatic Adverse Reactions: Abnormalities in liver tests have been seen in clinical trial patients treated with rezafungin. Monitor patients who develop abnormal liver tests and evaluate patients for their risk/benefit of continuing rezafungin therapy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভেলপমেন্ট এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাইট কবিত্বের সত্যতা নিশ্চিত	ইস্যু নিয়ন্ত্রণ কবিত্বের নিশ্চিত
138.	Incepta Pharmaceuticals Ltd.; Zirabdo, Dhaka Drug International Ltd 31/1, Satrong, Tongi I/A, Gazipur. DBL Pharmaceuticals Ltd. Surabai, Kashimpur, Gazipur Navana Pharmaceuticals Limited EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchipur, Narayanagiri Square Pharmaceuticals PLC, Kailakor, Gazipur Beacon Pharmaceuticals PLC, Kathali.	Etrasmiod 2mg Tablet	Etrasmiod INN 2mg	Therapeutic Class: Unclassified agents Therapeutic Code: 075	Etrasmiod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis in adults	<p><b>ADVERSE REACTIONS:</b> Most common adverse reactions (incidence <math>\geq</math> 5%) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia</p> <p><b>CONTRAINDICATIONS:</b> 1. In the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure. 2. History or 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.</p> <p><b>WARNINGS AND PRECAUTIONS:</b> <b>Infections:</b> May increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 5 weeks after discontinuation. Consider interruption of treatment if a serious infection develops. Avoid use of live attenuated vaccines during and for up to 5 weeks after treatment. <b>Bradycardia and Atrioventricular Conduction Delays:</b> May result in a transient decrease in heart rate and AV conduction delays. Obtain an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting treatment. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate. <b>Liver Injury:</b> Elevations of aminotransferases may occur. Obtain transaminase and bilirubin levels before initiating Etrasmiod. Discontinue if significant liver injury is confirmed. <b>Macular Edema:</b> May increase the risk of macular</p>	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান রেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	চিকিৎসকগণ শরৎ কবিরের সঙ্গীত পিঙ্কস	ঔষধ নিয়ন্ত্রণ কমিটির পিঙ্কস
139.	Incepta Pharmaceuticals Ltd.; Zirabo, Zirabo, Dhaka  Drug International Ltd., 31/1, Satrong, Tongi I/A, Gazipur	Nirsevimab 100mg/ml a single dose pre-filled syringe solution for intramuscular injection	Nirsevimab (100mg/ml) ready to fill bulk (NM/In-house eqv. to Nirsevimab 100mg/ml	Therapeutic Class: Unclassified Agents Therapeutic Code: 075	Nirsevimab is a respiratory syncytial virus (RSV) F protein-derived fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in: • Neonates and infants born during or entering their first RSV season. • Children up to 24 months of age who remain vulnerable to severe RSV	<b>Contra-indication:</b> Nirsevimab is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab- <i>alip</i> or to any of the excipients. <b>Side-effects:</b> Most common adverse reactions were rash (0.9%) and injection site reactions (0.3%) <b>Warnings and Precautions:</b> Hypersensitivity including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been	New	USFDA	অনুরোধের সুশীলতা করা হয়।	অনুরোধ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল ন্যাব কবিত্তির সত্তার বিক্রান্ত	উৎপন্ন নিবন্ধন কবিত্তির বিক্রান্ত
140.	Inceptia Pharmaceuticals Ltd.; Zirabo, Zirabo, Dhaka Drug International Ltd 31/1, Satrong, Tongi I/A, Gazipur.	Nirsevimab (100mg/ml) ready to fill bulk eqv. to Nirsevimab 50mg/0.5ml a single dose pre-filled syringe solution for Intramuscular Injection	Nirsevimab (100mg/ml) ready to fill bulk (N/N)/In-house eqv. to Nirsevimab 50mg/0.5ml	Therapeutic Class: Unclassified Agents Therapeutic Code: 075	Nirsevimab is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in: • Neonates and infants born during or entering their first RSV season. • Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	observed with other human IgG1 monoclonal antibodies. Initiate appropriate medications and/or supportive therapy.  <b>Contraindication:</b> Nirsevimab is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-imp or to any of the excipients. <b>Side-effects:</b> Most common adverse reactions were rash (0.9%) and injection site reactions (0.3%) <b>Warnings and Precautions:</b> Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human IgG1 monoclonal antibodies. Initiate appropriate medications and/or supportive therapy.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
141.	Inceptia Pharmaceuticals Ltd.; Zirabo, Zirabo, Dhaka Navara Pharmaceuticals Limited EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kancharpur, Narayanganj, BANGLADESH Square Pharmaceuticals PLC, Kallakoir, Gazipur	Orphenadrine Citrate 50mg + Aspirin 770mg + Caffeine 60mg Tablet	Orphenadrine Citrate BP/Ph. Eur. 50mg + Aspirin BP/Ph. Eur. 770mg + Caffeine BP/Ph. Eur. 60mg	Therapeutic Class: Non-steroidal anti-inflammatory Therapeutic code: 064	Orphenadrine Citrate, Aspirin and Caffeine (Orphenadrine Citrate, Aspirin and Caffeine 50 mg/ 770 mg/ 60 mg) Tablets are indicated in: Symptomatic relief of mild to moderate pain of acute musculoskeletal disorders. The orphenadrine component is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions.	<b>Contraindication:</b> Because of the mild anticholinergic effect of orphenadrine, Orphenadrine Citrate, Aspirin and Caffeine Tablets should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy or obstructions at the bladder neck. Orphenadrine Citrate, Aspirin and Caffeine 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. <b>Side-effects:</b> Side effects of Orphenadrine Citrate, Aspirin and Caffeine Tablets are those seen with aspirin and caffeine or those usually associated with mild anticholinergic agents. These may include tachycardia, palpitation, urinary hesitancy or retention, dry mouth, blurred vision, dilation of the pupil, increased intraocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, and rarely, urticaria and other dermatosis. Infrequently,	New	USFDA	ঔষধোত্তম নৈই বিধায় নামঞ্জুরের সুপারিশ করা হয়।	ঔষধোত্তম নৈই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ডেভিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	চিকিৎসকাল শার কার্যটির স্বাধীন সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কার্যটির সিদ্ধান্ত
142.	Incepta Pharmaceuticals Ltd., Savar, Dhaka Beacon Pharmaceuticals PLC, Kathail, Bhailuka, Mymensingh	Niraparib 50 mg + Abiraterone Acetate 500mg Tablet	Niraparib Tosylate INN/In-house 79.65mg eq. to Niraparib 50 mg + Abiraterone Acetate USP 500mg	Anticancer Therapeutic Code: 010	Niraparib and Abiraterone acetate is a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer	<b>Contra-indication:</b> No data available <b>Side Effect:</b> The most common adverse reactions (≥10%), including laboratory abnormalities, are decreased hemoglobin, decreased lymphocytes, decreased white blood cells, musculoskeletal pain, fatigue, decreased platelets, increased alkaline phosphatase, constipation, hypertension, nausea, decreased neutrophils, increased creatinine, increased potassium, decreased potassium,	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHR / EMA/PMDA / TGA	টেকনিক্যাল সাব কমিটি'র সভার সিদ্ধান্ত	ড্রাগ নিয়ন্ত্রণ কমিটি'র সিদ্ধান্ত
143.	Incepta Pharmaceuticals Ltd., Savar, Dhaka	Bimekizumab 160 mg/ml Subcutaneous Injection (PFS)	Bimekizumab INN/in-house 160 mg/ml	Unclassified Agents Therapeutic Code: 075	BIMEKIZUMAB is a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	increased AST, increased ALT, edema, dyspnea, decreased appetite, vomiting, dizziness, COVID-19, headache, abdominal pain, hemorrhage, urinary tract infection, cough, insomnia, increased bilirubin, weight decreased, arrhythmia, fall, and pyrexia <b>Warnings and Precautions:</b> Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): MDS/AML, including cases with fatal outcome, has been observed in patients treated with nintaparib, a component of Nintaparib and Abiraterone acetate 50/500mg Tablet. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed. • Myelosuppression: Test complete blood counts weekly for the first month, every two weeks for the next two months, monthly for the remainder of the first year, then every other month, and as clinically indicated. • Hypokalemia, Fluid Retention, and Cardiovascular Adverse Reactions: Monitor patients for hypertension, hypokalemia, and fluid retention at least weekly for the first two months, then once a month. Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia, or fluid retention. Control hypertension and correct hypokalemia before and during treatment with Nintaparib and Abiraterone acetate 50/500mg Tablet.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USEDA / BNF / UKMHR / EMA / PMDA / TGA	উৎপাদকাল সার্বকর্মটির সত্যতা নিশ্চিত	উষধ নিয়ন্ত্রণ কর্মটির সত্যতা
						<p>behavior.</p> <p><b>Infections:</b> May increase risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer BIMEKIZUMAB until the infection resolves.</p> <p><b>Tuberculosis (TB):</b> Avoid use in patients with active TB. Initiate treatment of latent TB prior to BIMEKIZUMAB treatment.</p> <p><b>Liver Biochemical Abnormalities:</b> Elevated serum transaminases were reported in clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to routine patient management. Permanently discontinue use of BIMEKIZUMAB in patients with causally - associated combined elevations of transaminases and bilirubin.</p> <p><b>Inflammatory Bowel Disease (IBD):</b> Cases of IBD were reported in clinical trials with IL-17 inhibitors, including BIMEKIZUMAB. Avoid use of BIMEKIZUMAB in patients with active IBD. Monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.</p>				

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKMhra/ EMA/PMDA/ TGA	ঔষধিকাল শব্দ কনিষ্টির সত্যতা নিশ্চিত	ঔষধ নিয়ন্ত্রণ কনিষ্টির নিশ্চিত
144.	Incepta Pharmaceuticals Ltd., Dharmrai Unit, Dhaka	(Bacitracin Zinc 0.8333g eqv. to 50,000 units + Lidocaine Hydrochloride 4.9298g eqv. to Lidocaine 4g + Neomycin Sulfate 0.35g + Polymyxin B Sulfate 0.1539g eqv. to 10,00,000 unit)/100g Ointment	(Bacitracin Zinc USP 0.8333g eqv. to 50,000 units + Lidocaine Hydrochloride USP 4.9298g eqv. to Lidocaine 4g + Neomycin Sulfate USP 0.35g + Polymyxin B Sulfate USP 0.1539g eqv. to 10,00,000 unit)/100g	Therapeutic Class: Skin and Mucous membrane preparations Therapeutic Code: 071	The combined ointment contains Bacitracin Zinc (500 units), Lidocaine, Neomycin Sulfate (3.5 mg), and Polymyxin B. It is used for the following purposes:  First Aid: This combination product is used as a first aid to help prevent infection and provide temporary pain relief in minor cuts, scrapes, burns, Superficial Bacterial Skin Infections: It is used topically alone or in fixed combination with other anti-infectives for prevention of superficial bacterial skin infections associated with minor cuts, scrapes, or burns. Infected Corticosteroid-responsive Dermatoses: It is used topically in fixed combination with other anti-infectives and a corticosteroid for treatment of corticosteroid-responsive dermatoses with secondary infection	<b>Contra-indication:</b> The combined ointment contains Bacitracin Zinc (500 units), Lidocaine, Neomycin Sulfate (3.5 mg), and Polymyxin B. Here are the contra-indications for its use:  Allergy: Do not use if you are allergic to any of the ingredients. Eye Contact: Do not use in or near the eyes. Large Areas: Do not use over large areas of the body. Deep Wounds and Burns: Do not use in case of deep or puncture wounds, animal bites, or serious burns. Long-Term Use: Do not use longer than 1 week unless directed by a doctor.  <b>Side-effects:</b> Burning, redness, or irritation of the skin may occur. Mild itching or rash. Minor skin irritation after using the medicine. A rare but serious side effect of neomycin is hearing loss, which has occurred in people using other forms of neomycin. It's unlikely that you would absorb enough of this medicine through your skin to cause this effect. If you notice any changes in your hearing or if you have severe redness or irritation, swelling, pus, oozing, or other signs of infection, you should call your doctor at once. In case of an allergic reaction, symptoms may include: Hives Difficulty breathing Swelling of your face, lips, tongue, or throat. <b>Warnings and Precautions:</b> The mentioned ointment contains Bacitracin Zinc (500 units), Lidocaine, Neomycin Sulfate (3.5 mg), and Polymyxin B. Here are some precautions for its use:	New	USFDA OTC	ঔষধিকাল শব্দ কনিষ্টির সত্যতা নিশ্চিত ঔষধ নিয়ন্ত্রণ কনিষ্টির সত্যতা নিশ্চিত	ঔষধ নিয়ন্ত্রণ কনিষ্টির নিশ্চিত

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান রেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMhra / EMA/PMDA / TGA	টেকনিক্যাল শার করিটির সাথে সিদ্ধান্ত	ইচ্ছা নিয়ন্ত্রণ করিটির সিদ্ধান্ত
145.	Incepta Pharmaceuticals Ltd., Dharmal Unit, Dhaka	Risperidone 12.5 mg/Vial long-acting Injection	Risperidone Extended-Release Microspheres for Injection In-house Risperidone USP 12.5 mg/Vial	Therapeutic Class: Antipsychotic Therapeutic Code: 028	Schizophrenia Bipolar Mania Irritability Associated with Autistic Disorder	<b>Contraindications:</b> Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been observed in patients treated with risperidone. Therefore, Risperidone is contraindicated in patients with a known hypersensitivity to the product. <b>Side-effects:</b> somnolence, vision abnormal, dizziness, palpitations, weight increase, erectile dysfunction, ejaculation disorder sexual function abnormal, fatigue, skin discoloration. <b>Warnings and Precautions:</b> Increased Mortality in Elderly Patients with Dementia-Related Psychosis Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. (risperidone) is not approved for the treatment of dementia-related psychosis.	Risperidone 25 mg/vial Injection, Risperidone 100 mg/100 ml Syrup, Risperidone 1 mg, 2 mg, 4 mg Tablet	USFDA	অনুমোদনের সুপারিশ করা করা	অনুমোদন করা করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটি সভার কার্যক্রম সিকার্ড	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
146.	Incepta Pharmaceuticals Ltd.; Zirabo, Dhaka	(Dextromethorphan Hydrobromide 0.40 gm + Guafenesin 4.00 gm + Phenylephrine Hydrochloride 0.1218 gm eqv. to Phenylephrine 0.1 g)/ 100 ml Pediatric Drops	(Dextromethorphan Hydrobromide 0.40 gm + Guafenesin 4.00 gm + Phenylephrine Hydrochloride 0.1218 gm eqv. to Phenylephrine 0.1 g)/ 100 ml	Therapeutic Class: Antitussives, Expectorants and Guafenesin BP/Ph. Eur. 4.00 gm + Phenylephrine Hydrochloride BP/Ph. Eur. 0.1218 gm eqv. to Phenylephrine 0.1 g)/ 100 ml Therapeutic Code: 031	This combination medication is used to temporarily treat cough, chest congestion, and stuffy nose symptoms caused by the common cold, flu, allergies, hay fever, or other breathing illnesses (e.g., sinusitis, bronchitis). Guafenesin is an expectorant that helps to thin and loosen mucus in the lungs, making it easier to cough up the mucus. Dextromethorphan is a cough suppressant that affects a certain part of the brain (cough center), reducing the urge to cough. This product also contains a decongestant, which helps relieve stuffy nose symptoms. This medication is usually not used for ongoing coughs from smoking, asthma, other long-term breathing problems (e.g., emphysema), or coughs with a lot of mucus, unless directed by your doctor.	<b>Contraindications:</b> Some medicines can cause unwanted or dangerous effects when used together. Not all possible interactions are listed in this medication guide. Taking this medicine with other drugs that make you sleepy or slow your breathing can worsen these effects. Ask your doctor before taking this medicine with a sleeping pill, narcotic pain medicine, muscle relaxer, or medicine for anxiety, depression, or seizures. <b>Side Effects:</b> Dizziness, headache, nausea, nervousness, or trouble sleeping may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. If your doctor has prescribed this drug, remember that your doctor has prescribed it 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 if any of these unlikely but serious side effects occur: mental/mood changes (e.g., confusion, hallucinations), shaking (tremors), weakness. Tell your doctor if any of these rare but very serious side effects occur: fast/slow/irregular heartbeat.	New	USFDA	প্রয়োজন নেই বিধায় নামজ্বরের সুপারিশ করা হয়।	প্রয়োজন নেই বিধায় নামজ্বরের সুপারিশ করা হয়।
147.	Incepta Pharmaceuticals Ltd.; Zirabo, Zirabo, Dhaka  The ACME Laboratories Ltd. Dhamrai, Dhaka	Topipronin 300 mg Delayed Release Tablet	Topipronin INN 300 mg	Unclassified Agents Therapeutic Code: 075	Topipronin 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	<b>CONTRAINDICATIONS:</b> Hypersensitivity to topipronin or any component of Topipronin <b>WARNINGS AND PRECAUTIONS:</b> Proteinuria, including nephrotic syndrome, and membranous nephropathy, has been reported with topipronin use. Pediatric patients receiving greater than 50 mg/kg of topipronin per day may be at increased risk for proteinuria Hypersensitivity reactions have been reported during topipronin treatment. <b>ADVERSE REACTIONS:</b> Most common adverse reactions (≥10%) are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.	New	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	অনুসন্ধান করা হয়।
148.	M/s Orion Pharma Ltd. D/28/2,	Meropenem 1 gm + Vaborbactam 1.0 gm/Vial Injection	Meropenem USP 1.0 gm + Vaborbactam	Antibacterial, Therapeutic	It is indicated for the treatment of the following infections in adults: • Complicated urinary tract infection	<b>Contraindications:</b> Meropenem and Vaborbactam is contraindicated in patients with known hypersensitivity to any components of	Meropenem 1.0gm/Vial	USFDA	অনুসন্ধানের সুপারিশ করা হয়।	নামজ্বর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সপেক্ষে সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
	Sumilpara, Siddhirganj, Narayanganj		USP 1 gm/Vial	code: 023	(cUTI), including pyelonephritis • Complicated intra-abdominal infection (cIAI) • Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP).	meropenem and vaborbactam, or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactam antibacterial drugs. <b>Side effects:</b> Like all medicines, this medicine can cause side effects, although not everybody gets them. <b>Serious side effects:</b> • Severe allergic reactions that could include sudden swelling of your lips, face, throat or tongue, difficulty swallowing or breathing or a severe rash or other severe skin reactions, or a decrease in blood pressure (which could make you feel faint or dizzy). Such reactions may be life-threatening. • Diarrhoea that keeps getting worse or does not go away, or stools that contains blood or mucus-this may happen during or after treatment with Vaboram is stopped. It may be, due to bacteria called Clostridium difficile. If this happens, do not take medicines that stop or slow bowel movement. Common side effects: (may affect up to 1 in 10 people) • Increase in the number of platelets (a type of blood cell) – shown in blood tests • Decrease in the amount of potassium or sugar- seen in blood tests • Headache • Low blood pressure • Diarrhoea • Feeling sick (nausea) or being sick (vomiting) • Swelling, redness and/or pain around the needle where the medicine is given into a vein • Fever • Increase in the amount of enzymes produced by your liver called alanine aminotransferase or				

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMHRA/ EMA/PMDA/ TGA	ডাক্তারদের সবার কমিটির সভার সিদ্ধান্ত	উষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
149.	M/s. JENPHAR Bangladesh Limited, Faridpur, Sheepur, Gazipur  Ziska Pharmaceuticals Ltd.	Cabozantinib S-Malate 20mg Tablet	Cabozantinib S-Malate INN 25.350 mg eq. to Cabozantinib 20mg	Anticancer Therapeutic Code: 010	Cabozantinib INN : It is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer	<b>Contraindication:</b> None  <b>Side-effect:</b> The most commonly reported adverse drug reactions (≥25%) are diarrhea, stomatitis, palmar-plantar erythrodysesthesia syndrome (PPES), decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, and constipation. The most common laboratory abnormalities (≥25%) are increased AST, increased ALT, lymphopenia, increased alkaline phosphatase, hypocalcemia, neutropenia, thrombocytopenia, hypophosphatemia, and hypertriglyceridemia.	Cabozantinib S-Malate INN 20mg Tablet	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
150.	One Pharma Ltd., Plot No. C23-24, BSCIC, Bogura	Leniolisib 70 mg Tablet	Leniolisib Phosphate INN 85.19 mg eq. to Leniolisib 70 mg	Immune-suppressant Therapeutic Code: 058	It is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older	<b>Contraindications:</b> None  <b>Side-effects:</b> Headache, Nasal congestion, Runny nose, Dry and itchy skin, Red or Scaly rash, Diarrhea, Tiredness, Neck or back pain, Hair loss.  <b>Warnings &amp; Precautions:</b> Embryo-Fetal Toxicity: It may cause fetal harm. Advise patients of the potential risk to a fetus and to use effective	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান ড্রুগসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UK/MHRA/ EMA/PMDA/ TGA	কেন্দ্রিকাল শব্দ কমিটির সমস্ত সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
151.	Opsonin Pharma Limited, Rupatali, Barishal.	Acetic Acid Ear Drops	Acetic Acid USP 2%	Ear and Nose Preparations: Therapeutic Code: 050	Otitis Externa	contraception. Vaccinations: Live, attenuated vaccinations may be less effective if administered during treatment. <b>Contraindications:</b> Hypersensitivity to Acetic Acid Otic Solution or any of the ingredients. Perforated tympanic membrane is considered a contraindication to the use of any medication in the external ear canal. <b>Side effects:</b> Redness, itching or hives, slight pain in or around the ears <b>Precautions &amp; warnings:</b> Transient stinging or burning may be noted occasionally when the solution is first instilled into the acutely inflamed ear.	New	USFDA	খরাজান নাই বিশেষ নামঞ্জুর সুপারিশ করা হয়।	খরাজান নাই বিশেষ নামঞ্জুর করা হয়।
152.	Opsonin Pharma Limited, Rupatali, Barishal.	Aminocaproic Acid 500 mg Tablet	Aminocaproic Acid USP 500mg	Blood Coagulating agent Therapeutic Code: 033	It is useful in enhancing hemostasis when fibrinolysis contributes to bleeding.	<b>Contraindications:</b> Aminocaproic Acid should not be used when there is evidence of an active intravascular clotting process. When there is uncertainty as to whether the cause of bleeding is primary fibrinolysis or disseminated intravascular coagulation (DIC), this distinction must be made before administering Aminocaproic Acid. <b>Side effects:</b> Aminocaproic Acid is generally well tolerated. The following side effects have been reported: Edema, headache, malaise, allergic and anaphylactic reactions, anaphylaxis, injection site reactions, pain, bradycardia, hypotension, peripheral ischemia, thrombosis, abdominal pain, diarrhea, nausea, vomiting, Agrenulocytosis, coagulation disorder, leukopenia, thrombocytopenia, CPK increased, muscle weakness, myalgia, myopathy, myositis, rhabdomyolysis, confusion, convulsions, delirium, dizziness, hallucinations, intracranial hypertension, stroke, syncope. <b>Precautions &amp; warnings:</b> In patients with upper urinary tract bleeding, Aminocaproic Acid administration has been known to cause intrarenal obstruction in the form of glomerular capillary	1.5 mg/ 5 ml Injection	USFDA	অনুমানের সুপারিশ করা হয়।	অনুমান করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অডিটিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMIRA / EMA/PMDA / TGA	টেকনিক্যাল সাব কমিটির সভার বিজ্ঞপ্তি	ঔষধ নিয়ন্ত্রণ কমিটির বিজ্ঞপ্তি
153.	Opsonin Pharma Limited, Rupatali, Barishal.	Aminocaproic Acid 1000 mg Tablet	Aminocaproic Acid USP 1000mg	Blood Coagulating agent Therapeutic Code: 033	It is useful in enhancing hemostasis when fibrinolysis contributes to bleeding.	<p>thrombosis or clots in the renal pelvis and ureters. For this reason, Aminocaproic Acid should not be used in hematuria of upper urinary tract origin, unless the possible benefits outweigh the risk. Rarely, skeletal muscle weakness with necrosis of muscle fibers has been reported following prolonged administration.</p> <p>Aminocaproic Acid inhibits both the action of plasminogen activators and to a lesser degree, plasmin activity. The drug should NOT be administered without a definite diagnosis and/or laboratory finding indicative of hyperfibrinolysis (hyperplasminemia).</p> <p><b>Contraindications:</b> Aminocaproic Acid should not be used when there is evidence of an active intravascular clotting process. When there is uncertainty as to whether the cause of bleeding is primary fibrinolysis or disseminated intravascular coagulation (DIC), this distinction must be made before administering Aminocaproic Acid.</p> <p><b>Side effects:</b> Aminocaproic Acid is generally well tolerated. The following side effects have been reported: Edema, headache, malaise, allergic and anaphylactic reactions, anaphylaxis, injection site reactions, pain, bradycardia, hypotension, peripheral ischemia, thrombosis, abdominal pain, diarrhea, nausea, vomiting, Agranulocytosis, coagulation disorder, leukopenia, thrombocytopenia, CPK increased, muscle weakness, myalgia, myopathy, myositis, rhabdomyolysis, confusion, convulsions, delirium, dizziness, hallucinations, intracranial hypertension, stroke, syncope.</p> <p><b>Precautions &amp; warnings:</b> In patients with upper urinary tract bleeding, Aminocaproic Acid administration has been known to cause intrarenal obstruction in the form of glomerular capillary thrombosis or clots in the renal pelvis and ureters. For this reason, Aminocaproic Acid should not be</p>	1.5 mg/5 ml Injection	USFDA	<p>ধরোজন লাই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।</p>	<p>ধরোজন লাই বিধায় নামঞ্জুর করা হয়।</p>

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/ PMDA/ TCA	টেকনিক্যাল সার কার্টির সত্যতা নিশ্চিত	অন্যান্য নিয়ন্ত্রণ কার্ভার নিশ্চিত
154.	Opsonin Pharma Limited, Rupatali, Barishal.	Aminocaproic 25gm/100 ml Oral Solution	Aminocaproic Acid USP 25gm/100 ml	Blood Coagulating agent Therapeutic Code: 033	It is useful in enhancing hemostasis when fibrinolysis contributes to bleeding.	<b>Contraindications:</b> Aminocaproic Acid should not be used when there is evidence of an active intravascular clotting process. When there is uncertainty as to whether the cause of bleeding is primary fibrinolysis or disseminated intravascular coagulation (DIC), this distinction must be made before administering Aminocaproic Acid.  <b>Side effects:</b> Aminocaproic Acid is generally well tolerated. The following side effects have been reported: Edema, headache, malaise, allergic and anaphylactic reactions, anaphylaxis, injection site reactions, pain, bradycardia, hypotension, peripheral ischemia, thrombosis, abdominal pain, diarrhea, nausea, vomiting, Aggranulocytosis, coagulation disorder, leukopenia, thrombocytopenia, CPK increased, muscle weakness, myalgia, myopathy, myositis, rhabdomyolysis, confusion, convulsions, delirium, dizziness, hallucinations, intracranial hypertension, stroke, syncope.  <b>Precautions &amp; warnings:</b> in patients with upper urinary tract bleeding, Aminocaproic Acid administration has been known to cause intrarenal obstruction in the form of glomerular capillary thrombosis or clots in the renal pelvis and ureters. For this reason, Aminocaproic Acid should not be used in hematuria of upper urinary tract origin.	1.5 mg/ 5 ml Injection	USFDA	অন্যায়ন নই বিধায় নামঞ্জুর করা নৃপাশিন করা হয়।	অন্যায়ন নই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UK/MHRA/ EMA/PMDA/ TGA	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ড্রাগ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
155.	Opsonin Pharma Limited, Rupatali, Barishal.	Carisoprodol 200mg + Aspirin 325 mg Tablet	Carisoprodol USP 200 mg + Aspirin USP 325 mg	Skeletal Muscle Relaxant Therapeutic Code: 070	It is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.  <b>Important Limitations:</b> Aspirin and Carisoprodol should only be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use has not been established and because acute, painful musculoskeletal conditions are generally of short duration.	<b>Contra-indications:</b> Carisoprodol and Aspirin are contraindicated in patients with a history of: • A serious GI complication • Aspirin-induced asthma • Hypersensitivity reaction to a carbamate such as meperobamate <b>Side effects:</b> Tachycardia, postural hypotension, facial flushing, drowsiness, dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope, insomnia, and seizures, nausea, vomiting, and epigastric discomfort, leukopenia and pancytopenia. <b>Precautions &amp; warnings:</b> Since the sedative effects of Carisoprodol and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) may be additive, appropriate caution should be exercised with patients who take more than one of these CNS depressants simultaneously.	Carisoprodol 250 mg & 350 mg Tablet	USFDA	ধারাবাহিক বোর্ড বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	ধারাবাহিক বোর্ড বিধায় নামঞ্জুর করা হয়।
156.	Opsonin Pharma Limited, Rupatali, Barishal  Incepta Pharmaceuticals Ltd., Zirabo, Dhaka  Nivista Pharma Ltd. Tongi, Gazipur	Cefoperazone Sodium 1000 mg + Sublactam Sodium 0.5gm/Vial Powder for Injection	Cefoperazone Sodium USP 1000mg + Sublactam Sodium USP 500mg/Vial	Anti-Infective Therapeutic Code: 023	Respiratory Tract Infections, Urinary Tract Infections (Upper and Lower), Intra-abdominal Infections, Septicemia, Meningitis, Skin and Soft Tissue Infections, Bone and Joint Infections, Endometritis, Other Infections of the Genital Tract	<b>Contra-indications:</b> Contraindicated in patients who have known hypersensitivity to the active substances (sublactam, cefoperazone), to beta-lactams or to any of the excipients. <b>Side effects:</b> Haemorrhage cases, sometimes fatal including fatalities, have been reported with the use of cefoperazone/sublactam. As with other antibiotics, a vitamin K deficiency has occurred in patients treated with sublactam/cefoperazone which has generated coagulopathy. <b>Precautions &amp; warnings:</b> Cefoperazone is extensively excreted in bile. The serum half-life of cefoperazone is usually prolonged and urinary excretion of the drug	Cefoperazone 1000 mg/vial Injection	USFDA	অনুশোধনের সুপারিশ করা হয়।	পরবর্তী টেকনিক্যাল সাব কমিটির সভায় উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।

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**Annex-A: স্থানীয়ভাবে উপাদানের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	ঔষধ নিয়ন্ত্রণ কর্তৃক কার্যকর করার পিছনে	ঔষধ নিয়ন্ত্রণ কর্তৃক পিছনে
157.	Opsonin Pharma Limited, Rupatali, Barishal.	Epinephrine 125 mcg/ Metered Dose Inhaler	Epinephrine Bitartrate USP 227.409mcg eq. to 125 mcg Epinephrine	Drugs used in Bronchial Asthma: Therapeutic Code: 044	Epinephrine inhalation is used to treat mild symptoms of asthma, including wheezing, chest tightness, and shortness of breath.	<b>Contraindications:</b> if any patient taking a monoamine oxidase inhibitor (MAOI) (certain drugs taken for depression, psychiatric or emotional conditions, or Parkinson's disease), should not take this inhaler or may take 2 weeks after stopping the MAOI drug. <b>Side effects:</b> Headache, nausea, vomiting, nervousness, dizziness, shaking (tremor), trouble sleeping, stomach upset, sweating, dry mouth, bad taste, cough, or sore throat may occur. <b>Precautions &amp; warnings:</b> This product may contain inactive ingredients, which can cause allergic reactions or other problems. Patients having heart disease (such as high blood pressure, abnormal heart rhythm, coronary insufficiency), seizures, overactive thyroid (hyperthyroidism), diabetes, low blood potassium level (hypokalemia), glaucoma (narrow-angle), Parkinson's disease, urination problems (such as trouble urinating due to enlarged prostate) need to be cautious before taking the medicine.	New	USFDA	ঔষধ নিয়ন্ত্রণ কর্তৃক কার্যকর করার পিছনে হয়।	ঔষধ নিয়ন্ত্রণ কর্তৃক পিছনে হয়।
158.	Opsonin Pharma Limited, Rupatali, Barishal.	Hydroxy Propyl Methyl Cellulose Powder for Nasal Spray	Hydroxypropyl Methylcellulose BP 744 mg/Bottle	Ear & Nose Preparations Therapeutic Code: 050	It is used as a preventative treatment in the fight against hay fever and allergies.	<b>Contraindication:</b> Contraindicated in patients with hypersensitivity to Hydroxy Propyl Methyl Cellulose or any component of this product. <b>Side effects:</b> Very few cases of allergic reactions to this product have been reported. During first use, patient may experience a tingling or burning sensation in the nose or light sneezing. <b>Precautions &amp; warnings:</b> If concurrent use of another nasal spray is required, HPMC should	New	USFDA	ঔষধ নিয়ন্ত্রণ কর্তৃক কার্যকর করার পিছনে হয়।	ঔষধ নিয়ন্ত্রণ কর্তৃক পিছনে হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMIRA / EMA/PMDA / TGA	টেকনিক্যাল নাম কামটির সবার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
159.	Opsonin Pharma Limited, Rupatali, Barishal.	Hydroxy Propyl Methyl Cellulose Powder for Nasal Spray	Hydroxypropyl Methylcellulose BP 760 mg	Ear & Nose Preparations Therapeutic Code: 050	It is used as a preventative treatment in the fight against hay fever and allergies.	Contraindication: Contraindicated in patients with hypersensitivity to Hydroxy Propyl Methyl Cellulose or any component of this product. Side effects: Very few cases of allergic reactions to this product have been reported. During first use, patient may experience a tingling or burning sensation in the nose or light sneezing. Precautions & warnings: If concurrent use of another nasal spray is required, HPMC should be re-applied afterwards so that the barrier created is not disturbed. Do not use this product if sensitive to cellulose. Avoid contact with eyes & open wounds. If powder gets into eye, rinse with water. Do not use for more than 30 days continuously.	New	USFDA	অয়োজন নেই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	অয়োজন নেই বিধায় নামঞ্জুর করা হয়।
160.	Opsonin Pharma Limited, Rupatali, Barishal.	Hydroxy Propyl Methyl Cellulose Powder for Nasal Spray	Hydroxypropyl Methylcellulose BP 776 mg	Ear & Nose Preparations Therapeutic Code: 050	It is used as a preventative treatment in the fight against hay fever and allergies.	Contraindication: Contraindicated in patients with hypersensitivity to Hydroxy Propyl Methyl Cellulose or any component of this product. Side effects: Very few cases of allergic reactions to this product have been reported. During first use, patient may experience a tingling or burning sensation in the nose or light sneezing. Precautions & warnings: If concurrent use of another nasal spray is required, HPMC should be re-applied afterwards so that the barrier created is not disturbed. Do not use this product if sensitive to cellulose. Avoid contact with eyes & open wounds. If powder gets into eye, rinse with water. Do not use for more than 30 days continuously.	New	USFDA	অয়োজন নেই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	অয়োজন নেই বিধায় নামঞ্জুর করা হয়।
161.	Opsonin Pharma Limited, Rupatali, Barishal.	Hydroxy Propyl Methyl Cellulose Powder for Nasal Spray	Hydroxypropyl Methylcellulose BP 788 mg	Ear & Nose Preparations Therapeutic Code: 050	It is used as a preventative treatment in the fight against hay fever and allergies.	Contraindication: Contraindicated in patients with hypersensitivity to Hydroxy Propyl Methyl Cellulose or any component of this product. Side effects: Very few cases of allergic reactions to this product have been reported. During first use, patient may experience a tingling or burning sensation continuously.	New	USFDA	অয়োজন নেই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	অয়োজন নেই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান রেভিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	চিকিৎসকাল শব্দ কবিতার স্বাক্ষর	ঔষধ নিয়ন্ত্রণ কবিতার স্বাক্ষর
162.	Opsonin Pharma Limited, Rupatali, Barshal	Indomethacin BP 50 mg Suppository	Indomethacin BP	Nonsteroidal Anti-inflammatory; Therapeutic Code: 084	- Moderate to severe rheumatoid arthritis including acute flares of chronic disease - Moderate to severe ankylosing spondylitis - Moderate to severe osteoarthritis - Acute painful shoulder (bursitis and/or tendinitis) - Acute gouty arthritis	In the nose or light sneezing. <b>Precautions &amp; warnings:</b> If concurrent use of another nasal spray is required, HPMC should be re-applied afterwards so that the barrier created is not disturbed. Do not use this product if sensitive to cellulose. Avoid contact with eyes & open wounds. If powder gets into eye, rinse with water. Do not use for more than 30 days continuously. <b>Contraindications:</b> Known hypersensitivity to Indomethacin or any components of the drug product. <b>Side Effects:</b> Most common adverse reactions (incidence $\geq$ 3%) are headache, dizziness, dyspepsia and nausea. <b>Precautions &amp; warnings:</b> History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. - In the setting of CABG surgery. - In patients with a history of proctitis or recent rectal bleeding.	Indomethacin 25mg, 75 mg Capsule & 100 mg suppository	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
163.	Opsonin Pharma Limited, Rupatali, Barshal	Teriparatide 750mcg/3 ml Pre Filled Syringe Injection	Teriparatide USP 750mcg/3 ml Pre Filled Syringe	Drug used in Osteoporosis Therapeutic Code: 048	It is indicated for the treatment of post-menopausal women with osteoporosis who are at high risk for fracture.	<b>Contraindications:</b> Teriparatide should not be given to patients with hypersensitivity to Teriparatide or to any of its excipients. <b>Side effects:</b> Adverse events associated with Teriparatide usually were mild and generally did not require discontinuation of therapy. Reported events that appeared to be increased by Teriparatide treatment were dizziness and leg cramps. <b>Precautions &amp; warnings:</b> The safety and efficacy of Teriparatide have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years is not recommended.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	নামঞ্জুর করা হয়।
164.	Opsonin Pharma Limited, Rupatali, Barshal.	Carisoprodol 200mg + Aspirin 325 mg + Codeine Phosphate 16mg Tablet	Carisoprodol USP 200 mg + Aspirin USP 325 mg + Codeine Phosphate USP 16 mg	Skeletal Muscle Relaxant Therapeutic Code: 070	It is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults. <b>Important Limitations:</b> It should only be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use has not been	<b>Contraindications:</b> Carisoprodol and Aspirin with Codeine contraindicated in patients with a history of: • A serious GI complication • Aspirin-induced asthma • Hypersensitivity reaction to a carbamate such as meprobamate • Acute intermittent porphyria <b>Side effects:</b> Tachycardia, postural hypotension, facial flushing, drowsiness, dizziness, vertigo.	Carisoprodol 250mg Tablet & 350mg Tablet	USFDA	একোজন লাই বিধায় নামঞ্জুর করা সুপারিশ করা হয়।	একোজন লাই বিধায় নামঞ্জুর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMHRRA/EMA/PMDA/TGA	উৎপাদনকারী সবার কনিষ্ঠ পিতা	ই-বর্ধ নিয়ন্ত্রণকারী পিতা
165.	Opsonin Pharma Limited, Rupatali, Barishal.	Bismuth Subsalicylate 262.50mg Tablet + Metronidazole 280 mg Tablet + Tetracycline Hydrochloride 500 mg Capsule Combi Pack	Bismuth Subsalicylate BP 262.50mg Tablet + Metronidazole BP 280 mg Tablet + Tetracycline Hydrochloride BP 500 mg Capsule Combi Pack	Antacid Therapeutic Code: 007 + Anti-Infective Therapeutic Code: 023 + Anti-Infective Therapeutic Code: 023	Indicated for the treatment of patients with an active duodenal ulcer associated with H. pylori infection. The eradication of H. pylori has been demonstrated to reduce the risk of duodenal ulcer recurrence. Appropriate doses of an H2 antagonist indicated for the treatment of active duodenal ulcer should be prescribed for ulcer healing.	<b>Contra-indications:</b> This therapy is contraindicated in the following patient populations: • Pregnant or nursing women • Pediatric patients • Patients with renal or hepatic impairment • Patients with known hypersensitivity to bismuth subsalicylate, metronidazole or other nitroimidazole derivatives, or any of the tetracyclines <b>Side effects:</b> It may cause your tongue to become darker in color. It may also cause your stools to appear black in color. These are harmless and temporary side effects. <b>Precautions &amp; warnings:</b> Alcohol during therapy and at least 1 day after completion of all doses due to potential metronidazole effects. Sun lamps or sun because of possible photosensitivity secondary to tetracycline. Administer with caution in patients with central nervous system diseases. Administer with caution in	120mg Tablet 87.5 mg/5 ml Suspension	USFDA	অন্যায়ন নই বিশাশ নামাঙ্কনের মুগাশিশ করা হয়।	অন্যায়ন নই বিশাশ নামাঙ্কর করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKM/HRA/ EMA/PMDA/ TGA	টেকনিক্যাল নাম কনিটর সভার বিবরণ	ইয়ম নিয়ন্ত্রণ কনিটর বিবরণ
166.	Opsonin Pharma Limited, Rupatali, Barishal Incepta Pharmaceuticals Ltd.; Zirabo, Dhaka Navista Pharma Ltd. Tongi, Gazipur	Cefoperazone Sodium 500 mg + Sulbactam Sodium 0.5 gm/ Vial Powder for Injection	Cefoperazone Sodium USP 500mg + Sulbactam Sodium USP 500 mg/Vial	Anti-Infective Therapeutic Code: 023	Respiratory Tract Infections, Urinary Tract Infections (Upper and Lower), Intra-abdominal Infections, Septicemia, Meningitis, Skin and Soft Tissue Infections, Bone and Joint Infections, Endometritis, Other Infections of the Genital Tract	<b>Contraindications:</b> Contraindicated in patients who have known hypersensitivity to the active substances (sulbactam, cefoperazone), to beta-lactams or to any of the excipients. <b>Side effects:</b> Haemorrhage cases, sometimes fatal including fatalities, have been reported with the use of cefoperazone/sulbactam. As with other antibiotics, a vitamin K deficiency has occurred in patients treated with sulbactam/cefoperazone which has generated coagulopathy. <b>Precautions &amp; warnings:</b> Cefoperazone is extensively excreted in bile. The serum half-life of cefoperazone is usually prolonged and urinary excretion of the drug increased in patients with hepatic diseases and/or biliary obstruction. Even with severe hepatic dysfunction, therapeutic concentrations of cefoperazone are obtained in bile and only a 2- to 4-fold increase in half-life is seen. Dose modification may be necessary in cases of severe biliary obstruction, severe hepatic disease or in cases of renal dysfunction coexistent with either of those conditions.	Cefoperazone 500 mg/vial Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	গরবর্তী টেকনিক্যাল নাম কনিটর সভার উৎপাদনের বিবরণ গৃহীত হয়।
167.	Opsonin Pharma Limited, Rupatali, Barishal EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchnpur, Narayanagiri	Momeclonib 200mg Tablet	Momeclonib INN 200 mg	Drug used in Anemia and other Blood disorder Therapeutic Code: 045	Indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.	<b>Contraindications:</b> Hypersensitivity to this product or any of its components. <b>Side effects:</b> Low blood platelets, bleeding, fatigue, dizziness, diarrhea, nausea, abdominal pain, itching, elevated liver enzymes, rash, kidney and urinary tract infection (UTI), irregular heartbeats (arrhythmias), and low white blood cells (neutropenia). <b>Precautions &amp; warnings:</b> Do not initiate Momeclonib in patients with an active infection. Monitor for signs and symptoms of infection. Thrombocytopenia and Neurotoxicity, Hepatotoxicity, Major Adverse Cardiovascular Events (MACE).	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF/ UKMIRA/ EMA/PMDA/ TGA	টেকনিক্যাল সার কেমিস্ট্রি সাক্সেস পিজাভ	ঔষধ নিয়ন্ত্রণ কমিটি'র সিদ্ধান্ত
168.	Pharmasia Limited, Bhowal, Mirzapur, Gazipur  Orion Pharma Ltd. D/28/2, Sumilpara, Siddhinganj, Narayanjanj	Isavuconazonium Sulfate 186 Capsule	Isavuconazonium Sulfate INN 186.00 mg	Antifungals	It is an azole antifungal indicated for use in the treatment of invasive aspergillosis and invasive mucormycosis.	<b>Contraindication:</b> Isavuconazonium Sulfate is contraindicated in persons with known hypersensitivity to isavuconazole. Coadministration of strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir (400 mg every 12 hours), with Isavuconazonium Sulfate is contraindicated because strong CYP3A4 inhibitors can significantly increase the plasma concentration of Isavuconazole. Coadministration of strong CYP3A4 inducers, such as rifampin, carbamazepine, St. John's wort, or long acting barbiturates with Isavuconazonium Sulfate is contraindicated because strong CYP3A4 inducers can significantly decrease the plasma concentration of Isavuconazole. Isavuconazonium Sulfate shortened the QTc interval in a concentration-related manner. Isavuconazonium Sulfate is contraindicated in patients with familial short QT syndrome. <b>Side-effects:</b> Most frequent Side effects: nausea, vomiting, diarrhea, headache, elevated liver chemistry tests, hypokalemia, constipation, dyspnea, cough, peripheral edema, and back pain. <b>CONTRAINDICATIONS</b> Known or suspected androgen-dependent tumors, such as prostatic carcinoma or breast carcinoma in the male.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।
169.	Popular Pharmaceuticals Ltd, 164, Tongi Industrial Area, Monmunagar, Gazipur	Recombinant Human Chorionic Gonadotropin (r-HCG) 6500 IU (equivalent to 250mcg)/0.5ml Injection/Subcutaneous	Recombinant Human Chorionic Gonadotropin (r-HCG) 6500 IU (equivalent to 250mcg)/0.5ml	Therapeutic Class: Hormone Therapeutic code: 056	In the female • Ovulation induction in infertility due to anovulation or impaired follicle-ripening. • Preparation of follicles for puncture in controlled ovarian hyperstimulation programs (ART). • Luteal phase support. • Threatened and habitual abortion  In the male • Hypogonadotropic hypogonadism (also cases of idiopathic dysparemias have shown a positive response to gonadotropins). • Delayed puberty associated with	<b>WARNINGS AND PRECAUTIONS:</b> In pregnancies occurring after induction of ovulation with gonadotropic preparations, there is an increased risk of multiples birth.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান রেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMIRA / EMA/PMDA / TGA	উৎপাদনকারী শারীরিক প্রতিষ্ঠানের নাম	উৎপাদনকারীর নাম
170.	Popular Pharmaceuticals Ltd., 164, Tongi Industrial Area, Monunagar, Gazipur	Famotidine 10mg + Calcium Carbonate 800mg + Magnesium Hydroxide 165mg Chewable Tablet	Famotidine USP 10mg + Calcium Carbonate BP 800mg + Magnesium Hydroxide BP 165mg	Therapeutic Class: H <sub>2</sub> Receptor Blocking Therapeutic code: 055	Relieves heartburn associated with acid indigestion and sour stomach • Insufficient gonadotropic pituitary function. • Cryptorchidism, (not due to anatomical obstruction) • Used to treat oligospermia	<b>CONTRAINDICATIONS</b> History of serious hypersensitivity reactions to Famotidine or Calcium Carbonate or Magnesium Hydroxide. <b>WARNINGS AND PRECAUTIONS:</b> Allergy alert: Do not use if you are allergic to famotidine or other acid reducers Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Do not use with other acid reducers.	New	USFDA	এরোজন লেই বিখ্যাত নামগুলোর সুপারিশ করা হয়।	এরোজন লেই বিখ্যাত নামগুলোর সুপারিশ করা হয়।
171.	Popular Pharmaceuticals Ltd., 164, Tongi Industrial Area, Monunagar, Gazipur	Recombinant Follicle Stimulating Hormone (r-FSH) BP 450 IU/0.54ml Injection	Recombinant Follicle Stimulating Hormone (r-FSH) BP 450 IU/0.54ml	Therapeutic Class: Hormone Therapeutic code: 056	<b>In the Female</b> Ovulation Induction r-FSH administered SC with HCG in a sequential manner, which is indicated for ovulation induction in patients who have previously received pituitary suppression. Multi-follicular Development During ART r-FSH administered SC in conjunction with HCG is indicated for multiple follicular developments (controlled ovarian stimulation) during ART cycles in patients who have previously received pituitary suppression. Polycystic Ovarian Syndrome (PCOS). <b>In the Male</b> Male infertility treatment in combination with HCG induction of Spermatogenesis in men deficient spermatogenesis due to Hypogonadotropic-hypogonadism.	<b>CONTRAINDICATIONS</b> • Tumours of the ovary, breast, uterus, pituitary or hypothalamus • Pregnancy or lactation • Undiagnosed vaginal bleeding • Hypersensitivity to the active substance or to any of the excipients • Primary ovarian failure • Fibroid tumors of the uterus incompatible with pregnancy • Primary testicular failure <b>WARNINGS AND PRECAUTIONS:</b> The presence of uncontrolled non gonadal endocrinopathies (e.g. thyroid, adrenal or pituitary disorders) should be excluded.	75 IU/vial Injection	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।
172.	Popular Pharmaceuticals	Recombinant Follicle Stimulating Hormone (r-	Recombinant Follicle	Therapeutic Class:	<b>In the Female</b> Ovulation Induction	<b>CONTRAINDICATIONS</b>	75 IU/vial Injection	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান অডিটিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/ BNF/ UKM/HRA/ EMA/PMDA/ TGA	ডকুমেন্টেশন করে কবিত্বের স্বাক্ষর	উপর নিয়ন্ত্রণ কবিত্বের স্বাক্ষর
173.	Popular Pharmaceuticals Ltd, 164, Tongi Industrial Area, Moulmanagar, Gazipur	r-FSH) BP 600 IU/0.72ml Injection	Stimulating Hormone (r-FSH) BP 600 IU/0.72ml	Hormone Therapeutic code: 056	<p>r-FSH administered SC with HCG in a sequential manner, which is indicated for ovulation induction in patients who have previously received pituitary suppression.</p> <p><b>Multi-follicular Development</b> During ART r-FSH administered SC in conjunction with HCG is indicated for multiple follicular developments (controlled ovarian stimulation) during ART cycles in patients who have previously received pituitary suppression.</p> <p><b>Polycystic Ovarian Syndrome (PCOS).</b> Used to treat Polycystic Ovarian Syndrome (PCOS) related infertility.</p> <p><b>In the Female</b> Ovulation induction r-FSH administered SC with HCG in a sequential manner, which is indicated for ovulation induction in patients who have previously received pituitary suppression.</p> <p><b>Multi-follicular Development</b> During ART r-FSH administered SC in conjunction with HCG is indicated for multiple follicular developments (controlled ovarian stimulation) during ART cycles in patients who have previously received pituitary suppression.</p> <p><b>Polycystic Ovarian Syndrome (PCOS).</b> Used to treat Polycystic Ovarian Syndrome (PCOS) related infertility.</p>	<p>• Tumours of the ovary, breast, uterus, pituitary or hypothalamus</p> <p>• Pregnancy or lactation</p> <p>• Undiagnosed vaginal bleeding</p> <p>• Hypersensitivity to the active substance or to any of the excipients</p> <p>• Primary ovarian failure</p> <p>• Fibroid tumors of the uterus incompatible with pregnancy</p> <p>• Primary testicular failure</p> <p><b>WARNINGS AND PRECAUTIONS:</b> The presence of uncontrolled non gonadal endocrinopathies (e.g. thyroid, adrenal or pituitary disorders) should be excluded.</p> <p><b>CONTRAINDICATIONS</b></p> <ul style="list-style-type: none"> <li>• Tumours of the ovary, breast, uterus, pituitary or hypothalamus</li> <li>• Pregnancy or lactation</li> <li>• Undiagnosed vaginal bleeding</li> <li>• Hypersensitivity to the active substance or to any of the excipients</li> <li>• Primary ovarian failure</li> <li>• Fibroid tumors of the uterus incompatible with pregnancy</li> <li>• Primary testicular failure</li> </ul> <p><b>WARNINGS AND PRECAUTIONS:</b> The presence of uncontrolled non gonadal endocrinopathies (e.g. thyroid, adrenal or pituitary disorders) should be excluded.</p>	75 IU/ml Injection	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য বিজ্ঞান মৌজিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMhra / EMA/PRMDA / TGA	টেকনিক্যাল শব্দ কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
174.	Radiant Pharmaceuticals Limited B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710, Bangladesh	Flecainide Acetate 50mg Tablet	Flecainide Acetate USP 50mg	Antiarrhythmic Therapeutic Code: 009	<p><b>In the Male</b> Male infertility treatment in combination with HCG induction of Spermato-genesis in men deficient to Hypogonadotrophic-hypogonadism.</p> <p>Treatment of AV nodal reciprocating tachycardia; arrhythmias associated with Wolf-Parkinson-White Syndrome and similar conditions with accessory pathways, when other treatment has been ineffective.</p> <ul style="list-style-type: none"> <li>Treatment of severe symptomatic and life-threatening paroxysmal ventricular arrhythmia which has failed to respond to other forms of therapy or where other treatments have not been tolerated.</li> <li>Treatment of paroxysmal atrial arrhythmias (atrial fibrillation, atrial flutter, and atrial tachycardia) in patients with disabling symptoms after conversion provided that there is a definite need for treatment on the basis of severity of clinical symptoms when other treatment has been ineffective. Structural heart disease and/or impaired left ventricular function should be excluded because of the increased risk for pro-arrhythmic effects.</li> </ul>	<p><b>Contraindication:</b></p> <ul style="list-style-type: none"> <li>Hypersensitivity to the active substance or to any of the excipients listed in.</li> <li>Flecainide is contraindicated in cardiac failure and in patients with a history of myocardial infarction who have either asymptomatic ventricular ectopics or asymptomatic non-sustained ventricular tachycardia.</li> <li>Patients with long-standing atrial fibrillation in whom there has been no attempt to convert to sinus rhythm</li> <li>Patients with reduced or impaired ventricular function, cardiogenic shock, severe bradycardia (less than 50 bpm), and severe hypotension.</li> <li>Use in combination with Class I antiarrhythmic drugs. (Sodium channel blockers)</li> <li>In patients with hemodynamically significant valvular heart disease.</li> <li>Unless pacing rescue is available, flecainide must not be given to patients with sinus node dysfunction, atrial conduction defects, second-degree or greater atrioventricular block, bundle branch block, or distal block.</li> <li>Patients with asymptomatic or mildly symptomatic ventricular arrhythmias must not be given flecainide.</li> <li>Use in patients with significant electrolyte imbalance.</li> <li>Known as Brugada syndrome.</li> </ul> <p><b>Side Effect:</b></p> <ul style="list-style-type: none"> <li>Difficult or labored breathing</li> <li>dizziness, fainting, or lightheadedness</li> <li>fast, irregular, pounding, or racing heartbeat or pulse</li> </ul>	100mg Tablet (DCC-239 approved)	USFDA BNF-85, Page-112 EMA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNE/ UKMHRA/ EMA/PMDA/ TGA	কোম্পানির সার কনিটিন সত্তর সিদ্ধান্ত	ক্রম নিয়ন্ত্রণ কনিটিন সিদ্ধান্ত
175.	Renata Limited Mirpur, Dhaka	Abiraterone Acetate 125mg Tablet	Abiraterone Acetate USP 125mg	Anticancer Therapeutic Code:010	It is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castrationresistant prostate cancer (CRPC)	<ul style="list-style-type: none"> <li>• shortness of breath</li> <li>• tightness in the chest</li> <li>wheezing</li> </ul> <p><b>Contraindication:</b> Pregnancy. <b>Side-effect:</b> The most common adverse reactions (<math>\geq 10\%</math>) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and constipation. The most common laboratory abnormalities (<math>&gt; 20\%</math>) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.</p>	250mg Tablet	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধন করা হয়।
176.	Renata Limited Mirpur, Dhaka	Estradiol 5mg/ml IM Injection	Estradiol USP 5mg/ml	Hormone Therapeutic Code: 056	It is indicated in the treatment of: 1. Moderate to severe vasomotor symptoms associated with the menopause. 2. Hypoestrogenism due to hypogonadism.	<p><b>Contraindication:</b> Estrogens should not be used in individuals with any of the following conditions: 1. Undiagnosed abnormal genital bleeding. 2. Known or suspected cancer of the breast. 3. Known or suspected estrogen-dependent neoplasia. 4. Active deep vein thrombosis, pulmonary embolism or history of these conditions. 5. Active or recent (e.g., within the past year) arterial thromboembolic disease (e.g., stroke, myocardial infarction). 6. Liver dysfunction or disease. 7. It should not be used in patients with known hypersensitivity to its ingredients. 8. Known or suspected pregnancy. There is no indication for it in pregnancy. There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins from oral contraceptives inadvertently during early pregnancy.</p> <p><b>Side-effects:</b> <b>Less common but serious side effects include:</b> • Breast cancer • Cancer of the uterus • Stroke • Heart attack • Blood clots • Gallbladder disease • Ovarian cancer</p>	NEW	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য ডিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	টেকনিক্যাল নাম কারিটির সত্তার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কারিটির সিদ্ধান্ত
177.	Renata Limited Mirpur, Dhaka Beacon Pharmaceuticals P.L.C, Kathali, Bhaluka, Myrmenisingh	Eltrombopag 25mg Powder for Oral Suspension	Eltrombopag Olaniline INN 31.90 mg equivalent to Eltrombopag 25mg	Anticoagulants Therapeutic Code: 012	Eltrombopag is a thrombopoietin receptor agonist indicated for the treatment of: •thrombocytopenia in adult and pediatric patients 6 years and older with chronic Immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or	<p><b>These are some of the warning signs of serious side effects:</b> • Breast lumps • Unusual vaginal bleeding • Dizziness and faintness • Changes in speech • Severe headaches • Chest pain • Shortness of breath • Pains in your legs • Changes in vision • Vomiting</p> <p><b>Common side effects include:</b> • Headache • Breast pain • Irregular vaginal bleeding or spotting • Stomach/abdominal cramps, bloating • Nausea and vomiting Other side effects include: • High blood pressure • Liver problems • High blood sugar • Fluid retention • Enlargement of benign tumors of the uterus ("fibroids") • Vaginal yeast infections • Hair loss</p> <p><b>Warnings and precautions:</b> Talk to your doctor or pharmacist before taking Proglynova before you start the treatment, as these may return or become worse during treatment with Proglynova often for check-ups: Iside your womb (endometrosis) or a history of excessive growth of the womb lining (endometrial hyperplasia) (see "Blood clots in a vein (thrombosis)") - sensitive cancer (such as mother, sister or grandmother who has had breast cancer) tumour affects many organs of the body (systemic lupus erythematosus, SLE) Epilepsy &amp; Asthma.</p>	Eltrombopag 12.5mg 25mg 50mg Tablet	USFDA	অনুরোধের সুপারিশ করা হয়।	অনুরোধ হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMHR/EMA/PMDA/TGA	টেকনিক্যাল সার কনিট্রোল সত্তার সিদ্ধান্ত	উৎস নিয়ন্ত্রণ কনিট্রোল সিদ্ধান্ত
178.	Renata Limited Mirpur, Dhaka Beacon Pharmaceuticals PLC, Kalthail, Mymensingh	Trazodone Hydrochlorid 50mg Film Coated Tablet	Trazodone Hydrochloride USP 50 mg	Antidepressant Therapeutic Code: 014	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD).  splenectomy. Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. Limitations of Use: • Etrionbopag should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. • Etrionbopag should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. • Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.	equal to 10% and greater than placebo) were upper respiratory tract infection, nasopharyngitis, and rhinitis. • In patients with chronic hepatitis C - associated thrombocytopenia, the most common adverse reactions (greater than or equal to 10% and greater than placebo) were: anemia, pyrexia, fatigue, headache, nausea, diarrhea, decreased appetite, influenza-like illness, asthenia, insomnia, cough, pruritus, chills, myalgia, alopecia and peripheral edema. In patients with severe aplastic anemia, the most common adverse reactions (greater than or equal to 20%) were: nausea, fatigue, cough, diarrhea, and headache.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA/BNF/UKMHRA/EMA/PMDA/TGA	টেকনিক্যাল গার কমিটির সভার সিদ্ধান্ত	উষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
179.	Renata Limited Mirpur, Dhaka  Beacon Pharmaceuticals PLC, Kathail, Bhaluka, Mymensingh	Trazodone Hydrochlorid 100 mg Film Coated Tablet	Trazodone Hydrochloride USP 100 mg	Antidepressant Therapeutic Code: 014	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD).	<p>SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment. • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval. • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension. • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk. • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed.</p> <p>• Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania</p> <p>• potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery. • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.</p>	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRA / EMA/PMDA / TGA	চরুকালিকাল সার কার্গিটির সত্যতা নিশ্চিত	ঔষধ নিয়ন্ত্রণ কার্গিটির নিশ্চিত
180.	Renata Limited Mitpur, Dhaka  Beacon Pharmaceuticals PLC, Kathali, Bhaluka, Mymensingh  Opsonin Pharma Ltd., Barishal	Trazodone Hydrochlorid 150 mg Tablet	Trazodone Hydrochlorid USP 150 mg	Antidepressant Therapeutic Code: 014	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD)	SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed  • Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania • potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.	New	USFDA	অনুমোদনের সুপারিশ করা হয়।	অনুমোদন করা হয়।

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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/ Existing Molecule)	USFDA/ BNF/ UKMIRA/ EMA/PMDA/ TGA	উৎপাদনকারী/ কামের শর্তাধীনে/ নিষিদ্ধ	উষধ নিয়ন্ত্রণ কর্তৃক/ নিষিদ্ধ
181.	Renata Limited Mirpur, Dhaka	Trazodone Hydrochlorid 300 mg Tablet	Trazodone Hydrochlorid USP 300 mg	Antidepressant Therapeutic Code: 014	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD)	<p>supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed</p> <p>• Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania</p> <p>• potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.</p> <p><b>Contraindications:</b> Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs. Side effects: Most common adverse reactions (incidence <math>\geq 5\%</math> and twice that of placebo) are: edema, blurred vision, syncope, drowsiness, fatigue, diarrhea, nasal congestion, weight loss.</p> <p><b>Warning &amp; Precaution:</b></p> <p>• Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that</p>	New	USFDA	অনুপ্রাপনের সুপারিশ করা করা।	অনুপ্রাপন করা

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**Annex-A: স্থানীয়ভাবে উৎপাদনের জন্য হিউম্যান মেডিসিন এর তালিকা**

Sl. 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 / Existing Molecule)	USFDA / BNF / UKMHRRA / EMA/PMDA / TGA	উৎপাদনকারী/কর্মসূচী স্থান	উৎপাদন নিয়ন্ত্রণ কর্মসূচী স্থান
						<p>also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed</p> <ul style="list-style-type: none"> <li>• Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania</li> <li>• potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.</li> </ul>				

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