ঔষধ নিয়ন্ত্রণ কমিটির ৩০ অক্টোবর ২০১৩ তারিখে অনুষ্ঠিত ২৪২ তম সভার কার্য বিবরণী

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের সচিব জনাব এম এম নিয়াজ উদ্দিন এঁর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৪২ তম সভা বিগত ৩০ অক্টোবর ২০১৩ তারিখ বেলা ২:০০ ঘটিকায় মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

সভায় কমিটির নিম্নবর্ণি ত সদস্যগণ উপস্থিত ছিলেন(জ্যেষ্ঠতার ক্রমানুসারে নয়)ঃ

১। জনাব মোঃ নাজমুল হাসান, প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা।

২। জনাব সুকুমার রঞ্জন ঘোষ, প্রতিনিধি, বাংলাদেশ ফার্মাসিউটিক্যালস্ ইম্পোটার্স এসোসিয়েশন, ঢাকা।

৩। মেজর জেনারেল মোঃ রবিউল হোসেন, কনসালট্যান্ট ফিজিশিয়ান, বাংলাদেশ আর্মড ফোর্সেস মেডিকেল সার্ভিসেস।

৪। ডাঃ মোঃ আইনুল হক, পক্ষে মহাপরিচালক, প্রাণিসম্পদ অধিদপ্তর, ঢাকা।

৫। অধ্যাপক ডাঃ মোঃ ইসমাইল খান, ডীন চিকিৎসা অনুষদ, ঢাকা বিশ্ববিদ্যালয় ও প্রতিনিধি, ফার্মাকোলজি বিভাগ, ঢাকা মেডিকেল কলেজ।

৬। অধ্যাপক ফরিদা বেগম, ক্লিনিক্যাল ফার্মেসী ও ফার্মাকোলজি বিভাগ, ঢাকা বিশ্ববিদ্যালয়।

৭। অধ্যাপক মোঃ আজিজুল কাহহার, মেডিসিন বিভাগ, ঢাকা মেডিকেল কলেজ।

৮। অধ্যাপক ডাঃ এ কে এম শরিফুল ইসলাম, চর্ম ও যৌন রোগ বিশেষজ্ঞ, স্যার সলিমুলস্নাহ্ মেডিকেল কলেজ, ঢাকা।

৯। অধ্যাপক সামছুন নাহার বেগম, বিভাগীয় প্রধান, গাইনী এন্ড অবঃ বিভাগ, স্যার সলিমুলস্নাহ্ মেডিকেল কলেজ, ঢাকা।

১০। ডাঃ মোসত্মাক আহম্মদ, প্রতিনিধি, বাংলাদেশ মেডিকেল এসোসিয়েশন, ঢাকা।

১১। জনাব মোঃ নাসের শাহরিয়ার জাহেদী, প্রতিনিধি, বাংলাদেশ ফার্মেসী কাউন্সিল, ঢাকা।

১২। ডা. মোমেনুল হক, সিনিয়র সহ সভাপতি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং ব্যবস্থাপনা পরিচালক, জেনারেল ফার্মাসিউটিক্যালস্ লিঃ।

১৩। জনাব আবদুল মুক্তাদির, মহা-সচিব, বাংলাদেশ ঔষধ শিল্প সমিতি এবং ব্যবস্থাপনা পরিচালক, ইনসেপ্টা ফার্মাসিউটিক্যালস্ লিঃ।

১৪। মেজর জেনারেল মোঃ জাহাংগীর হোসেন মলিস্নক, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।

সভায় আলোচ্য বিষয় সমূহঃ

১। বিগত ২০-০৫-২০১২ তারিখে অনুষ্ঠিত ঔষধ নিয়ন্ত্রণ কমিটির ২৪১ তম সভার কার্য বিবরণী নিশ্চিতকরণ প্রসঙ্গে (সভার কার্য বিবরণীর কপি সংযুক্ত)।

২। ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব কমিটির গত ২৭-০৬-২০১৩ তারিখে অনুষ্ঠিত ৫৯ তম সভার সুপারিশসমূহের বিষয়ে আলোচনা ও সিদ্ধামত্ম গ্রহণ প্রসঙ্গে।

৩। সভাপতি মহোদয়ের অনুমতিক্রমে যে কোন বিষয়।

সভায় উপরিউক্ত বিষয়সমূহ বিসত্মারিত আলোচনাপূর্ব ক নিম্নবর্ণি ত সিদ্ধামত্মগ্রহণ করা হলঃ

১। বিগত ২০-০৫-২০১২ তারিখে অনুষ্ঠিত ঔষধ নিয়ন্ত্রণ কমিটির ২৪১ তম সভার কার্য বিবরণী নিশ্চিতকরণ প্রসঙ্গে।

বিগত ২০-০৫-২০১২ তারিখে অনুষ্ঠিত ঔষধ নিয়ন্ত্রণ কমিটির ২৪১ তম সভার কার্য বিবরণী সভায় উপস্থাপন করা হয়। কার্য বিবরণী সঠিকভাবে লিপিবদ্ধ হয়েছেবলে সদস্যগণ মত প্রকাশ করেন।

সভায় সর্ব সম্মতিক্রতে২৪১ তম সভার কার্য বিবরণী নিশ্চিত করা হয়।

২। ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব কমিটির গত ২৭-০৬-২০১৩ তারিখে অনুষ্ঠিত ৫৯ তম সভার সুপারিশসমূহের বিষয়ে আলোচনা ও সিদ্ধামত্ম গ্রহণ প্রসঙ্গে।

২.১। **Human and Veterinary-ঔষধের একই মাত্রার ইনজেকশন জাতীয় পদের পৃথক প্যাক সাইজের পৃথক রেজিস্ট্রেশন প্রদান প্রসঙ্গেঃ**

ঔষধ নিয়ন্ত্রণ কমিটির ২৪০ তম সভায় ইনজেকশন জাতীয় ঔষধের প্রতিটি প্যাক সাইজের জন্য পৃথক পৃথক রেজিস্ট্রেশন এর সিদ্ধামত্ম গৃহীত হয়। ঔষধ নিয়ন্ত্রণ কমিটির ২৪১ তম সভায় উক্ত সিদ্ধামত্ম পুনর্মূ ল্যায়নের জন্য ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাৰকমিটির পরবর্তী সভায় উপস্থাপনের জন্য বলা হয়।

বিভিন্ন প্রতিষ্ঠান একই মাত্রার ইন্জেকশন/ইনফিউশনের বিভিন্ন প্যাক সাইজ অনুমোদনের জন্য প্রসত্মাব করে থাকে। মাত্রা এক হলে বিভিন্ন প্যাক সাইজের জন্য ভিন্ন ভিন্ন রেজিস্ট্রেশনের প্রয়োজন হবে কিনা, এ বিষয়ে সিদ্ধামেত্ম জন্য টেকনিক্যাল সাব-কমিটির ৫৯ তম সভায় উপস্থাপন করা হলে বিসত্মারিত আলোচনা শেষে নিম্নরূপ সুপারিশ প্রদান করা হয়।

টেকনিক্যালস্ সাব-কমিটির সুপারিশ ঃ একই Strength বিশিষ্ট ইন্জেকশন জাতীয় হিউম্যান এবং ভেটেরিনারী ঔষধের একক মাত্রার (Single Dose) ভিন্ন ভিন্ন প্যাক সাইজের জন্য পৃথক পৃথক রেজিস্ট্রেশন গ্রহণ করতে হবে।

উপর্যু ক্ত বিষয়ে সভায় বিসত্মারিত আলোচনাক্রমে টেকনিক্যাল সাৰকমিটি সভার সিদ্ধামত্ম বহাল রাখার বিষয়ে সদস্যগণ একমত পোষণ করেন।

সভার সিদ্ধামত্মঃ টেকনিক্যাল সাব-কমিটির সুপারিশ অনুমোদন করা হল।

২.২। একই মাত্রার অনুমোদিত ঔষধের বিভিন্ন ডোজেস ফর্মে র পরিবর্তিত রিলিজ প্যাটার্নে র ক্ষেত্রে রেজিস্ট্রেশন প্রদান প্রসঙ্গে।

ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক অনুমোদিত একই মাত্রার কন্ট্রোল রিলিজ **(**SR, MR, CR, XR, TR, PR**)** Tablet/Capsule এর Plain Form অথবা একই মাত্রার Plain Form এর Tablet/Capsule এর কন্ট্রোল রিলিজ (SR, MR, CR, XR, TR, PR) ফর্মে অনুমোদনের জন্য বিভিন্ন প্রতিষ্ঠান আবেদন করে থাকে।

এইরূপ আবেদন ড্রাগ কন্ট্রোল কমিটি (ডিসিসি)-তে উপস্থাপনের পরিবর্তে লাইসেন্সিং কর্তৃপক্ষ রেজিস্ট্রেশন প্রদান করতে পারবে কিনা, এ বিষয়ে টেকনিক্যাল সাব-কমিটি সভায় বিসত্মারিত আলোচনা করা হয়। সদস্যগণ মত প্রকাশ করেন যে, রিলিজ প্যাটার্ন পরিবর্তিত হলে ঔষধটির উৎপাদন প্রযুক্তি ও রিলিজ প্যাটার্ন মূল্যায়নের আবশ্যকতা রয়েছে এবং বিষয়গুলো মূল্যায়নের জন্য সংশিস্নষ্ট বিশেষজ্ঞদের সমন্বয়ে মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তরের নেতৃত্বে একটি বিশেষজ্ঞ কমিটি গঠন করা যেতে পারে।

টেকনিক্যাল সাব-কমিটির সুপারিশঃ কোন ঔষধের পরিবর্তিত রিলিজ প্যাটার্ন এর ক্ষেত্রে ঔষটির উৎপাদন প্রযুক্তি ও রিলিজ প্যাটার্ন এর মূল্যায়নের নিমিত্তে মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তরকে সংশিস্নষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি বিশেষজ্ঞ কমিটি গঠনের প্রসত্মাব করা হয়। একই মাত্রার অনুমোদিত কোন ঔষধের কন্ট্রোল রিলিজের Plain Form অথবা একই মাত্রার Plain Form এর কন্ট্রোল রিলিজ ফর্মে রজন্য যদি কোন প্রতিষ্ঠান আবেদন করে এবং ঔষধটি USFDA বা UKMHRA কর্তৃক অনুমোদিত অথবা BNF-এ অমত্মর্ভুক্ত থাকে তবে উক্ত বিশেষজ্ঞ কমিটির সুপারিশের ভিত্তিতে লাইসেন্সিং কর্তৃপক্ষ (ড্রাগস্) উক্ত ঔষধটির রেজিস্ট্রেশন প্রদান করতে পারবেন এবং রেজিস্ট্রেশনের আবেদনটি ড্রাগ কন্ট্রোল কমিটিতে উপস্থাপন করার প্রয়োজন হবে না।

সভার আলোচনাঃ সভায় উপস্থিত সদস্যগণ কন্ট্রোল রিলিজ ঔষধের বিষয়ে এই মর্মে মতামত প্রকাশ করেন যে, কন্ট্রোল রিলিজ ডোজেস ফর্ম জাতীয় ঔষধ নিয়ন্ত্রণ করা ঔষধ প্রশাসনের নিয়মিত কার্য ক্রমের অমত্মর্ভুক্ত। এজাতীয় ঔষধ মূল্যায়নে ঔষধ প্রশাসন অধিদপ্তরের কর্ম কর্তাগণ যথেষ্ট অভিজ্ঞ ও দক্ষ। ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক অনুমোদিত একই মাত্রার কন্ট্রোল রিলিজ (SR, MR, CR, XR, TR, PR) Tablet/Capsule এর Plain Form অথবা একই মাত্রার Plain Form-এর Tablet/Capsule এর কন্ট্রোল রিলিজ ফর্মে (SR, MR, CR, XR, TR, PR) রেজিস্ট্রেশন প্রদানের লÿÿ্য ঔষধ প্রশাসন অধিদপ্তরের কর্ম কর্তাদের সমন্বয়ে একটি কমিটি গঠন করা যেতে পারে। উক্ত কমিটি সংশিস্নষ্ট বিষয়ে প্রয়োজনে বিশেষজ্ঞদের পরামর্শ ও সহায়তা গ্রহণ করতে পারে।

সভার সিদ্ধামত্মঃ ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক অনুমোদিত একই মাত্রার কন্ট্রোল রিলিজ (SR, MR, CR, XR, TR, PR) Tablet/Capsule এর Plain Form অথবা একই মাত্রার Plain Form এর Tablet/Capsule এর কন্ট্রোল রিলিজ (SR, MR, CR, XR, TR, PR) ফর্ম মূল্যায়নের জন্য ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তরের কর্ম কর্তাদের সমন্বয়ে একটি কমিটি গঠন করবেন। উক্ত কমিটি প্রয়োজনে সংশিস্নষ্ট বিষয়ে বিশেষজ্ঞদের পরামর্শ ও সহায়তা গ্রহণ করবে। আবেদিত পদটি অবশ্যই USFDA বা UKMHRA কর্তৃক অনুমোদিত অথবা BNF-এ অমত্মর্ভুক্ত থাকতে হবে।

উক্ত কমিটির সুপারিশের ভিত্তিতে মহাপরিচালক, ঔষধ প্রশাসন, লাইসেন্সিং অথরিটি (ড্রাগস) উক্ত জাতীয় পদের রেজিস্ট্রেশন প্রদান করবেন। এ জাতীয় আবেদন, ঔষধ নিয়ন্ত্রণ কমিটিতে উপস্থাপন করার প্রয়োজন নাই।

২.৩। সভায় নিম্নবর্ণি ত নতুন ঔষধ এবং প্রচলিত ঔষধের নুতন মাত্রার ঔষধের রেজিস্ট্রেশন সম্পর্কে বিসত্মারিত আলোচনা করে নিম্নোক্ত মতামত প্রদান করা হয়ঃ

2. 3.1 Proposed Product for Locally manufacture (Human)

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	a) Diphenhydramine HCl 2% + Zinc Acetate 0.1% Topical spray Diphenhydramine HCl BP 2gm + Zinc Acetate BP 0.1gm/100gm **Topical antihistamine**	This topical spray is indicated to use for the temporary relief of pain and itching associated with: Insect bites , minor skin irritations, Sunburn, Minor burns , minor cuts , Scrapes, Rashes due to poison: livy Oak • Sumac, dries the oozing and Weeping of poison: •Ivy • Oak • Sumac	**Contraindications:** Chicken pox or measles. An unusual or allergic reaction to diphenhydramine, other medicines, foods, dyes, or preservatives **Side effects:** Side effects that you should report to your doctor or health care professional as soon as possible: allergic reactions like skin rash, itching or hives swelling of the face, lips, or tongue. Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome): drowsiness or dizziness, dry mouth, headache.	Diphenhydramine Hydrochloride 2% + Zinc Acetate 0.1% Cream		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Terbinafine HCl 1% Topical Spray Terbinafine HCl BP 1gm/100 gm **Antiinfective- Antifungal**	This spray is indicated in the treatment of fungal infections of the skin caused by dermatophytes such as trichophyton. It is also indicated in the treatment of pityriasis (tinea) versicolor due to malassezia furfur	**Contraindications:** Have liver or kidney problems. Allergic to terbinafine or to any of the ingredients present in the formulation. Pregnant or intend to become pregnant while using this medicine, Breast-feeding taking any other medicines, prescription or nonprescription (OTC), especially cimetidine or rifampicin. **Side effects:** Redness, itching, stinging may occur at the site of application; however, treatment rarely has to be discontinued for this reason. Tell your doctor if you notice any of these possible side effects.	1% Cream	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	c) Drospirenone 3 mg + Ethinylestradiol 0.02 mg + levomefolate Calcium 0.451 mg Tablet (Pink Colored 24 Tablets) & Levomefolate calcium 0.451 mg Tablet (Orange Colored 4 Tablets) Drospirenone BP 3 mg + Ethinylestradiol BP 0.02 mg + levomefolate Calcium INN 0.451mg (Pink Colored 24 Tablets) & Levomefolate calcium INN 0.451mg (Orange Colored 4 Tablets) **Endocrine System- Oral Contraceptive**	It is an Oral Contraceptive to Prevent pregnancy - 99% effective when taken as directed. Provides a daily dose of folate supplementation, which is recommended for women in their reproductive years. Folate lowers the risk of having rare neural tube defects in a pregnancy occurring during its use or shortly after stopping. It is indicated in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product. It is also indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of contraception. It is indicated for the treatment of moderate acne vulgaris in women at least 14 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche.	**Contraindications:** **Pregnancy**: There is little or no increased risk of birth defects in women who inadvertently use it during early pregnancy. Women who do not breast feed may start it no earlier than four weeks postpartum. **Nursing Mothers:** After oral administration of it, about 0.02% of the drospirenone dose was excreted into the breast milk of postpartum women within 24 hours. This results in a maximal daily dose of about 0.003 mg drospirenone in an infant. Studies to date indicate there is no adverse effect of folate on nursing infants. **Paediatric Use:** Safety and efficacy of this product has been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 18 and for users of 18 years and older. Use of this product before menarche is not indicated. **Geriatric Use:** It has not been studied in postmenopausal women and is not indicated in this population. **Patients with Renal Impairment:** It is contraindicated in patients with renal impairment. **Patients with Hepatic Impairment:** It is contraindicated in patients with hepatic diseases. **Side effects:** Adverse reactions commonly reported by COC users are: Irregular uterine bleeding, Nausea, Breast tenderness, Headache.	Drospirenone 3 mg + Ethinylestradiol .03mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দেশনা	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধান্ত্ম	সভার সিদ্ধান্ত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	d) Pirfenidone 267mg Capsule Pirfenidone INN 267 mg	It is indicated in the treatment of Idiopathic pulmonary fibrosis.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Concomitant use of fluvoxamine. Severe hepatic impairment or end stage liver disease. Severe renal impairment or end stage renal disease requiring dialysis. **Side effects:** The frequency of possible side effects listed below is defined using the following convention: 1. very common (affects more than 1 user in 10) 2. common (affects 1 to 10 users in 100) 3. Uncommon (affects 1 to 10 users in 1000)	New	MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Sitagliptin 50 mg + Metformin HCl extended release 500mg Tablet Sitagliptin Phosphate Monohydrate INN 64.25mg eq. to 50mg Sitagliptin + Metformin HCl BP extended release 500mg **Endocrine System-Antidiabetic**	Combination of Sitagliptin and Metformin tablet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin extended-release is appropriate.	**Contraindications:** It is contraindicated in patients with: Renal disease or renal dysfunction, e.g., as suggested by serum creatinine levels ≥1.5 mg/dl [males], ≥1.4 mg/dl [females] or abnormal creatinine learance which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. History of a serious hypersensitivity reaction to the combination or sitagliptin such as anaphylaxis or angioedema. **ADR/Side effects:** The most common adverse reactions reported in ≥5% of patients simultaneously started on sitagliptin and metformin and more commonly than in patients treated with placebo were diarrhea, upper respiratory tract infection, and headache. Adverse reactions reported in ≥5% of patients treated with sitagliptin in combination with sulfonylurea and metformin and more commonly than in patients treated with placebo in combination with sulfonylurea and metformin were hypoglycemia and headache. Hypoglycemia was the only adverse reaction reported in ≥5% of patients treated with sitagliptin in combination with insulin and metformin and more commonly than in patients treated with placebo in combination with Insulin and Metformin.	50 mg + 500 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	f) Sitagliptin 50 mg + Metformin HCl extended release 1000mg Tablet Sitagliptin Phophate Monohydrate INN 64.25mg eq. to 50mg Sitagliptin + Metformin HCl BP extended release 1000mg **Endocrine System-Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin extended-release is appropriate.	**Contraindications:** It is contraindicated in patients with: Renal disease or renal dysfunction, e.g., as suggested by serum creatinine levels ≥1.5 mg/dl [males], ≥1.4 mg/dl [females] or abnormal creatinine learance which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. History of a serious hypersensitivity reaction to the combination or sitagliptin such as anaphylaxis or angioedema. **ADR/Side effects:** The most common adverse reactions reported in ≥5% of patients simultaneously started on sitagliptin and metformin and more commonly than in patients treated with placebo were diarrhea, upper respiratory tract infection, and headache. Adverse reactions reported in ≥5% of patients treated with sitagliptin in combination with sulfonylurea and metformin and more commonly than in patients treated with placebo in combination with sulfonylurea and metformin were hypoglycemia and headache. Hypoglycemia was the only adverse reaction reported in ≥5% of patients treated with sitagliptin in combination with insulin and metformin and more commonly than in patients treated with placebo in combination with Insulin and Metformin.	50 mg + 1gm Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	g) Saxagliptin 5 mg + Metformn HCl extended release 500 mg Tablet Saxagliptin HCl Anhydrous INN 5.58mg eq. to 5mg Saxagliptin + Metformn HCl BP extended release 500mg **Endocrine System-Antidiabetic**	Combination of Saxagliptin and Metformin tablet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Saxagliptin and metformin extended-release is appropriate.	**Contraindications:** It is contraindicated in patients with: Renal impairment (e.g., serum creatinine levels ≥1.5 mg/dl for men, ≥1.4 mg/dl for women, or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia Hypersensitivity to metformin HCl. Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with Insulin. History of a serious hypersensitivity reaction to combination of Saxagliptin & Metformin HCl Extended-Release or saxagliptin, such as anaphylaxis, angioedema, or exfoliative skin conditions. **ADR/Side effects:** Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting. Adverse reactions reported in ≥5% of patients treated with saxagliptin and more commonly than in patients treated with placebo are: upper respiratory tract infection, urinary tract infection, and headache. Adverse reactions reported in ≥5% of treatment-naive patients treated with coadministered saxagliptin and metformin and more commonly than in patients treated with metformin alone are: headache and nasopharyngitis In the add-on to sulfonylurea and add-on to insulin trials, confirmed hypoglycemia was reported more commonly in patients treated with saxagliptin compared to placebo. Hypersensitivity-related events (e.g., urticaria, facial edema) were reported more commonly in patients treated with saxagliptin than in patients treated with placebo.	New	USFDA	এই মাত্রা প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	এই মাত্রা প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	h) Saxagliptin 5mg + Metformn HCl extended release 1000mg Tablet Saxagliptin HCl Anhydrous INN 5.58 mg eq. to 5mg Saxagliptin + Metformn HCl BP 1000 mg **Endocrine System-Antidiabetic**	Combination of Saxagliptin and Metformin tablet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Saxagliptin and metformin extended-release is appropriate.	**Do**	New	USFDA	এই মাত্রা প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	এই মাত্রা প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		i) Saxagliptin 2.5 mg + Metformn HCl extended release 1000mg Tablet Saxagliptin HCl INN 2.79 mg eq. to 2.5mg Saxagliptin + Metformn HCl BP 1000mg **Endocrine System-Antidiabetic**	Combination of Saxagliptin and Metformin tablet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes** mellitus when treatment with both Saxagliptin and metformin extended-release is appropriate.	**Do**	New	USFDA	এই মাত্রা প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	এই মাত্রা প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		j) Ivermectin 0.5% Lotion Ivermectin BP 0.5gm/100gm **Antoprotozoal-Antiparasitic**	Indicated for the topical treatment of head lice infestation in patients 6 months of age and older.	**Contraindications :** None **ADR/Side effects:** The most commonly observed side effects are eye redness or soreness, eye irritation, dandruff, dry skin, burning sensation of the skin etc.	3 mg & 6 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	k) Nicotinamide 4% Gel Nicotinamide BP 4gm/100gm **Nutrition-Vitamin B Group**	Indicated for the topical treatment of inflammatory acne.	**Contraindications:** It is contraindicated in persons who have shown hypersensitivity to any of its components. **ADR/Side effects:** The possible side effects include- skin dryness, itching, redness, burning sensation, skin irritation.	New	BNF-63; Page - 765	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		l) Erythromycin 2% + Isotretinoin 0.05% Gel Erythromycin BP 2gm + Isotretinoin BP 0.05gm/100gm **Antibacterial – Macrolides**	It is indicated for the topical treatment of moderate acne.	**Contraindications:** It is contraindicated in persons who have shown hypersensitivity to any of its components. **ADR/Side effects:** Slight stinging, flaking and redness of skin, increased sensitivity to sunlight may occur with the use of the preparation.	New	BNF-63; Page - 765	অপব্যবহার হতে পারে বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	অপব্যবহার হতে পারে বিধায় আবেদন নামঞ্জুর করা হল
		m) Amorolfine HCl 50 mg/ml Nail lacquer Solution Amorolfine HCl INN 50 mg/ml **Antifungal**	Treatment of onychomycosis without matrix involvement.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. **ADR/Side effects:** Adverse drug reactions are rare. Nail disorders (e.g. nail discoloration, broken nails, brittle nails) may occur. These reactions can also be linked to the onychomycosis itself. **System Organ Class** / **Frequency** / **Adverse drug reaction** Skin and subcutaneous tissue disorders / Rare (≥ 1/10000, ≤ 1/1000) / Nail disorder, nail discoloration, onychoclasis	New	BNF-63; Page - 776	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

					Very rare (≤ 1/10000)	Skin burning sensation, contact dermatitis				

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	n) Butoconazole Nitrate 2gm/100gm Vaginal Cream Butoconazole Nitrate USP 2gm/100gm **Antifungal**	Butoconazole 2% is indicated for the local treatment of vulvovaginal candidiasis (infections caused by Candida).	**Contraindication:** Butoconazole is contraindicated in patients with a history of hypersensitivity to any of the components of the product. **ADR/Side effects:**Of the 314 patients treated with Butoconazole for 1 day in controlled clinical trials, 18 patients (5.7%) reported complaints such as vulvar/vaginal burning, itching, soreness and swelling, pelvic or abdominal pain or cramping, or a combination of two or more of these symptoms. In 3 patients (1%) these complaints were considered treatment-related. Five of the 18 patients reporting adverse events discontinued the study because of them.	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		o) Fenticonazole Nitrates 200mg Vaginal Capsules Fenticonazole Nitrates BP 200mg **Antifungal**	Treatment of vulvovaginal candiasis	**Contraindication:** Ascertained hypersensitive to the product and to other imidazole derivatives. **ADR/Side effects:** After intravaginal administration slight transient burning, which usually disappears rapidly, may occasionally occur. Prolonged topical application may cause sensitisation reactions.	NEW	BNF-63; Page - 513	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	p) Aliskiren 150 mg + Amlodipine 5mg Tablet Aliskiren Hemifumarate INN 165.750 mg eq. to 150mg Aliskiren + Amlodipine Besilate BP 6.90 mg eq. to 5 mg Amlodipine **Cardiovascular System-Antihypertensive**	Aliskiren and Amlodipine combination drug is indicated for the treatment of hypertension alone or with other antihypertensive agents. Initial Therapy Aliskiren and Amlodipine combination drug can be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals. Add-On Therapy A patient whose blood pressure is not adequately controlled with Aliskiren alone or Amlodipine besilate (or another dihydropyridine calcium channel blocker), can be switched to combination therapy with Aliskiren and Amlodipine combination drug. Replacement Therapy Aliskiren and Amlodipine combination drug may be substituted for its titrated components.	**Contraindication:** Hypersensitivity to any component of this combination drug. **ADR/Side effects:** *Aliskiren and Amlodipine combination drug* In a placebo-controlled study, the overall incidence of adverse events on therapy with Aliskiren and Amlodipine combination drug was similar to the individual components. Discontinuation of therapy due to a clinical adverse event in this study occurred in 1.7% of patients treated with Aliskiren and Amlodipine combination drug (2.2% in the highest dose group) versus 1.5% of patients given placebo. Peripheral edema is a known, dose-dependent adverse effect of Amlodipine. The incidence of peripheral edema for Aliskiren and Amlodipine combination drug in short-term double-blind placebo-controlled studies was lower than or equal to that of the corresponding Amlodipine doses. The adverse event in a placebo-controlled trial that occurred in at least 2% of patients treated with Aliskiren and Amlodipine combination drug and at a higher incidence than placebo was peripheral edema (6.2% versus 1.0%). The incidence rate of peripheral edema at high dose was 8.9%. In a long-term safety trial, the safety profile of adverse events was similar to that seen in the short-term controlled trials.	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
				Aliskiren: In a placebo-controlled clinical trials, discontinuation of therapy because of a clinical adverse event, including uncontrolled hypertension, occurred in 2.2% of patients treated with Aliskiren versus 3.5% of patients given placebo. Two cases of angioedema with respiratory symptoms were reported with aliskiren use in the clinical studies. Two other cases of periorbital edema without respiratory symptoms were reported as possible angioedema and resulted in discontinuation. The rate of these angioedema cases in the completed studies was 0.06%. Aliskiren produces dose-related gastrointestinal (GI) adverse reactions. Diarrhea was reported by 2.3% of patients at 300 mg, compared to 1.2% in placebo patients. In women and the elderly (age ≥65) increases in diarrhea rates were evident starting at a dose of 150 mg daily, with rates for these subgroups at 150 mg similar to those seen at 300 mg for men or younger patients (all rates about 2%). Other GI symptoms included abdominal pain, dyspepsia, and gastroesophageal reflux, although increased rates for abdominal pain and dyspepsia were distinguished from placebo only at 600 mg daily. Diarrhea and other GI symptoms were typically mild and rarely led to discontinuation. Aliskiren was associated with a slight increase in cough in the placebo-controlled studies (1.1% for any Aliskiren use versus 0.6% for placebo). Other adverse reactions with increased rates for Aliskiren compared to placebo included rash (1% versus 0.3%), elevated uric acid (0.4% versus 0.1%), gout (0.2% versus 0.1%), and renal stones (0.2% versus 0%). Single episodes of tonic-clonic seizures with loss of consciousness were reported in two patients treated with Aliskiren in the clinical trials.	NEW	USFDA		

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
				Amlodipine besilate Adverse events that have been reported <1% but >0.1% of patients in controlled clinical trials were: *Cardiovascular:* arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, peripheral ischemia, syncope, postural hypotension, vasculitis *Central and Peripheral Nervous System:* neuropathy peripheral, paresthesia, tremor, vertigo, *Gastrointestinal:* anorexia, constipation, dyspepsia, dysphagia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia *General:* allergic reaction, asthenia, back pain, hot flushes, malaise, pain, rigors, weight gain, weight decrease *Musculoskeletal System:* arthralgia, arthrosis, muscle cramps, myalgia *Psychiatric:* sexual dysfunction (male and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization *Respiratory System:* dyspnea, epistaxis *Skin and Appendages:* angioedema, erythema multiforme, pruritus, rash, rash erythematous, rash maculopapular *Special Senses:* abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus *Urinary System:* micturation frequency, micturation disorder, nocturia *Autonomic Nervous System:* dry mouth, sweating increased *Metabolic and Nutritional:* hyperglycemia, thirst *Hemopoietic:* leukopenia, purpura, thrombocytopenia Other events reported with amlodipine at a frequency of ≤0.1% of patients include: cardiac failure, pulse irregularity, extrasystoles, skin discoloration, urticaria, skin dryness, alopecia, dermatitis, muscle weakness, twitching, ataxia, hypertonia, migraine, cold and clammy skin, apathy, agitation, amnesia, gastritis, increased appetite, loose stools, rhinitis, dysuria, polyuria, parosmia, taste perversion, abnormal visual accommodation, and xerophthalmia. Other reactions occurred sporadically and cannot be distinguished from medications or concurrent disease states such as myocardial infarction and angina.	NEW	USFDA		

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	q) Aliskiren 150 mg + Valsartan 160 mg Tablet Aliskiren Hemifumarate INN 165.750 mg eq. to 150 mg Aliskiren + Valsartan USP 160 mg **Cardiovascular System-Antihypertensive**	Aliskiren and Valsartan combination drug is indicated for the treatment of hypertension. Add-on Therapy A patient whose blood pressure is not adequately controlled with Aliskiren alone or Valsartan (or another angiotensin receptor blocker) alone may be switched to combination therapy with Aliskiren and Valsartan combination drug. Replacement Therapy Aliskiren and Valsartan combination drug may be substituted for the titrated components. Initial Therapy Aliskiren and Valsartan combination drug may be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.	**Contraindications:** Hypersensitivity to any component of this combination drug. **ADR/Side effects:** ***Aliskiren and Valsartan combination drug*** Aliskiren and Valsartan combination drug has been evaluated for safety in more than 1,225 patients, including over 316 patients for over 1 year. In placebo-controlled clinical trials, discontinuation of therapy because of a clinical adverse event (including uncontrolled hypertension) occurred in 1.4% of patients treated with Aliskiren and Valsartan combination drug versus 2.7% of patients given placebo. Adverse events in placebo-controlled trials that occurred in at least 1% of patients treated with Aliskiren and Valsartan combination drug and at a higher incidence than placebo included fatigue (2.6% vs. 1.4%), nasopharyngitis (2.6% vs. 2.2%), diarrhoea (1.4% vs 0.9%), upper respiratory tract infection (1.4% vs. 1.1%), urinary tract infection (1.4% vs. 0.6%), influenza (1.1% vs 0.2%), and vertigo (1.1% vs. 0.3%). Hyperkalemia has been observed as a serum electrolyte abnormality in Aliskiren and Valsartan combination drug clinical trials. **Aliskiren** In placebo-controlled clinical trials, discontinuation of therapy due to a clinical adverse event, including uncontrolled hypertension occurred in 2.2% of patients treated with Aliskiren, versus 3.5% of patients given placebo. Two cases of angioedema with respiratory symptoms were reported with Aliskiren use in the clinical studies. Two other cases of periorbital edema without respiratory symptoms were reported as possible angioedema and resulted in discontinuation. The rate of these angioedema cases in the completed studies was 0.06%. Aliskiren produces dose-related gastrointestinal (GI) adverse reactions. Diarrhoea was reported by 2.3% of patients at 300 mg, compared to 1.2% in placebo patients. In women and the elderly (age ≥65) increases in diarrhoea rates were evident starting at a dose of 150 mg daily, with rates for these	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna			subgroups at 150 mg comparable to those seen at 300 mg for men or younger patients (all rates about 2% to 2.3%). Other GI symptoms included abdominal pain, dyspepsia, and gastroesophageal reflux, although increased rates for abdominal pain and dyspepsia were distinguished from placebo only at 600 mg daily. Diarrhea and other GI symptoms were typically mild and rarely led to discontinuation. Aliskiren was associated with a slight increase in cough in the placebo-controlled studies (1.1% for any aliskiren use vs. 0.6% for placebo). Other adverse reactions with increased rates for aliskiren compared to placebo included rash (1% vs. 0.3%), elevated uric acid (0.4% vs. 0.1%), gout (0.2% vs. 0.1%), and renal stones (0.2% vs. 0%). Single episodes of tonic-clonic seizures with loss of consciousness were reported in two patients treated with Aliskiren in the clinical trials. One patient had predisposing causes for seizures and had a negative electroencephalogram (EEG) and cerebral imaging following the seizures; for the other patient, EEG and imaging results were not reported. Aliskiren was discontinued and there was no rechallenge in either case.				
		r) Amlodipine 5 mg + Valsartan 160 mg + Hydrochlorothiazide 12.5mg Tablet Amlodipine Besilate BP 6.90 mg eq. to Amlodipine 5 mg + Valsartan USP 160mg + Hydrochlorothiazide BP 12.5mg **Antihypertensive. (Calcium Channel Blocker-Angiotensin-II receptor Antagonists and Diuretics)**	Amlodipine + Valsartan + Hydrochlorothiazide combination tablet is indicated for the treatment of hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.	**Contraindication:** Because of the hydrochlorothiazide component, Amlodipine + Valsartan + Hydrochlorothiazide combination tablet is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. **ADR/Side effects:** Most common adverse events (≥2% incidence) are dizziness, peripheral edema, headache, dyspepsia, fatigue, muscle spasms, back pain, nausea and nasopharyngitis.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	s) Amlodipine 5mg + Olmesartan Medoxomil 20 mg + Hydrochlorothiazide 12.5 mg Tablet Amlodipine Besylate BP 6.90 mg eq. to 5mg Amlodipine + Olmesartan Medoxomil INN 20 mg + Hydrochlorothiazide BP 12.5 mg **Antihypertensive. (Calcium Channel Blocker-Angiotensin-II receptor Antagonists and Diuretics)**	Amlodipine, Olmesartan Medoxomil & Hydrochlorothiazide combination tablet is indicated for the treatment of hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.	**Contraindication:** Because of the hydrochlorothiazide component, this combination tablet is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. **ADR/Side effects:** Dizziness was one of the most frequently reported adverse reactions with this combination tablet. The other most frequent adverse reactions that occurred in at least 2% of subjects are peripheral edema, headache, fatigue, nasopharyngitis, muscle spasm, nausea, upper respiratory tract infection, diarrhoea, urinary tract infection, joint swelling, syncope etc.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		t) Calcium Carbonate 1000 mg + Simethicone 60mg Chewable Tablet Calcium Carbonate BP 1000 mg (eq. to elemental Calcium 400mg)+ Simethicone ph Grade (60%)100 mg eq. to 60mg Simethicone USP **Gastro-intestinal System-Antacid**	For the relieve of acid digestion, heartburn, sour stomach, upset of stomach associated with these symptoms, bloating and pressure commonly referred to as gas.	**Contraindications:** Constipation, diarrhoea. **ADR/Side effects:** Constipation, diarrhoea.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	u) Vitamin C 500 mg + Vitamin E 30 IU + Vitamin B-12 60 mcg + Biotin 150 mcg + Folic Acid 1 mg + Carbonyl Iron 150 mg + Elemental Copper 3 mg + Docusate Sodium (Sodium Dioctylsulfosuccinate) 50mg Tablet Vitamin C BP 500 mg + Vitamin E BP 30 IU + Vitamin B-12 BP 60 mcg + Biotin BP 150 mcg + Folic Acid BP 1 mg + Carbonyl Iron Ph. Gr. 150 mg + Elemental Copper BP 3 mg + Docusate Sodium (Sodium Dioctylsulfosuccinate) BP 50 mg **Multivitamin and Multimineral**	For the treatment of anaemia-Megaloblastic, macrocytic and iron-deficiency anemia, anemia of pregnancy and anemia occurring in a variety of malabsorption syndromes	**Contraindications:** This preparation is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		v) Azelasteine 125mcg + Fluticasone Propionate (Micronized) 50.00 mcg/Nasal Spray, Metered Dose Azelasteine HCl BP 137.00 mcg (eq. To 125mg Azelasteine + Fluticasone Propionate (Micronized) BP 50.00 mcg /Nasal Spray **Antihistamine +Corticosteroids (Anti-allergic)**	For the relief of symptoms of Seasonal allergic rhinitis	**Contraindications:** No evidence is found. **ADR/Side effects:** The most common adverse reactions (≥2% incidence) are: epistaxis, and headache.	New	USFDA	অনুমাদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	w) Simvastatin 10 mg + Sitagliptin 100 mg FC Tablet Simvastatin USP 10 mg + Sitagliptin Phosphate Monohydrate INN 128.50mg eq. to 100 mg Sitagliptin **(Antidiabetic + Lipid Regulating Drugs)**	Sitagliptin: Sitagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin: Reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B) and triglycerides (TG) and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson type IIb). Moreover Simvastatin is used,To reduce the risk of total mortality by reducing CHD deaths. To reduce the risk of non-fatal myocardial infarction and stroke. To reduce the need for coronary and non-coronary revascularization procedures.	**Contraindications:** History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. Concomitant administration of strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, posaconazole, HIV protease inhibitors, erythromycin, clarithromycin, telithromycin and nefazodone).Concomitant administration of gemfibrozil, cyclosporine or diazole. Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. **ADR/Side effects:** **Sitagliptin** In controlled clinical studies as monotherapy and combination therapy with metformin, pioglitazone, or rosiglitazone and metformin, the overall incidence of adverse reactions, hypoglycemia, and discontinuation of therapy due to clinical adverse reactions with sitagliptin were similar to placebo. **Simvastatin** The most common adverse reactions that led to treatment discontinuation were: gastrointestinal disorders (0.5%), myalgia (0.1%), and arthralgia (0.1%). The most commonly reported adverse reactions (incidence ≥5%) in simvastatin controlled clinical trials were: upper respiratory infections (9.0%), headache (7.4%), abdominal pain (7.3%), constipation (6.6%), and nausea (5.4%).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	x) Simvastatin 20 mg + Sitagliptin 100 mg FC Tablet Simvastatin USP 20 mg + Sitagliptin Phosphate Monohydrate INN 128.50mg eq. to 100 mg Sitagliptin **(Antidiabetic +Lipid Regulating Drugs)**	Sitagliptin: Sitagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Simvastatin: Reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B) and triglycerides (TG) and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson type IIb). Moreover Simvastatin is used, to reduce the risk of total mortality by reducing CHD deaths, to reduce the risk of non-fatal myocardial infarction and stroke, to reduce the need for coronary and non-coronary revascularization procedures.	**Contraindications:** History of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any component of this medication. Concomitant administration of strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, posaconazole, HIV protease inhibitors, erythromycin, clarithromycin, telithromycin and nefazodone).Concomitant administration of gemfibrozil, cyclosporine or diazole. Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. **ADR/Side effects:** **Sitagliptin** In controlled clinical studies as monotherapy and combination therapy with metformin, pioglitazone, or rosiglitazone and metformin, the overall incidence of adverse reactions, hypoglycemia, and discontinuation of therapy due to clinical adverse reactions with sitagliptin were similar to placebo. **Simvastatin:** The most common adverse reactions that led to treatment discontinuation were: gastrointestinal disorders (0.5%), myalgia (0.1%), and arthralgia (0.1%). The most commonly reported adverse reactions (incidence ≥5%) in simvastatin controlled clinical trials were: upper respiratory infections (9.0%), headache (7.4%), abdominal pain (7.3%), constipation (6.6%), and nausea (5.4%).		USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
02.	Square Pharmaceuticals Ltd., Dhaka Unit, Kaliakoir, Gazipur	a) Alosetron 0.5mg Tablet Alosetron HCl INN 0.562 mg eq. to 0.5 mg Alosetron **CNS-5HT3 Antagonist**	Alosetron is a selective serotonin 5-HT3 antagonist indicated only for women with severe diarrhea - Predominant irritable bowel syndrome (IBS) who have: • chronic IBS symptoms (generally lasting 6 months or longer), • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and Severe IBS includes diarrhea and 1 or more of the following: • frequent and severe abdominal pain/discomfort, • frequent bowel urgency or fecal incontinence, • disability or restriction of daily activities due to IBS.	**Contraindications:** Constipation, History of Severe Bowel or Hepatic Disorders, Concomitant Use of Fluvoxamine. **Side effects:** The side effects of treatment with Alosetron are common constipation & Ischemic colitis.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Alosetron 1.0 mg Tablet Alosetron HCl INN 1.124 mg eq. to 1.0 mg Alosetron **CNS-5HT3 Antagonist**	Alosetron is a selective serotonin 5-HT3 antagonist indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have: • chronic IBS symptoms (generally lasting 6 months or longer), • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and Severe IBS includes diarrhea and 1 or more of the following: • frequent and severe abdominal pain/discomfort, • frequent bowel urgency or fecal incontinence, • Disability or restriction of daily activities due to IBS.	**Contraindications:** Constipation, History of Severe Bowel or Hepatic Disorders, Concomitant Use of Fluvoxamine **Side effects:** The common side effects of treatment with Alosetron are Constipation & Ischemic colitis.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Dhaka Unit, Kaliakoir, Gazipur	c) Acetylcysteine 300.00mg/3ml Nebuliser Solution Acetylcysteine USP 300mg/3ml **Mucolytic Agent**	It is indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretions in such conditions as: Chronic bronchopulmonary disease (chronic emphysema, emphysema with bronchitis, chronic asthmatic bronchitis, tuberculosis, bronchiectasis and primary amyloidosis of the lung), Acute bronchopulmonary disease (pneumonia, bronchitis, tracheobronchitis) Pulmonary complications of cystic fibrosis Tracheostomy care: Pulmonary complications associated with surgery, Use during anesthesia, Post-traumatic chest conditions Atelectasis due to mucous obstruction, Diagnostic bronchial studies (bronchograms, bronchospirometry, and bronchial wedge catheterization)	**Contraindications:** Acetylcysteine is contraindicated in those patients who are sensitive to it. **Side effects:** Adverse effects have included stomatitis, nausea, vomiting, fever, rhinorrhea, Drowsiness, clamminess, chest tightness and bronchoconstriction. Clinically overt acetylcysteine induced bronchospasm occurs infrequently and unpredictably even in patients with asthmatic bronchitis or bronchitis complicating bronchial asthma. Acquired sensitization to acetylcysteine has been reported rarely. Reports of sensitization in patients have not been confirmed by patch testing. Sensitization has been confirmed in several inhalation therapists who reported a history of dermal eruptions after frequent and extended exposure to acetylcysteine. Reports of irritation to the tracheal and bronchial tracts have been received and although hemoptysis has occurred in patients receiving acetylcysteine such findings are not uncommon in patients with bronchopulmonary disease and a causal relationship has not been established.	100mg/ml and 200 mg/ml Respirator Solution	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Square Pharmaceuticals Ltd., Dhaka Unit, Kaliakoir, Gazipur	d) Mometasone Furoate 100mcg + Formoterol Fumarate Dihydrate 5mcg/ puff HFA Inhaler Mometasone Furoate BP 100mcg + Formoterol Fumarate Dihydrate BP 5mcg/ puff **Respiratory System (Corticosteroid-Adrenorector agonist)**	This combination product containing a corticosteroid and a long acting beta2-adrenergic agonist indicated for the treatment of asthma in Patients of 12 years of age and older.	**Contraindications:** **Status Asthmaticus** It is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. **Hypersensitivity** It is contraindicated in patients with known hypersensitivity to mometasone furoate, formoterol fumarate, or any of the ingredients in it. **Side-effects:** The most common side effects of this product include: inflammation of the nose and throat (nasopharyngitis), inflammation of the sinuses (sinusitis), Headache. Other side effects: Worsening asthma or sudden asthma attacks have been reported with the use of inhaled mometasone Furoate.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		e) Mometasone Furoate 200 mcg + Formoterol Fumarate Dihydrate 5mcg/ puff HFA Inhaler Mometasone Furoate BP 200 mcg + Formoterol Fumarate Dihydrate BP 5mcg/ puff **Respiratory System (Corticosteroid + Adrenorector agonist)**	This combination product containing a corticosteroid and a long acting beta2-adrenergic agonist indicated for the treatment of asthma in Patients of 12 years of age and older.	**Contraindications:** **Status Asthmaticus** It is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. **Hypersensitivity:** It is contraindicated in patients with known hypersensitivity to mometasone furoate, formoterol fumarate, or any of the ingredients in it. **Side effects:** The most common side effects of this product include: inflammation of the nose and throat (nasopharyngitis), inflammation of the sinuses (Sinusitis), headache. Other side effects: Worsening asthma or sudden asthma attacks have been reported with the use of inhaled mometasone Furoate.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
03.	Square Cephalosporins Ltd., Kaliakoir, Gazipur	a) Ceftriaxone Sodium 250mg + Tazobactam Sodium 31.25 mg/Vial Injection ; accompanied with 5 ml water for Injection BP Ceftriaxone Sodium USP 299.25mg eq. to Ceftriaxone 250 mg + Tazobactam Sodium USP 33.531mg eq. to Tazobactam 31.25 mg/Vial; accompanied with 5 ml water for Injection BP **Antibiotic-Cephalosporin**	Lower Respiratory Tract Infections, Acute Bacterial Ottitis Media, Skin and Skin Structure Infections, Urinary Tract Infections, Uncomplicated Gonorrhea, Pelvic Inflammatory Disease, Bacterial Septicemia, Bone and Joint Infections, Intra-Abdominal Infections, Meningitis, Surgical Prophylaxis	**Contraindications:** Ceftriaxone/Tazobactam combination is contraindicated in patients with known allergy to the cephalosporin or beta lactam class of antibiotics. **ADR/side effects:** Ceftriaxone & Tazobactam is generally well tolerated. Some side effects are pruritus, fever, diarrhea, headache or dizziness.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Ceftriaxone Sodium 500mg + Tazobactam Sodium 62.50mg/Vial Injection ; accompanied with 5 ml water for Injection BP Ceftriaxone Sodium USP 598.5mg eq. to Ceftriaxone 500 mg + Tazobactam Sodium USP 67.06mg eq. to Tazobactam 62.50mg/Vial; accompanied with 5 ml water for Injection BP **Antibiotic-Cephalosporin**	Lower Respiratory Tract Infections, Acute Bacterial Ottitis Media, Skin and Skin Structure Infections, Urinary Tract Infections, Uncomplicated Gonorrhea, Pelvic Inflammatory Disease, Bacterial Septicemia, Bone and Joint Infections, Intra-Abdominal Infections, Meningitis, Surgical Prophylaxis	**Contraindications:** Ceftriaxone/Tazobactam combination is contraindicated in patients with known allergy to the cephalosporin or beta lactam class of antibiotics. **ADR/side effects:** Ceftriaxone/Tazobactam is generally well tolerated. Some side effects are pruritus, fever, diarrhea, headache or dizziness.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Ceftriaxone Sodium 1000mg + Tazobactam Sodium 125mg/Vial Injection ; accompanied with 10 ml water for Injection BP Ceftriaxone Sodium USP 1197mg eq. to Ceftriaxone 1000 mg + Tazobactam Sodium USP 134.13 mg eq. to Tazobactam 125mg/Vial ; accompanied with 10 ml water for Injection BP **Antibiotic-Cephalosporin**	Lower Respiratory Tract Infections, Acute Bacterial Ottitis Media, Skin and Skin Structure Infections, Urinary Tract Infections, Uncomplicated Gonorrhea, Pelvic Inflammatory Disease, Bacterial Septicemia, Bone and Joint Infections, Intra-Abdominal Infections, Meningitis, Surgical Prophylaxis	**Contraindications:** Ceftriaxone/Tazobactam combination is contraindicated in patients with known allergy to the cephalosporin or beta lactam class of antibiotics. **ADR/side effects:** Ceftriaxone/Tazobactam is generally well tolerated. Some side effects are pruritus, fever, diarrhea, headache or dizziness.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
04.	Aristorpharma Ltd. Dhaka	a) Alteplase 10 mg /Vial Lyophilized Injection Alteplase USP 10 mg (5.8 million IU) /Vial **Fibrinolytic Drugs**	It is indicated for the treatment in acute myocardial infarction, in acute massive pulmonary embolism with haemodynamic instability, acute ischaemic stroke.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side effects**: The most common adverse reactions are bleeding from damaged blood vessels injection site haemorrhage, represents the major adverse reaction in the treatment of acute ischaemic stroke, respiratory tract haemorrhage, gastrointestinal haemorrhage, urogenital haemorrhage, blood transfusion.	New	BNF-60, Page-155 & 156.	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Alteplase 20 mg /Vial Lyophilized Injection Alteplase USP 20mg (11.6 million IU) /Vial **Fibrinolytic Drugs**	-do-	**-do-**	New	BNF-60, Page (155-56)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Alteplase 50 mg /Vial Lyophilized Injection Alteplase USP 50 mg (29 million IU) /Vial **Fibrinolytic Drugs**	-do-	**-do-**	New	USFDA and BNF-60, Page (155-56)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		d) Bisoprolol Fumarate 2.50mg + Amlodipine 5mg Film Coated Tablet Bisoprolol Fumarate USP 2.50mg + Amlodipine Besilate BP 6.94mg eq.to Amlodipine 5mg **Cardiovasculart System(Beta-adrenorector Blocking-Calcium Channel Blocker)**	It is indicated for the treatment of hypertension and angina.	**Contraindications:** Hypersensitivity to any component of this product or other sulphonamide derived agent. Uncontrolled cardiac failure excluding that due to hypertrophic obstructive cardiomyopathy. Patients with metabolic acidosis and sinus bradycardia. Patients suffering from second and third degree heart block. **Side Effect**: The most common side effects are Diarrhea, dizziness, fatigue, runny nose, swelling, anorexia, gastric irritation, nausea, vomiting, constipation, headache, photosensitivity reactions, postural hypotension, paraesthesia, impotence and yellow vision. Hypersensitivity reactions include skin rashes, pulmonary oedema and pneumonitis.	Bisoprolol 2.5mg, 5mg & 10mg Tablet, Amlodipine 5mg & 10mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Aristopharma Ltd. Dhaka	e) Esomeprazole Magnesium Trihydrate eq. to Esomeprazole 20mg as EC Pellets + Domperidone Maleate eq.to Domperidone 30mg as SR Pellets Capsule Esomeprazole Magnesium EC Pellets (22.5%)Ph. Gr. 89 mg (Esomeprazole Magnesium Trihydrate USP 26.097mg eq.to 20mg Esomeprazole) + Domperidone Maleate SR Pellets (30%) Ph.Gr.100mg (Domperidone Maleate BP 38.18mg eq. to 30mg Domperidone) **Proton Pump Inhibitor**	It is indicated for the treatment of functional dyspepsia, symptom associated with gastroesophageal reflux disease (GERD) like nausea, vomiting, abdominal discomfort, flatulence etc.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to esomeprazole or other substituted benzimidazoles or to Domperidone or other dopamine antagonists. **Side Effects**: Headache, nausea, vomiting, dizziness, vertigo, reversible confusion, agitation, depression and hallucinations.	Esomeprazole 20mg & 40mg Capsule & Tablet, Domperidone 10mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		f) Levosulpiride 25 mg FC Tablet Levosulpiride INN 25 mg **Antipsychotic and prokinetic (gastroprokinetic) agent**	It is an antipsychotic and prokinetic (gastroprokinetic) agent, for the treatment of gastroesophageal reflux disease, various forms of dyspepsia, diabetic gastroparesis, vomiting and nausea.	**Contraindications:** Levosulpiride is contraindicated in conditions like epilepsy, hyperprolactinaemia, breast feeding, and hypersensitivity to any component of product, gastrointestinal hemorrhage and pheochromocytoma. **Side effects**: The symptomatic adverse reactions produced by Levosulpiride are more or less tolerable and if they become severe, they can be treated symptomatically, these include sedation, hypotension, gynecomastia, galactorrhea, dyskinesia, hyperprolactinemia, tardive dyskinesia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
5.	Navana Pharmaceuticals Ltd.	a) Doxylamine Succinate 10mg + Pyridoxine HCl 10mg extended released Tablet Doxylamine Succinate BP 10mg + Pyridoxine HCl BP 10mg **Anticholinergic + Vitamin**	Prevention and treatment of Nausea and Vomiting during pregnancy (NVP).	**Contraindication:** Automobile drivers and machine operators due to drowsiness. It must be used with caution in combination with alcohol and other depressing drugs or with epileptic patients. **Side effects:** Dizziness, sedation, hypotension	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Zinc Sulphate 45 mg effervescent Tablet Zinc Sulphate BP 45 mg **Mineral**	Zinc deficiency or supplementation in zinc-losing conditions.	**Contraindication:** None. **Side effects:** Abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation; irritability, headache, lethargy.	20 mg & 10 mg Tab.	BNF 62	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Hyoscine Hydrobromide 150 mcg Tablet Hyoscine Hydrobromide BP 150 mcg **CNS- Drug used in nausea and vertigo**	Motion sickness, hypersalivation associated with clozapine therapy, premedication.	**Contraindications:** contraindicated in myasthenia gravis, paralytic ileus, pyloric stenosis, toxic megacolon and prostatic enlargement. **Side effects:** Side effects of antimuscarinics include constipation, transient bradycardia (followed by tachycardia, palpitation and arrythmias), reduced bronchial secretions, urinary urgency and retention, dilatation of pupil with loss of accommodation, photophobia, dry mouth, flushing and dryness of the skin, side-effects that occurs occationally include confusion (particularly in elderly), nausea, vomiting and giddiness; very rarely, angle-closure glaucoma may occur.	New	BNF 62	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Navana Pharmaceuticals Ltd.	d) Hyoscine Hydrobromide 300 mcg Tablet Hyoscine Hydrobromide BP 300 mcg **CNS- Drug used in nausea and vertigo**	Motion sickness, hypersalivation associated with clozapine therapy, premedication.	**Contraindication: C**ontraindicated in myasthenia gravis, paralytic ileus, pyloric stenosis, toxic megacolon and prostatic enlargement. **Side effects:** Side effects of antimuscarinics include constipation, transient bradycardia (followed by tachycardia, palpitation and arrythmias), reduced bronchial secretions, urinary urgency and retention, dilatation of pupil with loss of accommodation, photophobia, dry mouth, flushing and dryness of the skin, side-effects that occurs occationally include confusion (particularly in elderly), nausea, vomiting and giddiness; very rarely, angle-closure glaucoma may occur.	New	BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
06.	Acme Laboratories Ltd.	a) Gabapentin Enacarbil 600 mg Extended Release Tablet Gabapentin Enacarbil INN 600 mg **CNS-Antiepileptic Drugs**	Treatment of moderate to severe primary restless legs syndrome in adults	**Contraindication:** None **Side effects:** Signs of an allergic reaction: hives; fever; swollen glands; painful sores in or around your eyes or mouth; difficulty breathing; swelling of your face, lips, tongue, or throat.	600 mg, 300 mg & 100 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Dabigatran Etexilate 110 mg Capsule Dabigatran Etexilate Mesilate INN 126.84 mg eq. to Dabigatran Etexilate 110 mg **Cardiovascular System-Oral Anticoagulants**	Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation with one or more of the following risk factors: Previous stroke, transient ischaemic attack, or systemic embolism.	**Contraindication:** It is contraindicated in patients with: Active pathological bleeding History of a serious hypersensitivity reaction to Dabigatran Mechanical prosthetic heart valve **Side effects:** These were commonly dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including GERD, esophagitis, erosive gastritis, gastric hemorrhage, hemorrhagic gastritis, hemorrhagic erosive gastritis, gastrointestinal ulcer and anaphylactic shock.	75 mg & 150 mg Capsule	BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
07.	Jayson Pharmaceuticals Ltd.	a) Diazepam 0.2gm/100ml Rectal Solution (2.5mg/1.25 ml Tubes) Diazepam BP 0.2gm/100ml **CNS- Anxiolytics**	It is to be used for children in convulsion	**Contraindications:** Respiratory depression, marked neuromascular respiratory weakness including unstable Mysthenia Gravis, acute pulmonary insufficiency, sleep apnoea syndrome, not for chronic psychosis; phobic or obsessional states; hyperkinesis; should not be used alone in depression or in anxiety with depression ; avoid injections containing benzyl alcohol in neonates. **Side Effects:** Drowsiness, light-headedness the next day, confusion and ataxia (especially in the elderly); amnesia; dependence; paradoxical increase in aggression; muscle weakness, Occassionaly: Headache, vertigo, dizziness, slurred speech, hypotension, salivation changes, gastrointestinal disturbances, visual disturbances, dysarthria, tremor, changes in libido, gynaecomastia, incontinence, rarely apnoea, respiratory depression, blood disorders, jaundice, skin reactions; on intravenous injection, pain, thrombophlebitis.	5mg Tablet and 10mg/2ml Injection	BNF-63 Page: 308	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) White Soft Paraffin 57.3gm + Liquid Paraffin 42.5gm + Wool Alcohols 0.2gm/100 gm Eye Ointment White Soft Paraffin BP 57.3gm + Liquid Paraffin BP 42.5gm + Wool Alcohols BP 0.2gm/100gm	Dry eye conditions	**Contraindication:** Hypersensityvity to lanolin alcohols. **Side Effects:** Not Known	NEW	BNF-63 Page: 716	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
08.	Eskayef Bangladesh Ltd., Tongi, Gazipur	a) Parecoxib Sodium 20mg IM/IV injection Parecoxib Sodium INN 20mg **Non-steroidal anti-inflammatory Drugs**	Management of acute post-operative pain	**Contraindication**s: History of allergic drug reaction including sulfonamide hypersensitivity & Severe asthma, Nausea & Edema and also NSAIDs contraindication **Side effectss:** Hypotension, hypoaesthesia, alveolar osteitis, postoperative anaemia, hypokalaemia, sweating and also NSAIDs side effect.	NEW	BNF 63, page-826	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Phentarmine 3.75mg + Topiramate 23mg ER capsule Phentarmine USP 3.75mg + Topiramate INN 23mg **CNS - Antiepileptic drug**	It is an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30kg/m2 and 27kg/m2 or greater.	**Contraindications:** Pregnancy, Hyperthyroidism and Glaucomaz **Side effects:** Paraesthesia, dizziness, dysgeusia, inosomnia and constipation	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Phentarmine 7.5mg + Topiramate 46mg ER Capsule Phentarmine USP 7.5 mg + Topiramate INN 46mg **CNS - Antiepileptic drug**	It is an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30kg/m2 and 27kg/m2 or greater.	**Contraindications:** Pregnancy, hyperthyroidism and Glaucoma **Side effects:** Paraesthesia, dizziness, dysgeusia, inosomnia and constipation	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		d) Phentarmine 11.25mg + Topiramate 69 mg ER Csapsule Phentarmine USP 11.25mg + Topiramate INN 69 mg **CNS - Antiepileptic drug**	It is an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30kg/m2 and 27kg/m2 or greater.	**Contraindications:** Pregnancy, hyperthyroidism and Glaucoma **Side effects:** Paraesthesia, dizziness, dysgeusia, inosomnia and constipation	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	e) Phentarmine 15mg + Topiramate 92mg ER capsule Phentarmine USP 15mg + Topiramate INN 92mg **CNS - Antiepileptic drug**	It is an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30kg/m2 and 27kg/m2 or greater.	**Contraindications:** Pregnancy, Hyperthyroidism and Glaucoma **Side effects:** Paraesthesia, dizziness, dysgeusia, inosomnia and constipation	NEW	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		f) Potassium citrate 1620 mg ER tablet Potassium citrate USP 1620 mg **Urinary Alkalinizer**	Renal tubular acidosis (RTA) with calcium stones • Hypocitraturic calcium oxalate nephrolithiasis of any etiology • Uric acid lithiasis with or without calcium stones	**Contraindications:** Paients with peptic ulcer disease. Paitents with hyperkalemia & CKD, Abdominal discomfort, vomiting **Side effects:** Abdominal discomfort, vomiting, diarrhea, loose bowel movements or nausea.	1080mg & 540mg tablet	USFDA	পদটি Stable নয় বিধায় আবেদন নামঞ্জুর করা যেতে পারে। (Due to in-stability of formulation)	পদটি Stable নয় বিধায় আবেদন নামঞ্জুর করা হল। (Due to in-stability of formulation)
		g) Glucosamine Hydrochloride 750 mg + Chondroitin Sulphate Sodium 600 mg capsule Glucosamine Hydrochloride USP 750 mg + Chondroitin Sulphate Sodium USP 600 mg	Glucosamine and Chondroitin sulfates might be used in any joint condition involving the classical joint structure. They can also be used in osteoarthritis, chronic urinary tract infection, chronic sterile cystitis, collapsing trachea and intravertebral disc disease.	**Contraindication & Side-effects:** Hypersensitivity	250 mg + 200 mg Tab.		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		h) Esomeprazole 20 mg + Aspirin 81 mg Capsule Esomeprazole USP 20 mg + Aspirin USP 81 mg	Prevention of thrombtic cardiovascular (CV) events such as heart attack or stroke, in high-risk CV patients in need of daily low-dose ASA treatment and who are at risk of gastric ulcers.	**Contraindications:** Hypersensitivity to aspirin and esomeprazole. Due to the aspirin component is Axanum also contraindicated in patients with hemophilia, thrombocytopenia, liver cirrhosis, severe heart failure or severe renal insufficiency. **Side effects:** Vomiting, diarrhea, loose bowel movements or nausea.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	i) Ceftaroline Fosamil 600mg/Vial IV Injection Ceftaroline Fosamil INN 600mg **Antibacterial Drugs-Cephalosporins**	Anti-infective drugs. Acute Bacterial Skin and Skin Structure Infections, Community-Acquired Bacterial Pneumonia	**Contraindications:** Ceftaroline is contraindicated in patients with known serious hypersensitivity to ceftaroline or other members of the cephalosporin class. Anaphylaxis and anaphylactoid reactions have been reported with ceftaroline. **Side effects:** Hypersensitivity reactions, Clostridium difficile-associated diarrhea & Direct Coombs' test seroconversion	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		j) Ceftaroline Fosamil 400mg/Vial IV Injection Ceftaroline Fosamil INN 400mg **Antibacterial Drugs-Cephalosporins**	Acute Bacterial Skin and Skin Structure Infections, Community-Acquired Bacterial Pneumonia	**Contraindications:** Ceftaroline is contraindicated in patients with known serious hypersensitivity to ceftaroline or other members of the cephalosporin class. Anaphylaxis and anaphylactoid reactions have been reported with ceftaroline. **Side effects:** Hypersensitivity reactions, Clostridium difficile-associated diarrhea & Direct Coombs' test seroconversion	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		k) Glucosamine Hydrochloride1500 mg + Chondroitin Sulphate Sodium 1200 mg/Sachet powder for solution Glucosamine Hydrochloride USP 1500 mg + Chondroitin Sulphate Sodium USP 1200 mg/Sachet	Glucosamine and Chondroitin sulfates might be used in any joint condition involving the classical joint structure. They can also be used in osteoarthritis, chronic urinary tract infection, chronic sterile cystitis, collapsing trachea and intravertebral disc disease.	**Contraindications:** There is no known contraindication to glucosamine or chondroitin **Side effects:** Adverse effects have been limited to mild reversible gastrointestinal side effects with the use of glucosamine. In one trial, people with peptic ulcers and those taking diuretic drugs were more likely to experience side effects with the use of glucosamine. Nausea may occur at intakes of greater than 10 grams of chondroitin per day. No other adverse effects have been reported with chondroitin.	250 mg + 200 mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	l) Aceclofenac 200 mg ER tablet Aceclofenac BP 200mg **NSAIDS**	Rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and periarthritis of scapulohumerous, lumbago, ischiadynia, pain caused by nonaticular rheutism.	**Contraindications:** It should not be administered to patients hypersensitive to it or other NSAIDs, or patients with a history of aspirin or NSAID related allergic or anaphylactic reactions or with peptic ulcers or GI bleeding, moderate or severe renal impairment. **Side effects:** The majority of adverse reactions reported have been reversible and of a minor nature. The most frequent are GI disorders, in particular dyspepsia, abdominal pain, nausea and diarrhea, and occasional occurrence of dizziness. Dermatological complaints including pruritus and rash and abnormal hepatic enzyme and serum creatinine levels have also been reported.	Aceclofenac 50mg & 100mg tablet		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		m) Alfacalcidol 0.25 mcg FC Tablet Alfacalcidol BP 0.25mcg **Vitamin**	- Renal osteodystrophy. - Hypoparathyroidism. - Hyperparathyroidism (with bone disease) - Nutritional and malabsorptive rickets and osteomalacia. - Hypophosphataemic Vitamin D resistant rickets and osteomalacia. - Pseudo-deficiency (D-dependent Type 1) rickets & Nutritional and malabsorptive rickets and osteomalacia.	**Contraindications:** Patients with evidence of vitamin D toxicity or known hypersensitivity to the effects of Vitamin D or any of its analogues and peanut allergy. **Side effects:** Feeling sick, stomach pains or diarrhoea - General weakness, anorixia, thirst, weight loss - Sweating, vertigo, dizziness, headache - Excessive urination.	0.5 mcg & 1 mcg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	n) Esomeprazole 20 mg Powder For DR Suspension in Sachet Esomeprazole USP 20mg **Antiulcerant-PPI**	Gastroesophageal reflux disease (GERD); risk reduction of NSAIDs associated ulcer; short-term treatment in healing and symptomatic resolution of erosive esophagitis; maintenance of symptom resolution and healing of erosive esophagitis; H. pylori eradication to reduce the risk of duodenal ulcer recurrence; Pathological hypersecretory conditions including Zollinger-Ellison syndrome	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** The safety of esomeprazole was evaluated worldwide in over 10000 patients (aged 18 - 84 years). In clinical trials the most frequently occurring adverse events were headache, diarrhoea, nausea, flatulence, abdominal pain and constipation. Rarely dermatitis, pruritus, urticaria, dizziness and dry mouth were reported.	Esomeprazole USP 20 mg, 40 mg Tablet, Capsule and 40mg Injection 20 mg Powder for Suspension/Sachet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		o) Esomeprazole 40 mg Powder For DR Suspension in Sachet Esomeprazole USP 40 mg **Antiulcerant-PPI**	Gastroesophageal reflux disease (GERD); risk reduction of NSAIDs associated ulcer; short-term treatment in healing and symptomatic resolution of erosive esophagitis; maintenance of symptom resolution and healing of erosive esophagitis; H. pylori eradication to reduce the risk of duodenal ulcer recurrence; Pathological hypersecretory conditions including Zollinger-Ellison syndrome	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** The safety of esomeprazole was evaluated worldwide in over 10000 patients (aged 18 - 84 years). In clinical trials the most frequently occurring adverse events were headache, diarrhoea, nausea, flatulence, abdominal pain and constipation. Rarely dermatitis, pruritus, urticaria, dizziness and dry mouth were reported.	Esomeprazole USP 20mg, 40 mg Tablet, Capsule and 40mg Injection & 20 mg /Sachet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	p) Paracetamol 500mg + Diphenhydramine HCl 25mg tablet Paracetamol USP 500 mg + Diphenhydramine HCl USP 25mg **Analgesic + Muscle relaxant**	Short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.	**Contraindications**: This drug should not be used in neonates or premature infants. Because of the higher risk of antihistamines for infants generally, and for neonates and prematures in particular, antihistamine therapy is contraindicated in nursing mothers. **Side effects:** The following are some of the side effects that are known Drowsiness, Blurred vision. Disturbances of the gut such as constipation, nausea, vomiting or abdominal pain. Dry mouth, nose and throat Skin rash. Difficulty in passing urine (urinary retention).	New	MHRA BNF-41 Page-155	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		q) Itopride HCl 50mg tablet Itopride HCl INN 50mg **Gastrointestinal Agents**	The product is indicated for the treatment of symptoms caused by slow stomach emptying, such as the feeling of fullness in the stomach, to painful pressure in the upper abdomen, indigestion, heartburn, nausea and vomiting, digestive disorders that are not caused ulcer disease or organic disease-causing changes in the digestive tube passages.	**Contraindications:** Known hypersensitivity to Itopride or other ingredients. Itopride should not be patients for whom the accelerated gastric emptying may be harmful, such as bleeding from the digestive tract, mechanical obstruction or perforation. **Side effects:** Rarely such as diarrhea, upper abdominal pain, increased salivation, pain headache, irritability, sleep disturbances and dizziness, pain in the back or chest, and fatigue.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	r) Itopride HCl 100mg tablet Itopride HCl INN 100mg **Gastrointestinal Agents**	The product is indicated for the treatment of symptoms caused by slow stomach emptying, such as the feeling of fullness in the stomach, to painful pressure in the upper abdomen, indigestion, heartburn, nausea and vomiting, digestive disorders that are not caused ulcer disease or organic disease-causing changes in the digestive tube passages.	**Contraindications:** Known hypersensitivity to Itopride or other ingredients. Itopride should not be patients for whom the accelerated gastric emptying may be harmful, such as bleeding from the digestive tract, mechanical obstruction or perforation. **Side effects:** Rarely such as diarrhea, upper abdominal pain, increased salivation, pain headache, irritability, sleep disturbances and dizziness, pain in the back or chest, and fatigue.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		s) Omeprazole 20mg + Domperidone 10mg DR Tablet Omeprazole BP 20mg + Domperidone BP 10mg **Antiulcerant + Antiemetic**	It is indicated for the treatment of functional dyspepsia, symptom associated with gastroesophageal reflux disease (GERD) like nausea, Vomiting, abdominal discomfort, flatulence etc.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to Esomeprazole or other substituted benzimidazoles or to Domperidone or other dopamine antagonists. **Side Effect**: Headache, Nausea, vomiting, Dizziness, Vertigo, Reversible confusion, Agitation, Depression and hallucinations.	NEW		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		t) Methimazole 5mg Tablet Methimazole USP 5mg **Antithyroid Agent**	In patients with Graves' disease with hyperthyroidism or toxic multinodular goiter for whom surgery or radioactive iodine therapy is not an appropriate treatment option. To ameliorate symptoms of hyperthyroidism in preparation for thyroidectomy or radioactive iodine therapy.	**Contraindications:** Contraindicated in the presence of hypersensitivity to the drug or any of the other product components. **Side effects:** Major adverse reactions include inhibition of myelopoieses (agranulocytosis, granulocytopenia, thrombocytopenia, and aplastic anemia), drug fever, a lupus-like syndrome, insulin autoimmune syndrome (which can result in hypoglycemic coma), hepatitis (jaundice may persist for several weeks after discontinuation of the drug), periarteritis, and hypoprothrombinemia. Nephritis occurs very rarely.	20 mg Tablet	USFDA	Box warning-এ The Drug should be discontinued in the presence of agranulocytosis, aplastic anemia (pencytopenia), hepatitis, or exfoliative dermatitis. The patient's bone marrow function shoud be monitored উলেস্নখ করতে হবে এই শর্তে অনুমোদন করা যেতে পারে।	Box warning-এ The Drug should be discontinued in the presence of agranulocytosis, aplastic anemia (pencytopenia), hepatitis, or exfoliative dermatitis. The patient's bone marrow function shoud be monitored উলেস্নখ করতে হবে এই শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	u) Methimazole 10mg Tablet Methimazole USP 10mg **Antithyroid Agent**	In patients with Graves' disease with hyperthyroidism or toxic multinodular goiter for whom surgery or radioactive iodine therapy is not an appropriate treatment option. To ameliorate symptoms of hyperthyroidism in preparation for thyroidectomy or radioactive iodine therapy.	**Contraindications:** Contraindicated in the presence of hypersensitivity to the drug or any of the other product components. **Side effects:** Major adverse reactions include inhibition of myelopoieses (agranulocytosis, granulocytopenia, thrombocytopenia, and aplastic anemia), drug fever, a lupus-like syndrome, insulin autoimmune syndrome (which can result in hypoglycemic coma), hepatitis (jaundice may persist for several weeks after discontinuation of the drug), periarteritis, and hypoprothrombinemia. Nephritis occurs very rarely.	20 mg Tablet	USFDA	Box warning-এ The Drug should be discontinued in the presence of agranulocytosis, aplastic anemia (pencytopenia), hepatitis, or exfoliative dermatitis. The patient's bone marrow function shoud be monitored উলেস্নখ করতে হবে এই শর্তে অনুমোদন করা যেতে পারে।	Box warning-এ The Drug should be discontinued in the presence of agranulocytosis, aplastic anemia (pencytopenia), hepatitis, or exfoliative dermatitis. The patient's bone marrow function shoud be monitored উলেস্নখ করতে হবে এই শর্তে অনুমোদন করা হল।
		v) Dicycloverine hydrochloride 2.5mg + Aluminium hydroxide 200mg + Magnesium oxide 100mg + Simethicone 20mg/5ml Suspension Dicycloverine hydrochloride BP 2.5mg + Dried Aluminium hydroxide BP 200mg + Magnesium oxide BP 100 mg + Simethicone BP 20mg/5ml **Gastrointestinal antispas modic**	Symptomatic relief of gastro-intestinal disorders characterised by smooth muscle spasm	**Contraindication**: Antimuscarinics are contraindicated in myasthenia gravis, paralytic ileuse, pyloric stenosis toxic megacolon, and prostatic enlargement **Side effects:** Side effects of antimuscarinics include constipation, transient bradycardia, reduced bronchial secrations, urinary urgency and retention, dilatation of the pupils with loss of accommodation, photophobia, dry mouth, flushing and dryness of the skin. Side-effects that occur occasionally include confusion, nausea, vomiting and giddiness.	New	BNF 63 Page 48	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	w) Liothyronine 0.05mg FC Tablet Liothyronine sodium USP 0.052mg eq. to Liothyronine 0.05mg **Thyroid Supplement**	As replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. This category includes cretinism, myxedema and ordinary hypothyroidism in patients of any age (pediatric patients, adults, the elderly), or state (including pregnancy); primary hypothyroidism resulting from functional deficiency, primary atrophy, partial or total absence of thyroid gland, or the effects of surgery, radiation, or drugs, with or without the presence of goiter; and secondary (pituitary) or tertiary (hypothalamic) hypothyroidism. As pituitary thyroid-stimulating hormone (TSH) suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's) and multinodular goiter. As diagnostic agents in suppression tests to differentiate suspected mild hyperthyroidism or thyroid gland autonomy.	**Contraindications:** Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis and apparent hypersensitivity to any of their active or extraneous constituents. There is no well-documented evidence from the literature, however, of true allergic or idiosyncratic reactions to thyroid hormone. **Side effects:** Adverse reactions, other than those indicative of hyperthyroidism because of therapeutic over dosage, either initially or during the maintenance period are rare.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	x) Multivitamin & Multiminaral Tablet Vitamin A (as Vitamin A Palmitate & Beta Carotene) USP 2500 I.U. + Vitamin D_3 (as Cholecalciferol USP 400 IU+ Vitamin B1 (as Thiamine Mononitrate) USP 1.4mg+ Vitamin B2 (as Riboflavin) USP 1.4mg+ Vitamin C (as Ascorbic Acid) USP 90mg+ Vitamin B3 (as Niacin) USP 18mg+ Vitamin B6 (as Pyridoxine Hydrochloride) USP 1.9 mg+ Pantothenic Acid (as Calcium D-Pantothenate) USP 6mg+ Vitamin B12 (as Cyanocobalamin (1.0 %) USP 2.6mg+ Folic Acid USP 0.8mg+ Vitamin E (as Vitamin E acetate) USP 35 I.U+ Vitamin K (as Phytonadione) USP 0.03mg+ Biotin USP 0.03mg+ Iodine (as Potassium iodide) USP 250mg+ Potassium (as Potassium iodide & Potassium chloride) USP 80mg+ Chloride (As Potassium Chloride) USP 72mg+ Manganese (as Manganese Sulfate Monohydrate) USP USP 2mg+ Copper (as Cupric Sulfate) USP 0.9mg+ Zinc (as Zinc Sulfate Monohydrate) USP 11mg+ Calcium (as Calcium carbonate, Dibasic calcium phosphate and Calcium D-Pantothenate) USP 250mg+ Phosphorus (as Dibasic Calcium Phosphate) USP 20mg+ Magnesium (as Magnesium oxide) USP 50mg+ Iron (as Ferrous sulfate) USP 27mg+ Selenium (as Sodium selenate) Pharm. Grade 0.30mg+ Chromium (as Chromic chloride) USP 0.03mg+ Molybdenum (as Sodium Molybdate) Ph. Grade 0.05mg **Multivitamin- Multimineral**	It is used to treat the Multivitamin and Multimineral deficiency of female, pregnant women & after pregnancy	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side effects:** Allergic sensitization has been reported following administration of folic acid.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	y) Multivitamin & Multiminaral Tablet Vitamin A (as Vitamin A Palmitate & Beta Carotene) USP 1750 I.U + Vitamin D3 (as Cholecalciferol) USP 200 I.U+ Vitamin B1 (as Thiamine Mononitrate) USP 0.75mg + Vitamin B2 (as Riboflavin) USP 0.85mg + Vitamin C (as Ascorbic Acid) USP 30mg+ Vitamin B3 (as Niacin) USP 10mg + Vitamin B6 (as Pyridoxine Hydrochloride) USP 2.5mg+ Pantothenic Acid (as Calcium D-Pantothenate) USP 5mg+ Vitamin B12 (as Cyanocobalamin (1.0 %) USP 100 mcg+ Folic Acid USP 200mcg+ Vitamin E (as Vitamin E acetate) USP 15 I.U+ Vitamin K (as Phytonadione) USP 12.5mcg+ Biotin USP 15mcg+ Iodine (as Potassium iodide) USP 75mcg+ Potassium (as Potassium iodide & Potassium chloride) USP 32mg+ Chloride (As Potassium Chloride) USP 29mg+ Manganese (as Manganese Sulfate Monohydrate) USP 1mg+ Copper (as Cupric Sulfate) USP 0.35mg+ Zinc (as Zinc Sulfate Monohydrate) USP 3.75mg+ Calcium (as Calcium carbonate, Dibasic calcium phosphate and Calcium D-Pantothenate) USP 54mg+ Phosphorus (as Dibasic Calcium Phosphate) USP 40mg+ Magnesium (as Magnesium oxide) USP 20mg+ Iron (as Ferrous sulfate) USP 3mg+ Selenium (as Sodium selenate) Pharm. Grade 10mcg+ Chromium (as Chromic chloride) USP 60mcg+Molybdenum (as Sodium Molybdate) Pharm. Grade 37.5mg+Boron (as Boron citrate) Pharm. Grade 16mcg+Nickel (as Nickelous sulfate Hexahydrate) Pharm. Grade 16mcg+Tin (as Stannous fluoride) USP 5mcg+Vanadium (as Sodium metavandate) Pharm. Grade 5mcg+ Phytosterols BP 400mg **Multivitamin- Multimineral**	It is used to treat the Multivitamin and Multimineral deficiency of Cardiac patient or for the patients who are prone to it. **It** is given for- Lowering the LDL (bad) Cholesterol, Reducing the risk of Heart Disease	**Contraindications**: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side effects**: Allergic sensitization has been reported following administration of folic acid.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	z) Etoricoxib 60mg + Thiocolchicoside 8mg FC tablet Etoricoxib INN 60mg + Thiocolchicoside INN 8mg **Antiarthritic + muscle relaxant**	Acute treatment of inflammatory musculoskeletal disorders associated with painful muscle spasm in adults. May also be used to provide relief in gout, Osteoarthritis (OA), Rheumatoid Arthritis (RA) and other similar conditions.	**Contraindications :** Inflammatory bowel disease, Severe congestive heart failure, Active peptic ulceration, Cerebrovascular disease, Lactation child & Adolescent < 16 years **Side effects:** Sedation**,** Drowsiness, Blurred vision Constipation & diarrhea.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		aa) Etoricoxib 60mg + Thiocolchicoside 4mg FC tablet Etoricoxib INN 60mg + Thiocolchicoside INN 4mg **Antiarthritic + muscle relaxant**	Acute treatment of inflammatory musculoskeletal disorders associated with painful muscle spasm in adults. May also be used to provide relief in gout, Osteoarthritis (OA), Rheumatoid Arthritis (RA) and other similar conditions.	**Contraindications :** Inflammatory bowel disease, Severe congestive heart failure, Active peptic ulceration, Cerebrovascular disease, Lactation child & Adolescent < 16 years **Side effects:** Sedation**,** Drowsiness, Blurred vision Constipation & diarrhea.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ab) Spinosad 0.90gm/100gm topical suspension Spinosad INN 0.90gm/100gm **Pediculicide**	It is a pediculicide indicated for the topical treatment of head lice infestations in patients four (4) years of age and older.	**Contraindications:** None **Side effects:** Application site erythema, Ocular erythema.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	ac) 5% Amino Acid + Electrolytes + 10% Dextrose IV infusion **[Amino Acids:** L-Leucine USP 0.730gm + L-Phenylalanine USP 0.560 gm + L-Methionine USP 0.400gm + L-Lysine 0.580gm (as L-Lysine HCl USP 0.798 gm) + L-Isoleucine USP 0.600g + L-Valine USP 0.580g + L-Histidine USP 0.480 gm + L-Threonine USP 0.420gm + L-Tryptophan USP 0.180gm **Non - Essential Amino Acids :** L-Alanine USP 2.070gm + Aminoacetic acid USP 1.030g + L-Arginine USP 1.150gm + L-Proline USP 0.680gm + L-Tyrosine USP 0.040gm + L-Serine USP 0.500gm **Electrolytes :** Sodium Acetate trihydrate USP 0.680gm + Dibasic potassium Phosphate USP 0.522gm + Sodium Chloride USP 0.117gm + Magnesium Chloride Hexahydrate USP 0.102gm B) Dextrose Chamber : Dextrose Anhydrous 20.000gm]/100ml	Amino acid injections when administered with a caloric source are indicated as a source of amino acids in a variety of clinical conditions in which the patient cannot absorb sufficient oral nutrition or in which it is inadvisable to use the oral route of nutrition. The purpose of the solution is to replace protein losses which occur in relation to an intercurrent phenomenon which or suspected to be productive of a protein loss condition for short or moderate period of time.	**Contraindications:** Patients with acute renal failure. -patients with severe liver disease or hepatic coma. -Hypersensitivity to one or more amino acids. - Inborn errors of amino acid metabolism concerning one or more amino acid components. **Side effects:** None	5% Amino Acid, Electrolytes & 7.5% Dextrose IV infusion	USFDA	শুধুমাত্র হাসপাতালে সরবরাহের শর্তে অনুমোদন করা যেতে পারে।	শুধুমাত্র হাসপাতালে সরবরাহের শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	ad) 5% Amino Acid + Electrolytes + 20% Dextrose IV infusion [{**Non-Essential Amino acids**: L-Alanine USP 1.0350gm + L-Arginine USP 0.575gm + L-Proline USP 0.340gm + L-Serine USP 0.250gm + Glycine USP 0.515gm + L-Tyrosine USP 0.020gm **Essential Amino acids:** L-Histidine BP 0.240gm + L-Isoleucine USP 0.300gm+L-Leucine USP 0.365gm + L-Lysine Hydrochloride USP 0.290gm + L-Methionine USP 0.200gm + L-Phenyl Alanine USP 0.280gm + L-Threonine USP 0.210gm + L-Tryptophan USP 0.090gm + L-Valine USP 0.290gm **Carbohydrate:** Anhydrous Glucose BP 20gm **Electrolytes:** Sodium acetate trihydrate BP 0.340gm + Dibasic potassium phosphate USP 0.261gm + Sodium chloride BP 0.0585gm + Magnesium chloride hexahydrate BP 0.051gm}/100ml }/100ml]	Amino acid injections when administered with a caloric source are indicated as a source of amino acids in a variety of clinical conditions in which the patient cannot absorb sufficient oral nutrition or in which it is inadvisable to use the oral route of nutrition. The purpose of the solution is to replace protein losses which occur in relation to an intercurrent phenomenon which or suspected to be productive of a protein loss condition for short or moderate period of time.	**Contraindications:** Patients with acute renal failure. -patients with severe liver disease or hepatic coma. -Hypersensitivity to one or more amino acids. - Inborn errors of amino acid metabolism concerning one or more amino acid components. **Side effects:** None	5% Amino Acid, Electrolytes & 7.5% Dextrose IV infusion	USFDA	শুধুমাত্র হাসপাতালে সরবরাহের শর্তে অনুমোদন করা যেতে পারে।	শুধুমাত্র হাসপাতালে সরবরাহের শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	ae) 2.75% Amino Acid + Electrolytes + 5% Dextrose IV infusion **{Non-Essential Amino acids:** (L-Alanine USP 0.570gm +L-Arginine USP 0.316gm+L-Proline USP 0.187gm + L-Serine USP 0.1375gm+ Glycine USP 0.283gm +L-Tyrosine USP 0.011gm) **Essential Amino acids:** (L-Histidine BP 0.132gm+L-Isoleucine USP 0.165gm+L-Leucine USP 0.201gm+L-Lysine Hydrochloride USP 0.1595gm+L-Methionine USP 0.110gm+L-Phenyl Alanine USP 0.154gm+L-Threonine USP 0.115gm+ L-Tryptophan USP 0.0495gm+L-Valine USP 0.1595gm) **Carbohydrate** (Anhydrous Glucose BP 5gm) **Electrolytes:** Sodium acetate trihydrate BP 0.2155gm+Dibasic potassium phosphate USP 0.261gm+Sodium chloride BP 0.112gm+Magnesium chloride hexahydrate BP 0.051gm}/100ml	Amino acid injections when administered with a caloric source are indicated as a source of amino acids in a variety of clinical conditions in which the patient cannot absorb sufficient oral nutrition or in which it is inadvisable to use the oral route of nutrition. The purpose of the solution is to replace protein losses which occur in relation to an intercurrent phenomenon which or suspected to be productive of a protein loss condition for short or moderate period of time.	**Contraindications:** Patients with acute renal failure. -patients with severe liver disease or hepatic coma. -Hypersensitivity to one or more amino acids. - Inborn errors of amino acid metabolism concerning one or more amino acid components. **Side effects:** None	5% Amino Acid, Electrolytes & 7.5% Dextrose IV infusion	USFDA	শুধুমাত্র হাসপাতালে সরবরাহের শর্তে অনুমোদন করা যেতে পারে।	শুধুমাত্র হাসপাতালে সরবরাহের শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	af) Amlodipine 5mg + Perindopril 8mg tablet Amlodipine BP 5mg + Perindopril EP 8mg **Antihypertensive**	Amlodipine & Perindopril is indicated as substitution therapy for the treatment of hypertension and/or stable coronary heart disease in patients already controlled with separate doses of perindopril and amlodipine, given concurrently at the same dose level.	**Contraindications:** Previous hypersensitivity to perindopril or Amlodipine. During pregnancy and for lactating women **Side effects:** Nervous System disorders: dizziness, vertigo. Cardiac disorders: chest pain. Vascular Disorders: peripheral coldness. Respiratory, Thoracic and Mediastinal Disorders: cough. Gastro-intestinal disorders: diarrhea. Skin and Subcutaneous Tissue Disorders: eczema. Musculoskeletal and Connective Tissue Disorders: joint swelling. General Disorders and Administration Site Condition: oedema peripheral, fatigue, lethargy	10 mg + 5 mg Tablet & 10 mg + 10 mg Tablet	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ag) Amlodipine 10mg + Perindopril 8mg tablet Amlodipine BP 10mg & Perindopril EP 8mg **Antihypertensive**	Amlodipine & Perindopril is indicated as substitution therapy for the treatment of hypertension and/or stable coronary heart disease in patients already controlled with separate doses of perindopril and amlodipine, given concurrently at the same dose level.	**Contraindications:** Previous hypersensitivity to perindopril or Amlodipine. During pregnancy and for lactating women **Side effects:** Nervous System disorders: dizziness, vertigo. Cardiac disorders: chest pain. Vascular Disorders: peripheral coldness. Respiratory, Thoracic and Mediastinal Disorders: cough. Gastro-intestinal disorders: diarrhea. Skin and Subcutaneous Tissue Disorders: eczema. Musculoskeletal and Connective Tissue Disorders: joint swelling. General Disorders and Administration Site Condition: oedema peripheral, fatigue, lethargy	10 mg + 5 mg Tablet & 10 mg + 10 mg Tablet	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Eskayef Bangladesh Ltd., Tongi, Gazipur	ah) Ebastin 20mg tablet Ebastin BP 20mg **Antihistamine**	Seasonal and perennial allergic rhinitis. Idiopathic chronic urticaria	**Contraindications:** Patients with a known hypersensitivity to ebastin or any of its ingredients. The safety of ebastin during pregnancy and lactation has not been established. The safety and efficacy of ebastin tablet in children less than 12 years has not been established. **Side effects**: The most common side effects are headache, dry mouth and drowsiness. Other less commonly reported side effects include pharyngitis, abdominal pain, dyspepsia, asthenia, epistaxis, rhinitis, sinusitis, nausea and insomnia.	10mg tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
9.	Incepta Pharmaceuticals Ltd.	a) Boceprevir 200 mg Capsule Boceprevir INN 200mg **Anti-infective-Antiretroviral**	Boceprevir is a hepatitis C virus (HCV) NS3/4A Protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.	**Contraindications:** All contraindications to peginterferon alfa and ribavirin also apply since Boceprevir must be administered with peginterferon alfa and ribavirin. Because ribavirin may cause birth defects and fetal death, boceprevir in combination with peginterferon alfa and ribavirin is contraindicated in pregnant women. Coadministration with drugs that are highly dependent on CYP3A4/5 for clearance, and for which elevated plasma concentrations are associated with serious and/or life-threatening events. Potent CYP3A4/5 inducers (Copy Attached) where significantly reduced boceprevir plasma concentrations may be associated with reduced efficacy. **Side effects:** The most commonly reported adverse reactions (greater than 35% of subjects) in clinical trials in adult subjects receiving the combination of Boceprevir with PegIntron and Boceprevir were fatigue, anemia, nausea, headache and dysgeusia	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	b) Sitagliptin 100 mg + Metformin HCl 1000 mg Extended Release Tablet Sitagliptin Phosphate Monohydrate INN 128.52 mg eq. to Sitagliptin 100 mg + Metformin HCl BP 1000 mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin is appropriate	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients ▪ diabetic ketoacidosis ▪ diabetic pre-coma; ▪ moderate and severe renal impairment (creatinine clearance < 60 ml/min) ▪ Acute conditions with the potential to alter renal function such as: dehydration, severe infection & Shock. - Acute or chronic disease which may cause tissue hypoxia such as: cardiac or respiratory Infection. shock - hepatic impairment; - Acute alcohol intoxication, alcoholism; Lactation. **Side effects**: Common side effects when using Sitagliptin-Metformin Extended-Release Tablets: Diarrhea; gas; headache; indigestion; nausea; sore throat; stomach upset; stuffy or runny nose; vomiting; weakness. Severe allergic reactions (rash; hives; itching; difficulty swallowing or breathing; tightness in the chest; swelling of the mouth, face, lips, throat, or tongue; unusual hoarseness); chest pain or discomfort; decreased urination; dizziness or light-headedness; fast or difficult breathing; feeling of being unusually cold; general feeling of being unwell; muscle pain or weakness; red, blistered, swollen, or peeling skin; slow or irregular heartbeat; swelling of the hands or legs; symptoms of pancreas inflammation (eg, severe stomach or back pain with or without nausea or vomiting); unusual drowsiness; unusual or persistent stomach pain or discomfort; unusual tiredness or weakness.	50mg+500mg & 50mg + 1000mg ER Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	c) Prucalopride 2 mg Tablet Prucalopride Succinate INN 2.64 mg eq. to Prucalopride 2 mg **Gastro-intestinal system-Laxatives- 5HT$_4$ – Receptor Antagonist**	It is indicated for chronic constipation in women in whom laxatives fail to provide adequate response.	**Contraindications:** - Hypersensitivity to the active substance or to any of the excipients. - Renal impairment requiring dialysis. Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, - Severe inflammatory conditions of the intestinal tract, such as Crohn's disease, and ulcerative colitis and toxic megacolon/megarectum. - Hepatic Impairment - renal Impairment - breast Feeding **Side effects**: Metabolism and nutrition disorders Uncommon: anorexia Nervous system disorders Very common: headache Common: dizziness Uncommon: tremors Cardiac disorders Uncommon: palpitations Gastrointestinal disorders Very common: nausea, diarrhoea, abdominal pain Common: vomiting, dyspepsia, rectal haemorrhage, flatulence, abnormal bowel sounds Renal and urinary disorders Common: pollakiuria General disorders and administration site conditions Common: fatigue Uncommon: fever, malaise	1mg Tablet	BNF 62 page: 75	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	d) Dexamethasone 0.05% + Tobramycin 0.3% Ophthalmic Suspension Dexamethasone (Micronized & Sterile) BP 0.05gm + Tobramycin USP 0.3gm/100ml **Corticosteroid + Antibiotic**	It is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.	**Contraindications:** Tobramycin/Dexamethasone, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Hypersentivity to any component of the medications **Side effects:** The most frequent adverse reactions to topical ocular tobramycin are hypersensitivity and localized ocular toxicity, including eye pain, eyelids pruritus, eyelid edema, and conjunctival hyperemia.	0.1% + 0.3% Eye Drops	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Calcium lactate gluconate 1.36gm + Calcium carbonate 1.05gm + Colecalciferol 4mg Effervescent Tablet Calcium lactate gluconate USP 1.36gm + Calcium carbonate USP 1.05gm eq.to calcium 600mg + Colecalciferol Concerntrate 4mg eq. to Colecalciferol BP 10µg **Mineral + Vitamin**	It is indicated for Prevention & treatment of Calcium & Vitamin D deficiency. Calcium & Vitamin D suppliment as an adjunct to specific therapy in the prevention & treatment of osteoporosis for patients who are high risk of Calcium & vitamin D deficiency.	**Contraindications:** Conditions associated with hypercalcimia and hypercalciuria (some forms of malignant diseases) **Side effects:** Rarely gastro- intestinal; Distrubance, with injection bradycardia, arrhythmia, peripheral Vaso-dilatation, fall in blood pressure, sweating, injection-site reactions, severe tissue damage with extravasation.	New	BNF 62 Pg: 631	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	f) Calcium lactate gluconate 2.72gm + Calcium carbonate 2.10 gm + Colecalciferol 20 mcg Effervescent Tablet Calcium lactate gluconate 2.72gm + Calcium carbonate 2.1gm eq. to calcium 1200mg (Ca+2 30mmole) + Colecalciferol Concerntrate 8mg eq. to Colecalciferol BP 20µg (800 unit) **Mineral + Vitamin**	It is indicated for prevention & treatment of Calcium & Vitamin D Deficiency. Calcium & Vitamin D Suppliment As an adjunct to specific Therapy in the prevention & Treatment of osteoporosis for patients who are high risk of Calcium & vitamin D Deficiency.	**Contraindications:** Conditions associated with hypercalcimia and hypercalciuria (some forms of malignant diseases) **Side effects:** Rarely gastro- intestinal; Distrubance, with injection bradycardia, arrhythmia, peripheral Vaso-dilatation, fall in blood pressure, sweating, injection-site reactions, severe tissue damage with extravasation.	New	BNF 62 page: 631 MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		g) Cefixime 50mg + Clavulanic acid 31.25mg dispersible Tablet Cefixime BP 50mg as Cefixime Trihydrate BP + Clavulanic Acid 31.25mg as Potassium Clavulanate BP **Anti-infective - Cephalosporin**	It is indicated for the treatment of: - Uncomplicated Urinary Tract Infections - Otitis Media - Pharyngitis and Tonsillitis, is caused by S. pyogenes. - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis - Uncomplicated gonorrhea	**Contraindications:** It is contraindicated in patients with previous history of cholestatic jaundice/liver dysfunction, and hypersensitivity & in patients with known allergy to the cephalosporin group of antibiotics. **Side-effects:** The most frequent side effects seen with Cefixime & Clavulanic acid are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	h) Cefixime 50mg + Clavulanic acid 31.25mg/5ml Syrup Cefixime 50mg as Cefixime Trihydrate BP+ Clavulanic Acid 31.25mg as Potassium Clavulanate BP/5 ml **Anti-infective - Cephalosporin**	It is indicated for the treatment of: - uncomplicated urinary Tract Infections - Otitis Media - Pharyngitis and Tonsillitis, is caused by S. pyogenes. - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis - Uncomplicated gonorrhea.	**Contraindications:** It is contraindicated in patients with previous history of cholestatic jaundice/liver dysfunction, and hypersensitivity & in patients with known allergy to the cephalosporin group of antibiotics. **Side-effects:** The most frequent side effects seen with Cefixime & Clavulanic acid are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		i) Cefixime 100 mg + Clavulanic acid 62.5mg Dispersible Tablet Cefixime 100mg as Cefixime Trihydrate BP + Clavulanic Acid 62.5mg as Potassium Clavulanate BP **Anti-infective - Cephalosporin**	It is indicated for the treatment of: - Uncomplicated Urinary Tract Infections - Otitis Media - Pharyngitis and Tonsillitis, is caused by S. pyogenes. - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis - Uncomplicated gonorrhea	**Contraindicationss:** It is contraindicated in patients with previous history of cholestatic jaundice/liver dysfunction, and hypersensitivity & in patients with known allergy to the cephalosporin group of antibiotics. **Side effects:** The most frequent side effects seen with Cefixime & Clavulanic acid are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	**j)** Cefixime 100mg + Clavulanic acid 62.5mg/5ml Syrup Cefixime 100mg as Cefixime Trihydrate BP + Clavulanic Acid 62.5mg as Potassium Clavulanate BP/5 ml **Anti-infective - Cephalosporin**	It is indicated for the treatment of: - uncomplicated urinary Tract Infections - Otitis Media - Pharyngitis and Tonsillitis, is caused by S. pyogenes. - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis - Uncomplicated gonorrhea	**Contraindications:** It is contraindicated in patients with previous history of cholestatic jaundice/liver dysfunction, and hypersensitivity & in patients with known allergy to the cephalosporin group of antibiotics. **Side effects:** The most frequent side effects seen with Cefixime & Clavulanic acid are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		k) Doxoyphylline 400mg Tablet Doxophylline INN 400 mg **Antiasthmatic**	Doxophylline is primarily indicated in conditions like Bronchial asthma, Bronchospasm, Chronic asthmatic bronchitis	**Contraindications:** Doxophylline is contraindicated in conditions like Acute myocardial infarction, Hypersensitivity to xanthine derivatives. **Side effects:** The signs and symptoms that are produced after the acute overdosage of Doxophylline include Paroxysmal spasm crises, Arrhythmias. The symptomatic adverse reactions produced by Doxofylline are more or less tolerable and if they become severe, they can be treated symptomatically, these include Headache, Irritability, Nausea, Vomiting, Tachycardia, Insomnia, Abdominal pain, Shortening of breath, Contractions, Proteinuria, Hyperglycemia.	New		Box warning; contraindication-এ Contraindicated in acute myocardial infraction- উলেস্নখ করতে হবে এবং কেবলমাত্র বিশেষজ্ঞ চিকিৎসকের ব্যবস্থাপত্র অনুয়ায়ী ব্যবহার্য হবে এই শর্তে অনুমোদন করা যেতে পারে।	Box warning; contraindication-এ Contraindicated in acute myocardial infraction- উলেস্নখ করতে হবে এবং কেবলমাত্র বিশেষজ্ঞ চিকিৎসকের ব্যবস্থাপত্র অনুয়ায়ী ব্যবহার্য হবে এই শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Pharmaceuticals Ltd.	l) Sodium Bicarbonate 133.5mg + Calcium Carbonate 80mg + Sodium Alginate 250mg/5 ml oral suspension Sodium Bicarbonate BP 133.5mg + Calcium Carbonate BP 80mg + Sodium Alginate BP 250mg/5ml **Gastrointestinal agent (Antacid + Alginate)**	Relieving the symptoms of gastro-esophageal reflux, such as heartburn, indigestion and acid regurgitation Reflux oesophagitis	**Contraindications:** This medicine is not recommended for children under six years of age. This medicine should not be used if you are allergic to one or any of its ingredients. Please inform your doctor or pharmacist if you have previously experienced such an allergy. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately **Side effects:** Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with this medicine. Just because a side effect is stated here does not mean that all people using this medicine will experience that or any side effect. Very rare (affect less than 1 in 10,000 people): Allergic reactions such as an itchy rash (urticaria), breathing difficulties due to a narrowing of the airways (bronchospasm) or anaphylaxis The side effects listed above may not include all of the side effects reported by the medicine's manufacturer.	New	BNF 62 Page: 46	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
10.	Renata Limited Rajendrapur, Gazipur	a) Cefoperazone 500mg/Vial Injection Cefoperazone USP 500mg/Vial **Antibiotic- Cephalosporin**	Treatment of susceptible bacterial infection; mainly respiratory tract, skin and skin structure, bone and joint, urinary tract and gynecologic as well as septicemia.	**Contraindications:** Cefoperazone is contraindicated in patients with known allergy to the cephalosporin-class of antibiotics. **Side effects:** Increase risk of hypoprothrombinemia and bleeding, Rash (maculopapular or erythematous) (2%), Diarrhea (3%) Hematologic: Decreased neutrophils (2%), decreased hemoglobin or hematocrit (5%), Eosinophilia (10%) Hepatic: Increased transaminases (5% to 10%)	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Cefoperazone 1 gm/vial Injection Cefoperazone USP 1gm/Vial **Antibiotic- Cephalosporin**	Treatment of susceptible bacterial infection; mainly respiratory tract, skin and skin structure, bone and joint, urinary tract and gynecologic as well as septicemia.	**Contraindications:** It is contraindicated in patients with known allergy to the cephalosporin-class of antibiotics. **Side effects:** increase risk of hypoprothrombinemia and bleeding, Rash (maculopapular or erythematous) (2%), Diarrhea (3%) Hematologic: Decreased neutrophils (2%), decreased hemoglobin or hematocrit (5%), eosinophilia (10%) Hepatic: Increased transaminases (5% to 10%)	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Cefoperazone 2 gm/vial Injection Cefoperazone USP 2gm/Vial **Antibiotic- Cephalosporin**	Treatment of susceptible bacterial infection; mainly respiratory tract, skin and skin structure, bone and joint, urinary tract and gynecologic as well as septicemia.	**Contraindication :** Cefoperazone is contraindicated in patients with known allergy to the cephalosporin-class of antibiotics. **Side effects:** Increase risk of hypoprothrombinemia and bleeding, Rash (maculopapular or erythematous) (2%), Diarrhea (3%) Hematologic: Decreased neutrophils (2%), decreased hemoglobin or hematocrit (5%), eosinophilia (10%) Hepatic: Increased transaminases (5% to 10%)	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
11.	Renata Limited Mirpur, Dhaka	a) Dienogest 2 mg Tablet Dienogest BP 2 mg	Dienogest is indicated for the treatment of endometriosis.	**Contraindications :** As with all progestin contraindication for dienogest include • Thromboembolic disorder • Severe arterial diseases, including cardiovascular diseases • Diabetes with blood vessel damage • The presence or a history of severe liver diseases • The presence of a benign or malignant liver tumor • Unexplained vagainal bleeding • Allergy of dienogest • The presence or a history or suspected presence of a malignant sex-hormone dependent tumor such as cancer of the breast or the genital organs. Side Effects: The most frequently adverse reactions reported are headache, Breast discomfort, Depressed mood and Acne.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Paracetamol 125mg + DL Methionine 12.5mg/5ml Suspension Paracetamol BP 125mg + DL Methionine BP 12.5mg/5ml	All conditions requiring relief from pain and fever such as neuritis, neuralgia, headache, earache, toothache, pain due to rheumatic disorder, cold, influenza, dysmenorrhoea, postvaccination pain and fever of children etc.	**Contraindications:** Paracetamol is contraindicated in patients with severe renal function impairment and hepatic disease (Viral Hepatitis). **Side effects:** Side effects are significantly mild, though hematological Reactions have been reported. Pancreatitis, skin rashes, and other allergic reactions occur occasionally.	500 mg + 100 mg Tab.		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Renata Limited Mirpur, Dhaka	c) Paracetamol 250mg + DL-Methionine 25mg/5ml Suspension Paracetamol BP 250mg + DL-Methionine BP 25mg/5ml	All conditions requiring relief from pain and fever such as neuritis, neuralgia, headache, earache, toothache, pain due to rheumatic disorder, cold, influenza, dysmenorrhoea, postvaccination pain and fever of children etc.	**Contraindications:** Paracetamol is contraindicated in patients with severe renal function impairment and hepatic disease (Viral Hepatitis). **Side effects:** Side effects are significantly mild, though hematological reactions have bee reported. Pancreatitis, skin rashes, and other allergic reactions occur occasionally.	500 mg + 100 mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
12.	Beximco Pharmaceuticals Limited Tongi, Gazipur	a) Fenofibric Acid 135 mg Delayed Release Capsule Choline Fenofibrate Enteric Coated Pellets 60% Ph. Grade 225 mg eq. to Fenofibric Acid INN 135 mg **Lipid lowering agent**	Co-administration therapy with statins for the treatment of mixed dyslipidemia , treatment of severe hypertriglyceridemia, treatment of primary hypercholesterolemia or mixed dyslipidemia	**Contraindications:** It is contraindicated in: > severe renal impairment, including patient s receiving dialysis > active liver disease >patients with preexisting gallbladder disease > nursing mothers > patients with hypersensitivity to Fenofibric acid or Fenofibrate **Side effects:** The most common adverse events (≥ 3% of patients receiving Choline Fenofibrate or Choline Fenofibrate co-administered with statins) are headache, back pain, nasopharyngitis, nausea, myalgia, diarrhea, and upper respiratory tract infection	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Indacaterol 0.075mg Capsule for Dry Powder Inhaler Indacaterol Maleate INN 0.097 mg eq. to Indacaterol 0.075mg **Beta-2 Adrenergic Agonist**	It is indicated for maintenance bronchodilator; treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema.	**Contraindications:** All long-acting beta2-adrenergic agonist (LABA) are contraindicated in patients with asthma without use of a long-term asthma control medication. Indacaterol 0.075mg is not indicated for the treatment of asthma. It also is contraindicated in patients with a history of hypersensitivity to Indacaterol or to any of the ingredients. **Side effects:** Most common adverse reactions (>2% and more common than placebo) are cough, oropharyngeal pain, nasopharyngitis, headache and nausea.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	c) Permethrin 1% w/w Cream Rinse Permethrin INN 1gm/100gm **Anti-Parasitic**	It is indicated for the treatment of infections with pediculosis, head lice.	**Contraindication:** It is contraindicated in patients with a known hypersensitivity to its components and other pyrethroids or pyrethrins. **Side effects:** pruritus,erythema,and stinging;rarely rashes and oedama	5% Cream	USFDA, BNF and MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		d) Tenofovir Disoproxil 245mg + Emtricitabine 200 mg + Efavirenz 600 mg Tablet Tenofovir Disoproxil Fumerate INN 300 mg eq. to Tenofovir Disoproxil 245 mg + Emtricitabine INN 200 mg+ Efavirenz INN 600 mg **Anti-infective- Antiviral**	For the treatment of HIV-1 infections in adults and paediatric patients 12 years of age and older.	**Contraindication:** Previously demonstrated hypersensitivity (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to efavirenz. For some drugs, competition for CYP3A by efavirenz could result the serious and/or life-threatening adverse reactions (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression, serious psychiatric symptoms, Pregnancy first trimester, rash. **Side effects:** Lactic Acidosis/ Severe Hepatomegaly with Steatosis, Severe Acute Exacerbations of Hepatitis , Psychiatric Symptoms, Nervous System Symptoms, New Onset or Worsening Renal Impairment, Rash Hepatotoxicity, Decreases in Bone Mineral Density Immune Reconstitution Syndrome Drug Interactions. Most common adverse reactions (incidence greater than or equal to 10%) observed efavirenz, emtricitabine, and tenofovir DF are diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams.	New	USFDA, BNF-61, Page-385	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	e) Lopinavir 200 mg+ Ritonavir 50 mg Tablet Lopinavir INN 200 mg + Ritonavir INN 50mg **Anti-infective- Antiviral**	For the treatment of HIV-1 in combination with other antiretroviral agents.	**Contraindication:** Hypersensitivity to Lopinavir /Ritonavir (e.g., toxic epidermal necrolysis, StevensJohnson syndrome, erythema multiforme) or any of its ingredients, including Ritonavir. Co-administration with: >drugs highly dependent on CYP3A for clearance and for which elevated plasma levels may result in serious and/or life-threatening events. >Potent CYP3A inducer where significantly reduced Lopinavir plasma concentration may be associated with potential for loss of virologic response and possible resistance and cross resistance **Side effects:** PR interval prolongation, QT interval prolongation, Drug interaction, pancreatitis, hepatotoxicity. The most common adverse reactions are(>5%) are diarrhea, nausea, abdominal pain, asthenia, vomiting, headache, dyspepsia	Lopinavir 400 mg+ Ritonavir 100 mg/5 ml Oral Solution	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		f) Nabumetone 500 mg Tablet Nabumetone USP 500 mg **NSAIDS**	Acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis	**Contraindication:** Nabumetone is contraindicated in patients who have previously exhibited hypersensitivity to it.It is also contraindicated in patients in whom Nabumetone, aspirin, or other NSAIDs induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in such patients receiving NSAIDs. **Side effects:** More common side effects (Incidence ≥1%) are Diarrhea (14%), dyspepsia (13%), abdominal pain (12%), constipation Dizziness,, headache, fatigue, increased sweating, insomnia, nervousness, somnolence, Pruritus, rash, Tinnitus, edema.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	g) Nabumetone 750 mg Tablet Nabumetone USP 750 mg **NSAIDS**	Acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis	**Contraindications:** Nabumetone is contraindicated in patients who have previously exhibited hypersensitivity to it.It is also contraindicated in patients in whom Nabumetone, aspirin, or other NSAIDs induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in such patients receiving NSAIDs. **Side effects:** More common side effects (Incidence ≥1%) are Diarrhea (14%), dyspepsia (13%), abdominal pain (12%), constipation Dizziness, headache, fatigue, increased sweating, insomnia, nervousness, somnolence, Pruritus, rash, Tinnitus, Edema	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		h) Minocycline 55 mg ER Tablet Minocycline HCl BP 59.390 mg eq. to Minocycline 55 mg	It is indicated to treat only Inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age older.	**Contraindications:** This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines **Side effects:** The most commonly observed adverse reactions (incidence ≥ 5%) are headache, fatigue, dizziness, and pruritus.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		i) Minocycline 65 mg ER Tablet Minocycline HCl BP 70.190 mg eq. to Minocycline 65 mg	It is indicated to treat only Inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age older.	**Contraindication:** This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines **Side effects:** The most commonly observed adverse reactions (incidence ≥ 5%) are headache, fatigue, dizziness, and pruritus.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	j) Minocycline 80 mg ER Tablet Minocycline HCl BP 86.380 mg eq. to Minocycline 80 mg	It is indicated to treat only Inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age older.	**Contraindications:** This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines **Side effects:** The most commonly observed adverse reactions (incidence ≥ 5%) are headache, fatigue, dizziness, and pruritus.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		k) Fluticasone Propionate 0.500 mg/2ml Respirator Suspension for Nebulisation Fluticasone Propionate BP 0.500 mg/2ml **Respiratory system-Corticosteroids**	Prophylaxis of Asthma; 16 years and above for the management of severe chronic asthma, and children 4-16 years for the treatment of acute exacerbations of asthma.	**Contraindications:** Fluticasone propionate respiratory solutions are contraindicated in patients with a history of hypersensitivity to any component of the preparation. **Side effects:** Side effects are Candidiasis, Upper Respiratory Tract Infection, Cough, Lower Respiratory Tract Infection, Headache etc.	Fluticasone Propionate 500mcg,250mcg, 100mcg DPI, 250 mcg,500 mcg inhaler	BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		l) Fluticasone Propionate 2 mg/2ml Respirator Suspension for Nebulisation Fluticasone Propionate BP 2 mg/2ml **Respiratory system-Corticosteroids**	Prophylaxis of Asthma; 16 years and above for the management of severe chronic asthma, and children 4-16 years for the treatment of acute exacerbations of asthma.	**Contraindications:** Fluticasone propionate respiratory solutions are contraindicated in patients with a history of hypersensitivity to any component of the preparation. **Side effects:** Side effects are Candidiasis, Upper Respiratory Tract Infection, Cough, Lower Respiratory Tract Infection, Headache etc.	Fluticasone Propionate 500mcg, 250mcg, 100mcg DPI, 250 mcg, 500 mcg inhaler	BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	m) Sodium Alginate 250 mg + Sodium Bicarbonate 106.5 mg + Calcium Carbonate 187.5 mg Tablet Sodium Alginate BP 250 mg + Sodium Bicarbonate BP 106.5 mg + Calcium Carbonate BP 187.5 mg **Gastrointestinal agent (Alginate+Antacid)**	For the treatment of acid regurgitation, heartburn, indigestion and for symptoms of excess stomach acid (hyperacidity)	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients, including the esters of hydroxybenzoates (parabens). **Side effects:** Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions	New	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		n) Sodium Alginate 5 gm + Sodium Bicarbonate 2.130 gm + Calcium Carbonate 3.250 gm / 100 ml Suspension Sodium Alginate BP 5 gm + Sodium Bicarbonate BP 2.130 gm + Calcium Carbonate BP 3.250 gm / 100 ml **Gastrointestinal agent (Alginate+Antacid)**	For the treatment of acid regurgitation, heartburn, indigestion and for symptoms of excess stomach acid (hyperacidity)	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients, including the esters of hydroxybenzoates (parabens). **Side effects:** Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions	New	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	o) Macrogol (3350) 13.125 gm + Sodium Bicarbonate 178.5 mg+ Sodium Chloride 350.70mg+ Potassium Chloride 46.6 mg/Sachet Macrogol (3350) BP 13.125 g + Sodium Bicarbonate BP178.5 mg + Sodium Chloride BP 350.70 mg+ Potassium Chloride BP 46.6 mg/Sachet **Osmotic Laxatives**	For the treatment of chronic constipation. It is also effective in resolving fecal impaction	**Contraindications:** Intestinal perforation or obstruction, paralytic ileus, severe inflammatory conditions of the intestinal tract (such as Crohn's disease, ulcerative colitis, and toxic megacolon) **Side effects:** Reactions related to the gastrointestinal tract occur most commonly.	New	BNF, MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		p) Zidovudine 300 mg Tablet Zidovudine USP 300 mg **Antiinfective- Antiretroviral**	For the treatment of HIV-1 in combination with other antiretroviral agents. Preventions of maternal-fetal HIV -1 Transmission	**Contraindications:** Hypersensitivity to zidovudine (e.g., anaphylaxis, Stevens-Johnson syndrome). **Side effects:** In adult (incidence ≥15%) headache, malaise, nausea, anorexia, and vomiting. In Paediatric (incidence ≥15%) are fever, cough, and digestive disorders. In neonates (incidence ≥15%) in the prevention of maternal-fetal transmission HIV-1 are anemia and neutropenia.	100mg Tablet, 250 mg,100mg Capsule	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		q) Abacavir 300 mg Tablet Abacavir Sulphate INN 351.397 mg eqv. to Abacavir 300 mg **Antiinfective- Antiretroviral**	For the treatment of HIV infections.	**Contraindications:** Previously demonstrated hypersensitivity to Abacavir Moderate or severe hepatic impairment. **Side effects:** The most commonly reported adverse reactions of at least moderate intensity (incidence ≥10%) in adult are nausea, headache, malaise and fatigue, nausea and vomiting, and dreams/sleep disorders; in pediatric (incidence ≥5%) are fever and/or chills, nausea and vomiting, skin rashes, and ear/nose/throat infections.	New	USFDA, BNF-61, page-383	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	r) Cetyl alcohol 2.65% + Stearyl alcohol 0.26% w/w Cleansing lotion Cetyl alcohol BP 2.650 gm + Stearyl alcohol BP 0.260 gm/100 gm	For the treatment of mild skin cleanser for normal, dry and sensitive skin condition, Atopic dermatitis.	**Contraindication:** Hypersensitivity to active ingredients or to any of the excipients in the formulation. **Side effects:** none	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		s) Citric Acid anhydrous 0.720 gm +Sodium Citrate anhydrous 0.630 gm +Tartaric acid 0. 890 gm+ Sodium Bicarbonate 1.760 gm/ Sachet Citric Acid anhydrous BP 0.720 gm +Sodium Citrate anhydrous BP 0.630 gm + Tartaric acid BP 0. 890 gm + Sodium Bicarbonate 1.760 gm/Sachet	Relief from the burning pain of cystitis	**Contraindications:** Renal failure or hypernatraemia; in conjunction with hexamine mandelate or hexamine hippurate therapy because an acid urine is needed. **Side effects:** Mild laxative effect, systemic alkalosis and/or hypernatraemia	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		t) Citicoline 500 mg Tablet Citicoline Sodium INN 522.50 mg eq. to Citicoline 500 mg **Psychostimulant**	Citicoline is indicated for patients Suffering from Stroke, aged-associated memory impairment, head injury, cerebrovascular disorder. It is also indicated for cognitive support and support for nerves of the eye.	**Contraindication:** Hypersensitivity to citicoline or to any of the excipients in the formulation. **Side effects:** Headache, back pain, nasopharyngitis,	500mg/4ml Injection		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	পদটির প্রয়োজনীয়তা বিবেচনা করে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	u) Acetylcysteine 0.600gm Powder for Suspension/ sachet Acetylcysteine USP 0.600gm/Sachet **Mucolytic Agent**	Treatment of Chronic bronchopulmonary disease and Acute bronchopulmonary disease	**Contraindications:** It is contraindicated in those patients who are sensitive to it. **Side effects:** Stomatitis, nausea, vomiting, fever, rhinorrhea, drowsiness, clamminess, chest tightness and bronchoconstriction.	100mg/ml and 200 mg/ml Respirator Solution		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		v) Zidovudine 200 mg Tablet Zidovudine USP 200 mg **Anti-infective-Antiretroviral**	For the treatment of HIV-1 in combination with other antiretroviral agents.	**Contraindication:** Hypersensitivity to zidovudine (e.g., anaphylaxis, Stevens-Johnson syndrome). **Side effects:** In adult(incidence ≥15%) headache, malaise, nausea, anorexia, and vomiting. in Pediatric (incidence ≥15%) are fever, cough, and digestive disorders. in neonates (incidence ≥15%) in the prevention of maternal-fetal transmission HIV-1 are anemia and neutropenia.	250 mg,100mg Capsule		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		w) Lactase 100 mg Tablet Lactase USP 3000 FCCU (Food Chemical Codex Units) eq. to Lactase 100 mg	For the treatment of Lactose Intolerance and associated indigestion.	**Contraindication:** Hypersensitivity to lactase or to any of the excipients in the formulation. **Side effects:** When used as directed, lactase enzyme is not known to cause adverse side effects	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		x) Lactase 150mg Tablet Lactase USP 4500 FCCU (Food Chemical Codex Units) eq. to Lactase 150mg	For the treatment of Lactose Intolerance and associated indigestion.	**Contraindication:** Hypersensitivity to lactase or to any of the excipients in the formulation. **Side effects:** When used as directed, lactase enzyme is not known to cause adverse side effects	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	y) Lactase 300mg Tasblet Lactase USP 9000 FCCU (Food Chemical Codex Units) eq. to Lactase 300mg	For the treatment of Lactose Intolerance and associated indigestion.	**Contraindication:** Hypersensitivity to lactase or to any of the excipients in the formulation. **Side effects:** When used as directed, lactase enzyme is not known to cause adverse side effects	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		z) Glucosamine 0.666g + Malic acid 0.666g + Glycyrrhizinic acid 0.033g+ Zinc sulphate 0.005g + Ascorbic Acid 0.020 g + Pyridoxine HCl 0.60 mg + Folic Acid 0.0666 mg + Cyanocobalamin 0.0003mg + Calcium Pantothenate 0.002g + Arginine 0.666g+ Glycine 0.333g/Sachet Glucosamine BP 0.666 g + Malic acid BP 0.666 g+ Glycyrrhizinic acid INN 0.033 g+ Zinc sulphate USP 0.005g+Ascorbic Acid BP 0.020 g+ Pyridoxine HCl BP 0.60 mg+ Folic Acid BP 0.0666 mg + Cyanocobalamin BP 0.0003 mg+ Calcium Pantothenate USP 0.002 g + Arginine BP 0.666 g+ Glycine BP 0.333 g/Sachet	Alternative or supportive therapy for hepatitis, AIDS, herpes infection, malaria, dengue hemorrhagic fever & other viral infections.	**Contraindications:** Previous sensitivity to any component of the formulation. **Side effects:** Abdominal discomfort.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	aa) Voglibose 0.2 mg Tablet Voglibose INN 0.2 mg **Anti-diabetic**	To improve postprandial hyperglycemia in patient with type 2 Diabetes.	**Contraindications:** Inflammatory bowel disease; GI obstruction or patients predisposed to it; conditions which may deteriorate as a result of increased gas formation eg, hernia; severe ketosis; diabetic coma or pre-coma; severe infection; hypersensitivity; pregnancy; lactation. Not to be used as monotherapy in IDDM. **Side effects:** Flatulence; abdominal distension; diarrhoea; pain; skin reactions; hypoglycemia; increased LFT. Potentially Fatal: Hepatotoxicity.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ab) Voglibose 0.3 mg Tablet Voglibose INN 0.3 mg Tablet **Anti-diabetic**	To improve postprandial hyperglycemia in patient with type 2 Diabetes.	**Contraindications:** Inflammatory bowel disease; GI obstruction or patients predisposed to it; conditions which may deteriorate as a result of increased gas formation eg, hernia; severe ketosis; diabetic coma or pre-coma; severe infection; hypersensitivity; pregnancy; lactation. Not to be used as monotherapy in IDDM. **Side effects:** Flatulence; abdominal distension; diarrhoea; pain; skin reactions; hypoglycemia; increased LFT. Potentially Fatal: Hepatotoxicity.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ac) Paracetamol 500 mg+ Caffeine 60 mg + Pyrilamine Maleate 15 mg Tablet Paracetamol BP 500 mg+ Caffeine BP 60 mg + Pyrilamine Maleate USP 15 mg	For the temporary relief of these symptoms associated with menstrual periods:-cramps, bloating, water-weight gain, headache muscle aches etc.	**Contraindications:** liver disease, glucoma, difficulty in urination due to enlargement of the prostate gland, a breathing problem such as emphysema or chronic bronchitis. **Side effects:** Drowsiness, excitability especially in children, nervousness, irritability, sleeplessness and occasionally rapid heartbeat may occur.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beximco Pharmaceuticals Limited Tongi, Gazipur	ad) Calcium Orotate 740 mg Tablet Calcium Orotate INN 740 mg **Electrolyte**	It is used to treat conditions caused by low calcium levels such as bone loss (osteoporosis), weak bones (osteomalacia/rickets), decreased activity of the parathyroid gland (hypoparathyroidism), and a certain muscle disease (latent tetany).	**Contraindication:** Calcium can decrese the absorption of other drugs such as bis phosphonates (e.g., alendronate), tetracycline antibiotics (e.g. doxycyline, minocycline), estramustine, levothyroxine and quinolone antibiotics (e. g. ciprofloxacin, levofloxacin) **Side effects:** Constipation and upsetstomach may occur.	400 mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	পদটির প্রয়োজনীয়তা বিবেচনা করে অনুমোদন করা হল।
13.	Delta Pharma Ltd.	a) Emtricitabine 200mg + Tenofovir Disoproxil Fumarate 300 mg film-coated Tablet Emtricitabine INN 200 mg +Tenofovir Disoproxil Fumarate INN 300 mg **Anti-infective-Antiretroviral**	Emtricitabine INN 200 mg and Tenofovir Disoproxil Fumarate INN 300 mg is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. Emtricitabine INN 200 mg and Tenofovir Disoproxil Fumarate INN 300 mg is indicated in combination with safer sex practices for preexposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.	**Contraindication:** Do not use Emtricitabine INN 200 mg and Tenofovir Disoproxil Fumarate INN 300 mg for pre-exposure prophylaxis in individuals with Unknown or positive HIV-1 status. Emtricitabine INN 200 mg and Tenofovir Disoproxil Fumarate INN 300 mg should be used in HIV-infected patients only in combination with other antiretroviral agents. **Side-effect:** In HIV1 infected patients; the most common adverse reactions (incidence greater than or equal to 10%) are diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash. In HIV-1 uninfected individuals in PrEP trials, adverse reactions that were reported by more than 2% of Emtricitabine INN 200 mg and Tenofovir Disoproxil Fumarate INN 300 mg subjects and more frequently than by placebo subjects were headache, abdominal pain and weight decreased.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Delta Pharma Ltd.	b) Telbivudine 600 mg film-coated Tablet Telbivudine INN 600 mg **Anti-infective-Antiretroviral**	Telbivudine is an HBV nucleoside analogue reverse transcriptase inhibitor. It is indicated for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.	**Contraindication:** Combination of Telbivudine with pegylated interferon alfa-2a: Increased risk of Peripheral neuropathy. **Side-effect:** In clinical trials, the most common adverse reactions (greater than or equal to 3%), of any severity, were: fatigue, increased creatine kinase (CK), headache, cough, diarrhea, abdominal pain, nausea, pharyngolaryngeal pain, arthralgia, pyrexia, rash, back pain, dizziness, myalgia, ALT increased, dyspepsia, insomnia, and abdominal distension. The most common adverse events resulting in Telbivudine discontinuation included increased CK, nausea, diarrhea, fatigue, myalgia, and myopathy.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Acetaminophen 160 mg chewable Tablet Acetaminophen USP 160 mg **Analgesic and antipyretic**	Temporarily relieves minor aches and pains due to: the common cold, Flu, Headache, Sore throat, Toothache, Temporarily reduces fever. What's more, Acetaminophen can be used in children who: are allergic to aspirin. Have the flu or chicken pox.	**Contraindications:** Pregnancy category B **Side effect:** Side effects are usually mild, through hematological reactions including hrombocytopenia, leucopenia, pancytopenia, neutropenia have been reported; hypotension, flushing and tachycardia also reported on infusion; Important: liver damage (and also frequently renal damage) following overdosage.	500 mg tablet, 500 mg Orodispersible Tablet, 665 ER tablet,120 mg/5 ml suspension, 80 mg/ml Paediatric Drops,125 mg and 250 mg Suppository,120 mg dispersable tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Delta Pharma Ltd.	d) Lenalidomide 10 mg Capsule Lenalidomide INN 10 mg **Immune modulator**	Lenalidomide is a thalidomide analogue indicated for the treatment of: • Multiple myeloma (MM), in combination with dexamethasone, in Patients who have received at least one prior therapy. • Patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q Abnormality with or without additional cytogenetic abnormalities.	**Contraindication:** Lenalidomide may cause fetal harm when administered to a pregnant woman. Demonstrated hypersensitivity to lenalidomide. **Side-effect:** • MM: Most common adverse reactions (≥20%) include fatigue, neutropenia, constipation, diarrhea, muscle cramp, anemia, pyrexia, peripheral edema, nausea , back pain, upper respiratory tract infection, Dyspnea, dizziness, thrombocytopenia, tremor and rash. • MDS: Most common adverse reactions (>15%) include thrombocytopenia, neutropenia, diarrhea, pruritus, rash, fatigue, constipation, nausea, nasopharyngitis, arthralgia, pyrexia, back pain, peripheral edema, cough, dizziness, headache, muscle cramp, dyspnea, pharyngitis, and epistaxis.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Lenalidomide 25 mg Capsule Lenalidomide INN 25 mg **Immune Modulator**	-do-	-do-	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		f) Paracetamol 120 mg Chewable Tablet Paracetamol BP 120 mg **Anagesic and Antipyretic**	Paracetamol chewable tablet provide effective temporary relief from the pain and fever associated with • Earache • Headache • Cold & Flu symptoms • Teething • Immunisation	**Contraindication:** Known sensitivity to Paracetamol. **Side-effect:** Side effects are nausea, allergic reactions, skin rashes, acute renal tubular necrosis. Potentially Fatal: very rare, blood dyscrasias (e.g. thrombocytopenia, leucopenia, neutropenia, agranulocytosis); liver damage.	120 mg dispersable tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Delta Pharma Ltd.	g) Cefpodoxime 100 mg+ Clavulanic acid 62.5 mg/5ml Dry Syrup Cefpodoxime USP 100mg + Clavulanic acid BP 62.5mg/5ml **Anti-infective-Cephalosporin**	Indicated in the following infections when caused by susceptible organisms • Acute bacterial exacerbations of chronic bronchitis • Acute community acquired Pneumonia • Upper and lower respiratory tract infections • Skin and soft tissue infections • Urinary tract infections • Pharyngitis and/or tonsillitis • General gonorrhea (men and women) and rectal gonococcal infections (women) • Acute maxillary sinusitis	**Contraindications:** It is contraindicated in patients with known allergy to the Cephalosporin group of antibiotics. Clavulanic acid Penicillin allergy: Patients with penicillin allergy should not be given amoxicillin- Clavulanic acid, as the amoxicillin component is likely to precipitate a hypersensitivity reaction Glandular fever: Patients with suspected glandular fever or pharyngitis, who may be suffering from this condition, should not be given amoxicillin-Clavulanic acid, as the amoxicillin component is likely to cause maculopapular rash. Bacterial resistance: Clavulanic acid does not inactivate all beta-lactamases. Most chromosomally mediated beta-lactamases, e.g. the enzyme produced by pseudomonas. Aeruginosa are resistant to its action. Other organisms have different mechanisms of acquired resistance to beta-lactam antibiotics, against which Clavulanic acid is ineffective. These include Neisseria gonorrhoeae. **Side effects:** **Cefpodoxime:** Incidence greater than 1% include Diarrhea: 7%; Nausea: 3.3%; Vaginal Fungal Infections:1%; Vulvovaginal Infections:1.3%; Abdominal Pain: 1.2%; and Headache:1% Number of diarrhea or loose stools were dose related: decreasing from 10.4% of patients receiving 800 mg per day to 5.7% for those receiving 200 mg per day. Of patients with diarrhea, 10% had C. difficile organism or toxin in the stool. Other adverse events consists of difficulty breathing or swallowing, Hives, Itching, Mild skin rash, Painful mouth or throat sores, Severe skin rash, Sore throat, Unusual bleeding or bruising, Upset stomach, Vaginal infection, Vomiting, and Wheezing. **Clavulanic Acid:** Side effects include bloody diarrhea, bloody urine, painful or difficult urination, unusual weakness, easy bleeding and bruising, confusion, dry mouth, increased urination, chills, body aches, fever, sore throat, headache, seizures, chest pain and irregular heartbeat. These side effects are very rare and do not affect a large amount of users. Treatment should not normally exceed 14 days.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
14.	Ziska Pharmaceuticals Lts.	a) Azelastine Hydrochloride 0.1% + Fluticasone Propnionate 0.037% Nasal Spray Each spray delivers a volume of 0.137 ml suspension containing 137 Azelastine Hydrochloride INN 137 mcg + Fluticasone Propionate INN50.70 mcg **Antihistamine-Coticosteroids (Anti-allergic)**	Seasonal allergic rhinitis in patient with 12 years of age and older who requires treatment with both azelastine hydrochloride and fluticasone propionate for symptomatic relief	**Contraindication:** None **Side effects:** Somnolence, Local nasal effects, including epistaxis, nasal ulceration, nasal septal perforation, impaired wound healing, and Candida albicans infection, Cataracts and glaucoma, immunosuppression, Hypothalamic-pituitary-adrenal (HPA) axis effects, including growth reduction.	Fluticasone Propionate 50 mcg/ Spray	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Hyaluronic Acid 22.5 mg/ml (Corss-linked stabilized Gel) Hyaluronic Acid INN 22.5mg/ml **Cartilaginous Defect Repair Agent**	It is indicated for injection into the mild to deep dermis for correction of moderate to severe facial wrinkles and folds.	**Contraindications:** Contraindicated in patients with history of gram positive bacterial proteins.Hypersensitivity to any of its ingredients may cause vasculer occlation, infraction, or ambolic phenomena. **Side effects:** Swelling, Nodule, Bruising, pain, discoloration, pruritus, induration erythema	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Centella Asiatica 1.0% + Pinus Sylvestris 0.5% Cream Centella Asiatica INN 1.0 gm + Pinus Sylvestris INN 0.50g/100gm	It is indicated for the treatment of keloid and hypertrophic scars.	**Contraindications:** Person suffering from a bacterial infection in the course of therapy, and person hypersensitive to the drug. **Side effects:** Skin burning sensation, short term skin dryness, skin reddening, itching.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Ziska Pharmaceuticals Lts.	d) Desvenlafaxine Succinate 50 mg Extended Release Tablet Desvenlafaxine succinate INN 76 mg eq. to 50 mg desvenlafaxine **Antidepressants**	It is indicated for the treatment of major depressive disorder.	**Contraindications:** Hypersensitivity to desvenlafaxine succinate, venlafaxine HCl or any of the excipients in this formulation. **Side effects:** Nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Desvenlafaxine Succinate 100 mg Extended Release Tablet Desvenlafaxine succinate INN 152 mg eq. to 100 mg desvenlafaxine **Antidepressants**	It is indicated for the treatment of major depressive disorder.	**Contraindications:** Hypersensitivity to desvenlafaxine succinate, venlafaxine HCl or any of the excipients in this formulation. **Side effects:** Nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		f) Cholestyramine 4g/Sachet Cholestyramine USP 5.5g equivalent to Anhydrous Cholestyramine Resin Crystalline 4 g/Sachet **Lipid-lowering agent**	Hyperlipidaemias, particularly type IIa, in patients who have not responded adequately to diet and other appropriate measures; Primary prevention of coronary heart disease in men aged 35–59 years with primary hypercholesterolaemia who have not responded to diet and other appropriate measures; Pruritus associated with partial biliary obstruction and primary biliary cirrhosis; Diarrhoeal disorders	**Contraindications:** cholestyramine is contraindicated in patients with complete biliary obstruction. **Side effects:** Intestinal obstruction reported rarely and hyperchloraemic acidosis reported on prolonged use.	New	BNF-63	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Ziska Pharmaceuticals Lts.	g) Macrogol 3350 13.125 gm+ Sodium Chloride 350.7 mg + Sodium Bicarbonate 178.5 mg+Potassium Chloride 46.6 mg/Sachet, powder for oral solution Macrogol (3350) INN 13.125 gm + Sodium Chloride BP 350.7 mg + Sodium Bicarbonate BP 178.5 mg + Potassium Chloride BP 46.6mg/ sachet **Osmotic Laxatives**	It is used for effective relief from constipation, resolving faecal impaction defined as refractory constipation	**Contraindications:** Intestinal perforation or obstruction, paralytic ileus, severe inflammatory conditions of the intestinal tract. **Side effects:** Abdominal distention and pain, Nausea, Flatulence	New	BNF-63	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		h) Lidocaine 7% + Tetracaine 7% cream Lidocaine INN 70 mg + Tetracaine INN 70mg/gm **Local Anesthethic**	It is indicated for use on intact skin in adults to provide topicall local analgesia for superficial dermatological procedure such as dermal filler injection, pulsed dye laser therapy, facil laser resurfasing, and laser-assisted tattoo removal.	**Contraindications:** Lidocaine and tetracaine is contraindicated in patients with a known history of sensitivity to lidocaine, tetracaine, or local anesthetics of the amide or ester type.It is also contraindicated in patients with para-aminobenzoic acid (PABA) hypersensitivity and in patients with a known history of sensitivity to any other component of the product. **Side effects:** erythema, blanching,edema, rash, skin discoloration, pruritus, dizziness, headache, pain, nausea, confusion, dehydration, hyperventilation, hypotention, nervousness, paresthesia, pharyngitis, stupor, pallor, and sweating.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দেশনা	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Ziska Pharmaceuticals Lts.	i) Magnesium Sulfate 1.6 gm + Potassium Sulfate 3.13 gm + Sodium Sulfate 17.5 gm/177 ml Bottle Oral Solution Magnesium Sulfate USP 1.6 gm + Potassium Sulfate USP 3.13 gm + Sodium Sulfate USP 17.5 gm/177ml **Osmotic Laxative**	It is an osmotic laxative. It is used for cleansing of the colon in preparation for a medical procedure called a colonoscopy in adults.	**Contraindications:** Gastrointestinal obstruction, Bowel perforation, Gastric retention, Ileus , Toxic colitis or toxic megacolon , Known allergies to components of the kit **Side effects**: Abdominal Distension, Abdominal Pain, Abdominal cramping. Nausea, Vomiting	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		j) Sumatriptan 85 mg + Naproxen 500 mg FC Tablet Sumatriptan Succinate BP 119 mg eq. to Sumatriptan 85 mg + Naproxen Sodium BP 500 mg **Antimigraine drug**	Indicated for the acute treatment of migraine attacks with or without aura in adults.	**Contraindications:** Cardiac, Cerebrovascular, or Peripheral Vascular Disease, Uncontrolled Hypertension, Monoamine Oxidase-A Inhibitors, Ergotamine-Containing or Ergot-Type Medications, Other 5-HT1 Agonists, Hemiplegic or Basilar Migraine, Hepatic Impairment. **Side Effects:** Dizziness, drowsiness, Somnolence, Paresthesia, Nausea, Dyspepsia, dry mouth, chest pain or pressure, tight feeling in neck or jaw, pain spreading to arm or shoulder, sudden numbness or weakness, confusion, problems with vision, speech, or balance, bloody or tarry stools.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
15.	ACI Ltd.	a) Pramipexole 1.05mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 1.50 mg eq. to Pramipexole 1.05mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome.	**Contraindication:** None. **Side effects:** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Pramipexole 1.57mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 2.25 mg eq. to Pramipexole 1.57mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome.	**Contraindication:** None. **Side effects :** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA & BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Pramipexole 2.1mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 3.00 mg eq. to Pramipexole 2.1mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome.	**Contraindication:** None. **Side effects:** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA & BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	d) Pramipexole 2.62mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 3.75 mg eq. to Pramipexole 2.62mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome.	**Contraindication:** None. **Side effects:** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA & BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		e) Pramipexole 3.15mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 4.5 mg eq. to Pramipexole 3.15mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome**.**	**Contraindication:** None. **Side effects:** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA& BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		f) Pramipexole 0.260 mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 0.375 mg eq. to Pramipexole 0.260 mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome**.**	**Contraindication:** None. **Side effects :** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA & BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	g) Pramipexole 0.520mg Extended Release Tablet Pramipexole Dihydrochloride Monohydrate BP 0.797 mg eq. to Pramipexole 0.75 mg **Antiparkinsonian Drug**	It is indicated in Parkinson's disease alone or as an adjunct to co-beneldopa or co-carteldopa, moderate to severe restless legs syndrome**.**	**Contraindication:** None. **Side effects:** Nausia, constipation, vomiting, weight change, decreased apetite, hypotension, peripheral oedema, Dizziness, dyskinesia, halucination, headache, insomnia, skin rash, etc.	700mcg, 180mcg, 88mcg tablet	USFDA & BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		h) Cefixime 50mg/ml Paediatric Drops Cefixime Trihydrate USP 5.6gm eq. to Cefixime 5.00gm/100ml **Antibacterial – Cephalosporin**	Cefixime is indicated for the treatment of the following infections: Upper Respiratory Tract Infections (URTI) e.g. Ottitis Media; Lower Respiratory Tract Infections (LRTI) e.g. Bronchitis, Pneumonia, Urinary Tract Infections (UTI) eg Cystitis, Cystourethritis, etc; Enteric fever e.g. Typhoid.	**Contraindications:** Cefixime is contraindicated to patients with known hypersensitivity to Cephalosporin group of drugs. **Side effects:** It is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature. Among them; diarrhea, nausia, abdominal pain, dyspepsia, dizziness, etc.	2.5 gm/100 ml (25mg/ml) Paed. Drops		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		i) Quetiapine 300mg FC Tablet Quetiapine Fumarate INN 345.39 mg eq. to Quetiapine 300mg **Antipsychotic**	It is indicated for the treatment of Schizophrenia, mania, either alone or with mood stabilizers, depression in bipolar disorder, adjunctive in major depression disorder	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clrithromycin & nefazodone is contraindicated. **Side effects**: Dry mouth, constipation, dyspepsia, tachycardia, elevated plasma-triglyceride and cholesterol concentration, peripheral oedema, drowsiness, headache, irritability, dysarthria, asthenia, etc.	100mg , 25mg tablet	USFDA/BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	j) Potassium Nitrate 50mg + Sodium Fluoride 1.5mg/gm Toothpaste (Extra whitening) Potassium Nitrate BP 5.00gm + Sodium Fluoride BP 0.15gm/100gm	1. Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact 2. Aids in the prevention of dental cavities.	**Contraindication** : None **Side effects** : Not known	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		k) Potassium Nitrate 50mg + Sodium Fluoride 3.2mg/gm Toothpaste (Fluoride) Potassium Nitrate BP 5.00gm + Sodium Fluoride BP 0.32gm/100gm	1. Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact 2. Aids in the prevention of dental cavities.	**Contraindication** : None **Side effects** : Not known	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		l) Potassium Nitrate 50mg + Sodium Fluoride 1.45mg/gm Toothpaste (Full protection) Potassium Nitrate BP 5.00gm + Sodium Fluoride BP 0.145gm/100gm	1. Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact. 2. Aids in the prevention of dental cavities.	**Contraindication** : None **Side effects** : Not known	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	m) Lamotrigine 2mg Chewable Dispersible Tablet Lamotrigine BP 2mg **Anticonvulsant**	It is indicated for monotherapy and adjunctive treatment of focal seizures and generalized seizures including tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome; monotherapy of typical absence seizures in children; prevention of depressive episodes associated with bipolar disorder.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Side effects:** Nausea, vomiting, diarrhoea, dry-mouth, aggregation, agitation, headache, drowsiness, dizziness, tremor, insomnia, ataxia, back pain, arthalgia, nystagmus, diplopia, blurred vision, rash, hepatic failure, movement disorder, confusion, hallucination, blood disorder etc.	25mg , 50mg tablet	USFDA/BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		n) Lamotrigine 5mg Chewable Dispersible Tablet Lamotrigine BP 5mg **Anticonvulsant**	It is indicated for monotherapy and adjunctive treatment of focal seizures and generalized seizures including tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome; monotherapy of typical absence seizures in children; prevention of depressive episodes associated with bipolar disorder.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Side effects:** Nausea, vomiting, diarrhoea, dry-mouth, aggregation, agitation, headache, drowsiness, dizziness, tremor, insomnia, ataxia, back pain, arthalgia, nystagmus, diplopia, blurred vision, rash, hepatic failure, movement disorder, confusion, hallucination, blood disorder etc.	25mg , 50mg Tablet	USFDA/BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	o) Lamotrigine 25mg Chewable Dispersible Tablet Lamotrigine BP 25mg **Anticonvulsant**	It is indicated for monotherapy and adjunctive treatment of focal seizures and generalized seizures including tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome; monotherapy of typical absence seizures in children; prevention of depressive episodes associated with bipolar disorder.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Side effects:** Nausea, vomiting, diarrhoea, dry-mouth, aggregation, agitation, headache, drowsiness, dizziness, tremor, insomnia, ataxia, back pain, arthalgia, nystagmus, diplopia, blurred vision, rash, hepatic failure, movement disorder, confusion, hallucination, blood disorder etc.	25mg , 50mg Tablet	USFDA/BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		p) Lamotrigine 100mg Tablet Lamotrigine BP 100mg **Anticonvulsant**	It is indicated for monotherapy and adjunctive treatment of focal seizures and generalized seizures including tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome; monotherapy of typical absence seizures in children; prevention of depressive episodes associated with bipolar disorder.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Side effects:** Nausea, vomiting, diarrhoea, dry-mouth, aggregation, agitation, headache, drowsiness, dizziness, tremor, insomnia, ataxia, back pain, arthalgia, nystagmus, diplopia, blurred vision, rash, hepatic failure, movement disorder, confusion, hallucination, blood disorder etc.	25mg , 50mg Tablet	USFDA/BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	q) Lamotrigine 150mg Tablet Lamotrigine BP 150mg **Anticonvulsant**	Lamotrigines is indicated for monotherapy and adjunctive treatment of focal seizures and generalized seizures including tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome; monotherapy of typical absence seizures in children; prevention of depressive episodes associated with bipolar disorder.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Side effects:** Nausea, vomiting, diarrhoea, dry-mouth, aggregation, agitation, headache, drowsiness, dizziness, tremor, insomnia, ataxia, back pain, arthalgia, nystagmus,diplopia, blurred vision, rash, hepatic failure, movement disorder, confusion, hallucination, blood disorder etc.	25mg , 50mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		r) Lamotrigine 200mg Tablet Lamotrigine BP 200mg **Anticonvulsant**	Lamotrigines is indicated for monotherapy and adjunctive treatment of focal seizures and generalized seizures including tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome; monotherapy of typical absence seizures in children; prevention of depressive episodes associated with bipolar disorder.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Side effects:** Nausea, vomiting, diarrhoea, dry-mouth, aggregation, agitation, headache, drowsiness, dizziness, tremor, insomnia, ataxia, back pain, arthalgia, nystagmus,diplopia, blurred vision, rash, hepatic failure, movement disorder, confusion, hallucination, blood disorder etc.	25mg , 50mg Tablet	USFDA/BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	s) Mirtazapine 45mg FC Tablet Mirtazapine BP 45mg **Antidepressant**	It is indicated in the treatment of episodes of major depression.	**Contraindications**: It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. Concomitant administration with monoamine oxidase (MAO) inhibitors. **Side effects:** Increase appetite, weight gain, dry mouth, postural hypotension, peripheral oedema, drowsiness, fatigue, tremor, dizziness, abnormal dreams, confusion, and anxiety. Insomnia, arthralgia, myalgia, hypotension, maia, hallucination movement disorder, etc	30mg, 15mg Tablet	USFDA/ BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		t) Strong Ammonia Solution 0.1gm + Aromatic Ammonia Solution 6.04gm + Liquefied Phenol 0.494gm/100gm Cream Strong Ammonia Solution BP 0.1gm + Aromatic Ammonia Solution BP 6.04gm + Liquefied Phenol BP 0.494gm/100gm	For quick relief of occational cold sores, cracked lips or chapped lips.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to the active substances or any of the excipients. **Adverse effects:** Immune system disorders: Hypersensitivity reactions. General disorders: Application site irritation, swelling or inflammation.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		u) Chlorhexidine Gluconate 2% + Isopropey Alcohol 70% Hand Rub Gel Chlorhexidine Gluconate Solution BP 10ml eq. to Chlorhexidine Gluconate 2gm + Isopropey Alcohol BP 70ml/100ml **Antiseptics**	For hand hygiene	**Contraindications:** Hypersensitivity to Chlorhexidine, Dermatitis, allergic reaction, **Side effects :** Allergic reaction, Dry & itchy skin, dermatitis, stickiness of hands for 3-5 min.	Chlorhexidine Gluconate BP 0.5% w/v + Isopropey Alcohol BP 70% v/v	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	v) Alogliptin 25mg FC Tablet Alogliptin Benzoate INN 34mg eqv.to Alogliptin 25mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 Diabetes mellitus.	**Contraindications:** History of hypersensitivity to Alogliptin, e.g. anaphylexis, angioedema or severe cutaneous adverse reactions. **Side effects:** Most common side effects are stuffy or runny nose and sore throat, heahache, URTI.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		w) Alogliptin 12.5mg FC Tablet Alogliptin Benzoate INN 17mg eqv.to Alogliptin 12.5mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 Diabetes mellitus.	**Contraindications:** History of hypersensitivity to Alogliptin, e.g. anaphylexis, angioedema or severe cutaneous adverse reactions. **Side effects:** Most common side effects are stuffy or runny nose and sore throat, heahache, URTI.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		x) Alogliptin 6.25mg FC Tablet Alogliptin Benzoate INN 8.5mg eq.to Alogliptin 6.25mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 Diabetis mellitus.	**Contraindication:** History of hypersensitivity to Alogliptin, e.g. anaphylexis, angioedema or severe cutaneous adverse reactions. **Side effects:** Most common side effects are stuffy or runny nose and sore throat, heahache, URTI.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		y) Alogliptin 12.5mg + Metformin 500mg FC Tablet Alogliptin Benzoate INN 17mg eq.to Alogliptin 12.5mg + Metformin HCl BP 500mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 Diabteis Mellitus.In multiple clinical setting when treatment with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.	**Contraindication:** The combination is contraindicated in patients with renal impairment, metabolic acidosis, including diabetic ketoacidosis & also in history of a serious hypersensitivity reaction to Alogliptin or Metformin components of Alogliptin Benzoate + Metformin HCl such as anaphylaxis, angioedema or severe cutaneous adverse reaction. **Side effect:** Lactic Acidosis, cold like symptoms, stuffy or runny nose, sore throat, diarrhea, increase in blood pressure, headache, back pain, urinary tract infection.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	z) Alogliptin 12.5mg + Metformin 1000mg FC Tablet Alogliptin Benzoate INN 17mg eq.to Alogliptin 12.5mg + Metformin HCl BP 1000mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 Diabetes Mellitus.in Multiple clinical setting when treatment with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.	**Contraindication:** The combination is contraindicated in patients with renal impairment, metabolic acidosis, including diabetic ketoacidosis & also in history of a serious hypersensitivity reaction to Alogliptin or Metformin components of Alogliptin Benzoate + Metformin HCl such as anaphylaxis, angioedema or severe cutaneous adverse reaction **Side effect:** Lactic Acidosis, cold like symptoms, stuffy or runny nose, sore throat, diarrhea, increase in blood pressure, headache, back pain, urinary tract infection,	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		aa) Alogliptin 12.5mg + Pioglitazone 15mg FC Tablet Alogliptin Benzoate INN 17mg eq.to Alogliptin 12.5mg + Pioglitazone HCl INN 16.53 mg eq.to Pioglitazone 15mg **Antidiabetic**	It is a dipeptidyl peptidase-4 inhibitor and thiazolidinedione combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It should not be used in patients with type-1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, components of Alogliptin benzoate + Pioglitazone HCl, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Do not initiate Alogliptin benzoate + Pioglitazone HCl in patients with established NYHA Class III or IV heart failure. **Side effects:** Stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	ab) Alogliptin 12.5mg + Pioglitazone 30mg FC Tablet Alogliptin Benzoate INN 17mg eq.to Alogliptin 12.5mg + Pioglitazone HCl INN 33mg eq. to Pioglitazone 30mg **Antidiabetic**	It is a dipeptidyl peptidase-4 inhibitor and thiazolidinedione combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It should not be used in patients with type-1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, components of Alogliptin benzoate + Pioglitazone HCl, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Do not initiate Alogliptin benzoate + Pioglitazone HCl in patients with established NYHA Class III or IV heart failure. **Side effects:** Stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ac) Alogliptin 12.5mg+ Pioglitazone 45mg FC Tablet Alogliptin Benzoate INN 17mg eq.to Alogliptin 12.5mg + Pioglitazone HCl INN 49.50mg eq.to Pioglitazone 45mg **Antidiabetic**	It is a dipeptidyl peptidase-4 inhibitor and thiazolidinedione combination product indicated as an adjunct to diet and exercise to improve glycemic control in 4 adults with type 2 diabetes mellitus. It should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, components of Alogliptin benzoate + Pioglitazone HCl, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Do not initiate Alogliptin benzoate + Pioglitazone HCl in patients with established NYHA Class III or IV heart failure. **Side effects:** Stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	ACI Ltd.	ad) Alogliptin 25mg+ Pioglitazone 30mg FC Tablet Alogliptin Benzoate INN 34mg eq. to Alogliptin 25mg + Pioglitazone HCl INN 33mg eq.to Pioglitazone 30mg **Antidiabetic**	It is a dipeptidyl peptidase-4 inhibitor and thiazolidinedione combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, components of Alogliptin benzoate + Pioglitazone HCl, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Do not initiate Alogliptin benzoate + Pioglitazone HCl in patients with established NYHA Class III or IV heart failure. **Side effects:** Stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ae) Alogliptin 25mg + Pioglitazone 45mg FC Tablets Alogliptin Benzoate INN 34mg eq.to Alogliptin 25mg + Pioglitazone HCl INN 49.50mg eq.to Pioglitazone 45mg **Antidiabetic**	It is a dipeptidyl peptidase-4 inhibitor and thiazolidinedione combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It should not be used in patients with type 1 Diabetes Mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, components of Alogliptin benzoate + Pioglitazone HCl, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Do not initiate Alogliptin benzoate + Pioglitazone HCl in patients with established NYHA Class III or IV heart failure. **Side effects:** Stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		af) Alogliptin 25mg + Pioglitazone 15mg FC Tablets Alogliptin Benzoate INN 34mg eq.to Alogliptin 25mg + Pioglitazone HCl INN 16.53mg eq.to Pioglitazone 15mg **Antidiabetic**	It is a dipeptidyl peptidase-4 inhibitor and thiazolidinedione combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It should not be used in patients with type 1 Diabetes Mellitus or for the treatment of Diabetic ketoacidosis, as it would not be effective in these settings.	**Contraindications:** History of a serious hypersensitivity reaction to alogliptin or pioglitazone, components of Alogliptin benzoate + Pioglitazone HCl, such as anaphylaxis, angioedema or severe cutaneous adverse reactions. Do not initiate Alogliptin benzoate + Pioglitazone HCl in patients with established NYHA Class III or IV heart failure. **Side effects:** Stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
16.	Orion Pharma Ltd.	a) Vitamin A 1250 IU + Vitamin D3 200 IU + Inositol 100 mg + Vitamin C 75 mg + Elemental Magnesium 25 mg + Nicotinamide 22.5 mg + Para-aminobenzoic acid (PABA) 12.5 mg + vitamin E 12.5 mg + L-arginine 10 mg + Elemental Zinc 10 mg + Elemental Iron 9 mg + Thiamine Mononitrate 5 mg + Pyridoxine HCl 5 mg + Riboflavin 2.5 mg + Elemental Manganese 1.5 mg + Folic acid 1.5 mg + Elemental Copper 750 mcg + Vitamin B12 500 mcg + Elemental Selenium 100 mcg + Elemental Chromium 50 mcg + Elemental Iodine 50 mcg Tablet Vitamin A Acetate (Dry Vitamin A Acetate 500) USP 0.430 mg eq. to 1250 IU Vitamin A + Colecalciferol (Dry Vitamin D_3 100) BP 0.005 mg eq. to 200IU vitamin D_3 + Inositol USP 100mg + Sodium Ascrobate (Vitamin C) BP 88.20mg eq. to 75mg Vitamin C + Magnesium Oxide BP 41.65mg eq. to 25mg Magnesium + Nocotinamide BP 22.50 mg + Para-aminobezoic acid (PABA) BP 12.50mg + DL-alpha-Tocopherol Acetate (Tocopherol Acetate 50% dry	Enhancement of pregnancy rates in female infertility due to ovulation disorders and polycystic ovary syndrome (PCOS). Correction of multiple micronutrient deficiencies and reduction/correction of oxidative stress associated with infertility. Adjuvant therapy, along with drugs, for ovulation induction and assisted reproductive techniques (ART).	**Contraindications:** There have been several published reports of this interaction. The pharmacological explanation of why the interaction occurs is well documented and understood. There are usually controlled studies that have established that the interaction exists. **Side effects:** Hypothyroidism, PCOS, Hormonal Imbalance, Stress.			প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Pharma Ltd.	Powder) BP 12.50mg + Arginine (L- Arginine) BP 10.00mg + Zinc Sulfate Monohydrate (as Zinc) USP 27.40mg eq. to 10mg Zinc + Dride Ferrous sulphate (as Iron) BP 24.48mg eq. to 9.00mg Iron + Thiamine Mononitrate USP 5mg + Pyridoxine HCl BP 5mg + Riboflavin BP 2.50mg + Manganese Sulphate (as Manganese) BP 4.62mg eq. to 1.5mg Manganese + Folic Acid BP 1.5mg + Anhydrous Copper Sulphate (as Copper) BP 2.51mg eq. to 1.0mg Copper + Cyanocobalamin (Vitamin B_{12}) BP 0.50mg + Sodium Selenite (as Selenium) BP 0.219mg eq. to 0.1mg Selenium + Potassium Iodide (as Iodine) BP 0.0655 mg eq. to 0.05mg Iodine + Chromic Chloride Anhydrous (as Chromium) USP 0.153 mg Eq. to 0.05mg Chromium **Multivitamin - Minerals**					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Pharma Ltd.	b) Carbonyl iron 51 mg+ Folic acid 0.5 mg + Vitamin B12 15 mcg+ Vitamin C 75 mg + Zinc Sulphate monohydrate 61.8 mg Capsule Carbonyl iron INN 51mg eq. to elemental Iron 50mg + Folic acid BP 0.5mg + Vitamin B12 BP 15 mcg + Vitamin C BP 75 mg + Zinc Sulphate monohydrate USP 61.8 mg **Multivitamin - Minerals**	It is used for the treatment of Iron deficiency, Lactation, Pregnancy, blood loss, Anemia, menorrhagia.	**Contraindication**- :This product is contraindicated in patients with known hypersensitivity to any of the ingredients **Side effects**: The most common side effects are stomach upset, nausea, vomiting, constipation and diarrhea.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Cefpodoxime 100 mg+ Clavulanic acid 62.5 mg/5ml Powder for Suspension Cefpodoxime USP 100 mg+ Clavulanic acid INN 62.5 mg/5ml **Antibacterial - Cephalosporin**	It is indicated in the following infections when caused by susceptible organisms. As a switch therapy after parenteral cephalosporins, Upper and lower respiratory tract infections, Skin and soft tissue infections Urinary tract infections.	**Contraindications:** Cross hypersensitivity in penicillin sensitive patients, leading to serious acute hypersensitivity reactions may need treatment with epinephrine along with other emergency measures such as intravenous fluids, oxygen, airway management, and intravenous antihistamine, as clinically indicated. **Side effects:** Most common gastrointestinal adverse effects seen is diarrhoea,vomiting and abdominal pain	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		d) Cilnidipine 5 mg Tablet Cilnidipine INN 5 mg **Antihypertensive agent-Calcium channel blocker**	Essential hypertension, hypertension in elderly patients, hypertension and congestive heart disease, hypertension and diabetes mellitus, hypertension and dyslipidemia, hypertension and chronic renal insufficiency	**Contraindications:** Cardiogenic shock, recent MI or acute unstable angina, severe aortic stenosis **Side effects:** Dizziness, flushing, headache, hypotension, peripheral oedema, tachycardia, palpitations, GI disturbances, increased miturition frequency, lethargy, eye pain.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Pharma Ltd .	e) Cilnidipine 10 mg Tablet Cilnidipine INN 10 mg **Antihypertensive agent-Calcium channel blocker**	Essential hypertension, hypertension in elderly patients, hypertension and congestive heart disease, hypertension and diabetes mellitus, hypertension and dyslipidemia, hypertension and chronic renal insufficiency	**Contraindications:** Cordiogenic shock, recent MI oracute unstable angina, sever aortic stenosis **Side-effect:** Dizziness, flushing, headache, hypotension, peripheral oedema, tachycardia, palpitations, GI disturbances, increased miturition frequency, lethargy, eye pain.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		f) Daptomycin 500 mg/vial Injection Daptomycin INN 500 mg/vial **Antibacterial- Antibiotic**	Is indicated for the treatment of complicated skin and skin structure infections caused by susceptible strains of gram positive microorganisms, treatment of staphylococcus aureus bloodstream infections (bacteremia).	**Contraindications:** Anaphylaxis/hypersensitivity reactions: discontinue daptomycin and treat signs/symptoms. **Sideeffect:** Abdominal discomfort, salivation, flushing of the skin, sweating.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		g) Vardenafil HCl 10 mg Tablet Vardenafil HCl INN 10 mg **Drugs for Erectile Dysfunction**	It is indicated for the treatment of erectile dysfunction in adult males (inability to achieve or maintain penile erection sufficient for satisfactory sexual performance)	**Contraindications:** Contraindicated in patients reciving nitrates, in patients in whom vasodilation or sexual activity are inadvisable, or in patients with a previous history of non-arteritic anterior ischaemic optic neuropathy. In the absence of information, manufacturers contra-indicate these drugs in hypotension (avoid if systolic blood pressure below 90mmHg) recent stroke, unstable angina, and myocradila infaction, hereditary degenerative retinal disorders. **Side effects:** Dyspepsia, nausea, vomiting, headache, flushing, dizziness, myalgia, back pain, visual disturbances and nasal congestion.	New	BNF-63 Page 538 USFDA	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Pharma Ltd	h) Vardenafil HCl 20 mg Tablet Vardenafil HCl INN 20 mg **Drugs for Erectile Dysfunction**	It is indicated for the treatment of erectile dysfunction in adult males (inability to achieve or maintain penile erection sufficient for satisfactory sexual performance)	**Contraindication:** Contraindicated in patients reciving nitrates, in patients in whom vasodilation or sexual activity are inadvisable, or in patients with a previous history of non-arteritic anterior ischaemic optic neuropathy. In the absence of information, manufacturers contra-indicate these drugs in hypotension (avoid if systolic blood pressure below 90mmHg) recent stroke, unstable angina, and myocradila infaction, hereditary degenerative retinal disorders. **Side effects:** Dyspepsia, nausea, vomiting, headache, flushing, dizziness, myalgia, back pain, visual disturbances and nasal congestion.	New	BNF-63 Page 538 USFDA	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।
	.	i) Vitamin A (as Acetate) 1250 IU + Vitamin C 75 mg + L-Arginine 10 mg + L-Carnitine Tartarate 50 mg + Vitamin E Acetate 12.5 mg + Ginseng Extract 10 mg + Elemental Iron 5mg + Methylcobalamin 750 mcg+ Elemental Zinc 7.5 mg + Co- Enzyme Q-10 2.5 mg + Elemental Copper 1 mg + Lycopene 2 mg + Elemental Manganese 2 mg + Folic acid 1.5 mg + Elemental Selenium 100 mcg + Pyridoxine Hydrochloride 5 mg + Thiamine Mononitrate 12.5 mcg + Glutathione 2.5 mg Tablet	For positive outcome in treatment of male infertility. It provides a unique combination of essential micronutrients and vitamins, to help support male fertility. It provides carefully balanced micronutrients and vitamins. Lycopene improves sperm concentration and motility. L-Carnitine plays important role in the formation of sperm. Glutathione shows positive effect on sperm morphology. Antioxidant helps to reduce oxidative stress. It helps to prevent spermatozoa from oxidative damage, Improve sperm maturation, Improve sperm motility and quality, Enhance chances of pregnancy	**Contraindication:** No evidence of drug interactions with multiple micronutrients was observed during the course of clinical studies. **Side effects:** Some men experience nausea, headaches, fatigue, irregular periods and diarrhea.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Pharma Ltd	Vitamin A Acetate (Dry Vitamin A Acetate 500) USP 0.430 mg Eq. to 1250mg Vitamin A + Sodium Asorbate BP (Vitamin C) 84.0 mg eq. to 75 mg Vitamin C + Levocarnitine (Carnitine Tartarate) USP 50 mg + DL-alpha-Tocopherol Acetate (Tocopherol Acetate 50% dry powder) BP 12.5mg + Arginine (L-Arginine) BP 10 mg + Zinc sulphate Monohydrate (as Zinc) USP 20.25 eq. to 7.5 mg Zinc + Ginseng (Gineseng Extract) BP 10mg + Thiamine Monoitrate USP 5 mg + Pyrdoxine HCl BP 5.00 mg + Dried Ferrous Sulphate (as Iron) BP 13.60 Eq. to 5 mg Iron + Ubidecarenone (Co-Enzyme Q10) USP 2.5mg + Glutathionine BP 2.5mg + Manganese Sulphate (as Manganese) BP 6.16mg eq. to 2 mg Manganese + Lycopene USP 2 mg + Folic Acid BP 1.5mg + Anhudrous Copper Sulphate (as copper) BP 2.51mg eq. to 1.0 mg Copper + Methylcobalamin INN 0.75 mg + Sodium Selenite (as Selenium) BP 0.239 eq. to 0.1 mg Selenium **Multivitamin - Minerals**						

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
17.	Orion Infusion Ltd.	a) AMINO ACIDS (5%), SORBITOL + VITAMINS + ELECTROLYTES IV INFUSION **[Amino-acids:** L-Alanine USP 0.60gm + L-Arginine USP 0.620gm + L-Histidine USP 0.10gm + L-Isoleucine USP 0.320gm + L-Leucine USP 0.240gm+ L-Lysine (as L-Lysine HCl) USP 0.20 gm+ L-Methionine USP 0.30gm +L-Phenylalanine USP 0.40gm + L-Proline USP 0.20 gm + L-Threonine USP 0.20 gm + L-Tryptophan USP 0.10gm + L-Valine USP 0.320 gm + Glycine (Amioaceic acid) USP 1.40gm **Vitamins:** Ascorbic Acid BP 40.0 mg + Inositol BP 50.0 mg + Nicotinamide BP 6.0 mg + Pyridoxine HCl BP 4.0 mg + Riboflavin sodium phosphate BP 0.25 mg **Electrolytes:** Sodium Acetae, $3H_2O$ BP 0.476gm + Potassium Chloride BP 0.186gm + Magnesium Chloride, $6H_2O$ BP 0.051gm + Maleic Acid BP 0.130gm **Sorbitol:** D-sorbitol BP 10.000g]/100 ml	Recommended for provision of amino acids and energy in patients who require intravenous nutrition. Such conditions include surgery, infections, trauma, burns, prolonged disorders of the gastrointestinal tract, protein deficiency, preparation of patients for surgery, chemotherapy or radiation therapy, prolonged coma or refusal to eat.	**Contraindications:** Hypersensitivity to any ingredient of the preparation. Hereditary frucotose intolerance, hepaticcoma, azotemia, congestive cardiac failure, sever acidosis and disturbances. **Side effect s:** Hypersensitivity, chest discomfort and palpitations any occur.	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Infusion Ltd.	b) ESSENTIAL AMINO ACIDS (8.14%) + D-SORBITOL + ELECTROLYTES IV INFUSION **[Amino-acids:** [L-Arginine (as L-Arginine HCl) USP 0.660g + L-Histidine (as L-Histidine HCl,H_2O) BP 0.300g + L-Isoleucine USP 0.550g + L-Leucine USP 1.230g + L-Lysine (as L-Lysine HCl) USP 1.490g + L-Methionine USP 0.710g + L-Phenylalanine USP 0.870g + L-Threonine USP 0.540g + L-Tryptophan USP 0.180g + L-Valine USP 0.610g + Glycine (Aminoacetic acid) USP 1.000g **Electrolytes:** Sodium Chloride BP 0.070 gm, **Carbohydrate:** D-Sorbito BP 5.0 gm]/100 ml	Recommended for provision of amino acids and energy in patients who require intravenous nutrition. Such conditions include surgery, infections, trauma, burns, prolonged disorders of the gastrointestinal tract, hypoproteinemia, malnutrition, preparation of patients for surgery, chemotherapy or radiation therapy, prolonged coma or refusal to eat.	**Contraindications-** Hypersensitivity to any ingredient of the preparation. Hereditary frucotose intolerance, hepaticcoma, azotemia, congestive cardiac failure, sever acidosis and disturbances. **Side-effect:** Hypersensitivity, chest discomfort and palpitations any occur	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Orion Infusion Ltd.	c) 5% DEXTROSE + ELECTROLYTES IV INFUSION **[Electrolytes:** Calcium chloride $2H_20$ BP 0.022g + Potassium chloride BP 0.150g + Sodium chloride BP 0.216g + Sodium Acetate $3H_20$ BP 0.313g **Carbohydrate:** Dextrose anhydrous USP 5.000g + Hydrochloric Acid (2.5M) q.s]/100ml	As maintenance solution for children with hyponatremic and hypokalemic dehydration due to severe diarrhoea etc. For adults whose oral intake of water and electrolytes is insufficient due to various conditions	**Contraindication-** patients with hyperkalemia, elevented blood glucose concentrations. **Side effect-** Hyperglycemia, Fluid overload, hyperkalemia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
18.	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	a) Dasatinib 100 mg Tablet Dasatinib Monohydrate INN 103.69 mg eq. to. Dasatinib 100 mg **Anti Cancer**	1. Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. 2. Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. 3. Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.	**Contraindication:** None **Side effects:** Most common adverse reactions (≥10%) in patients with newly diagnosed chronic phase CML included myelosuppression, fluid retention, diarrhea, headache, musculoskeletal pain, and rash. Most common adverse reactions (≥20%) in patients with resistance or intolerance to prior imatinib therapy included myelosuppression, fluid retention events, diarrhea, headache, dyspnea, skin rash, fatigue, nausea, and hemorrhage.	New	USFDA BNF-62 Page No-556	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	b) Dasatinib 140 mg Tablet Dasatinib Monohydrate INN 145.166 mg eq. to. Dasatinib 140 mg **Anti Cancer**	1. Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. 2. Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. 3. Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.	**Contraindication:** None **Side effects:** Most common adverse reactions (≥10%) in patients with newly diagnosed chronic phase CML included myelosuppression, fluid retention, diarrhea, headache, musculoskeletal pain, and rash. Most common adverse reactions (≥20%) in patients with resistance or intolerance to prior imatinib therapy included myelosuppression, fluid retention events, diarrhea, headache, dyspnea, skin rash, fatigue, nausea, and hemorrhage.	New	USFDA BNF-62 Page No-556	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Exemestane 25 mg Tablet Exemestane INN 25 mg **Anti Cancer**	1. Adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer who have received two to three years of tamoxifen 2. The treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.	**Contraindications :** 1. Patients with a known hypersensitivity to the drug or to any of the excipients. 2. Women of premenopausal endocrine status, including pregnant women. **Side effects:** 1. CYP 3A4 inhibitors: Significant pharmacokinetic interactions appear unlikely. 2. CYP3A4 inducers: Caution, may significantly decrease exposure to exemestane	New	USFDA BNF-62 Page-582	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	d) Gefitinib 250 mg Tablet Gefitinib INN 250 mg **Anti Cancer**	Gefitinib is indicated as monotherapy for the continued treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies who are benefiting or have benefited from Gefitinib. In light of positive survival data with other agents including another oral EGFR inhibitor, physicians should use other treatment options in advanced non-small cell lung cancer patient populations who have received one or two prior chemotherapy regimens and are refractory or intolerant to their most recent regimen.	**Contraindications** : Gefitinib is contraindicated in patients with severe hypersensitivity to gefitinib or to any other component of Gefitinib **Side effects:** The safety database includes 941 patients from clinical trials and approximately 23,000 patients in the Expanded Access Program. Drug-related adverse events with an incidence of >5% for the 216 patients who received either 250 mg or 500 mg of IRESSA monotherapy for treatment of NSCLC. The most common adverse events reported at the recommended 250 mg daily dose were diarrhea, rash, acne, dry skin, nausea, and vomiting.	New	USFDA, BNF-62 Page-557	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।
		e) Denosumab 70mg /ml Vial Injection Denosumab INN 70 mg/ml Vial **Anti Cancer**	Prevention of skeletal-related events in patients with bone metastases from solid tumors.	**Contraindications:** Clinically significant hypersensitivity to any component of the product **Side effects:** The most common adverse reactions in patients receiving Denosumab (per patient incidence greater than or equal to 25%) were fatigue/asthenia, hypophosphatemia and nausea.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	f) Pertuzumab 420 mg/14ml Vial Injection Pertuzumab INN 420 mg/14ml Vial **Anti Cancer**	HER2/neu receptor antagonist indicated in combination with tastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	**Contraindication:** None **Side effects:** The most common adverse reactions (> 30%) with Pertuzumab in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy.	New	USFDA	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।
		g) Cetuximab 100 mg/ Vial Injection Cetuximab INN 100 mg/Vial **Anti Cancer**	1. Head and Neck Cancer 2. Colorectal Cancer	**Contraindication:** None. **Side effects:** The most common adverse reactions (incidence ≥25%) are: cutaneous adverse reactions (including rash, pruritus, and nail changes), headache, diarrhea, and infection.	New	USFDA	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।
		h) Cetuximab 5 mg/ml Vial Injection Cetuximab INN 5 mg/ml Vial **Anti Cancer**	1. Head and Neck Cancer 2. Colorectal Cancer	**Contraindication:** None. **Side effect:** The most common adverse reactions (incidence ≥25%) are: cutaneous adverse reactions (including rash, pruritus, and nail changes), headache, diarrhea, and infection.	New	USFDA BNF-62 Page-549	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।
		i) Etoposide 50mg Capsule Etoposide USP 50mg **Anti Cancer**	1.Bladder Cancer 2.Brain Tumours 3.Cervical cancer 4.Ependyoma 5.Germ cell tumour 6.Gestational trophoblastic neoplasia 7.Head and neck cancer 8.Ovarian cancer 9.Prostate cancer	**Contraindication:** In patients who have a history of hypersensitivity reactions to etoposide. **Side effects**: Hypersensitivity reaction during or immediately after IV administration (1-3%) cogestive heart failure hypotension with rapid IV administration (1-2%) myocardial infarction, fatigue fever.	100 mg/5ml Injection	USFDA BNF-62 Page-545	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	j) Etoposide 100mg Capsule Etoposide USP 100mg **Anti Cancer**	1.Bladder Cancer 2.Brain Tumours 3.Cervical cancer 4.Ependyoma 5.Germ cell tumour 6.Gestational trophoblastic neoplasia 7.Head and neck cancer 8.Ovarian cancer 9.Prostate cancer	**Contraindication:** In patients who have a history of hypersensitivity reactions to etoposide **Side effects**: Hypersensitivity reaction during or immediately after IV administration (1-3%) cogestive heart failure Hypotension with rapid IV Administration (1-2%) Myocardial infarction, fatigue fever.	100 mg/5ml Injection	USFDA BNF-62 Page-545	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		k) Temozolomide 20 mg Capsule Temozolomide USP 20 mg **Anti Cancer**	1. Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment. 2. Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.	**Contraindication:** Known hypersensitivity to any Temozolomide component or to dacarbazine (DTIC). **Side effect:** The most common adverse reactions (≥10% incidence) are alopecia, fatigue, nausea, vomiting, headache, constipation, anorexia, convulsions, rash, hemiparesis, diarrhea, asthenia, fever, dizziness, coordination abnormal, viral infection, amnesia, and insomnia. The most common Grade 3 to 4 hematologic laboratory abnormalities (≥10% incidence) that have developed during treatment with temozolomide are: lymphopenia, thrombocytopenia, neutropenia, and leukopenia. Allergic reactions have also been reported.	100 mg & 250 mg Capsule	USFDA BNF-62 Page-550	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	l) Doxapram Hydrochloride 20 mg/ml ampoule Solution for Injection Doxapram Hydrochloride USP 20 mg/ml	1) When the possibility of airway obstruction and/or hypoxia have been eliminated, doxapram may be used to stimulate respiration in patients with drug-induced post anesthesia respiratory depression or apnea other than that due to muscle relaxant drugs. 2) To pharmacologically stimulate deep breathing in the postoperative patient	**Contraindications:** Doxapram is contraindicated in patients with known hypersensitivity to the drug or any of the injection components. It should not be used in patients with epilepsy or other convulsive disorders.It is contraindicated in patients with proven or suspected pulmonary embolism. It is contraindicated in patients with mechanical disorders of ventilation such as mechanical obstruction, muscle paresis (including neuromuscular blockade), flail chest, pneumothorax, acute bronchial asthma, pulmonary fibrosis, or other conditions resulting in restriction of the chest wall, muscles of respiration, or alveolar expansion. **Side effects:** Central and Autonomic Nervous Systems Pyrexia, flushing, sweating; pruritus and paresthesia, such as a feeling of warmth, burning, or hot sensation, especially in the area of genitalia and perineum; apprehension, disorientation, pupillary dilatation, hallucinations, headache, dizziness, hyperactivity, involuntary movements, muscle spasticity, muscle fasciculations, increased deep tendon reflexes, clonus, bilateral Babinski, and convulsions.	New	USFDA BNF-61 Page-200	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		m) Axitinib 5 mg Tablet Axitinib INN 5 mg **Anti Cancer**	Axitinib is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.	**Contraindications**: None **Side effects:** The most common (≥20%) adverse reactions are diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, palmar-plantar erythrodysesthesia (hand-foot) syndrome, weight decreased, vomiting, asthenia, and constipation.	New	USFDA	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	n) Levocetirizine 5 mg + Montelukast Sodium 10 mg Tablet Levocetirizine USP 5 mg + Montelukast Sodium USP 10 mg **Antihistamine + Antiasthmatic**	Indicated for relief of symptoms of allergic rhinitis (seasonal and perennial), as prophylaxis in seasonal allergic rhinitis and treatment of comorbid asthma & allergic rhinitis in patients 15 years of age and older.	**Contraindications:** Contraindicated in patients with known hypersensitivity to Montelukast, levocetirizine, to other piperazine derivatives, or to any of the excipients. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Aso contradicted in patients with severe renal impairment at less than 10 ml/min creatinine clearance **Side effects:** Not given	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		o) Aprepitant 80 mg Capsule Aprepitant INN 80 mg	Aprepitant is a substance P/neurokinin 1 (NK1) receptor antagonist, indicated: in combination with other antiemetic agents for the: 1. Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin. 2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.	**Contraindications:** Hypersensitivity to any component of this medication. Aprepitant should not be used concurrently with pimozide, terfenadine, astemizole, or cisapride, since inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions. **Side effects:** Clinical adverse experiences for the CINV regimen in conjunction with highly and moderately emetogenic chemotherapy (incidence >10%) are: alopecia, anorexia, asthenia/fatigue, constipation, diarrhea, headache, hiccups, and nausea. Clinical adverse experiences for the PONV regimen (incidence >5%) are: constipation, hypotension, nausea, pruritus, pyrexia.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	p) Everolimus 0.5 mg Tablet Everolimus INN 0.5 mg **Anti Cancer**	Everolimus is an mTOR inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant. Use in combination with basiliximab and concurrently with reduced doses of cyclosporine and corticosteroids.	**Contraindications:** Patients with known hypersensitivity to everolimus, sirolimus, or to components of the drug product **Side effects:** The most common (incidence ≥20%) adverse events are: peripheral edema, constipation, hypertension, nausea, anemia, urinary tract infections and hyperlipidemia.	5mg and 10mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		q) Etizolam 0.5 mg Tablet Etizolam INN 0.5 mg **Anxiolytic agent**	Anxiety, tension, depression, neurasthenic symptoms or sleep disorders in neurosis. Cervical vertebral disease, low back pain and tension headache.	**Contraindications**: Benzodiazepines require special precaution if used in the elderly, during pregnancy, in children, alcohol or drug-dependent individuals and individuals with comorbid psychiatric disorders. **Side effects:** Nausea, stomach upset, skin rash, acute toxicity.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		r) Carboprost Tromethamine 250mcg/ml Injection Carboprost Tromethamine USP 250 mcg/ml	It is indicated for the treatment of postpartum hemorrhage due to uterine atony which has not responded to conventional methods of management. Prior treatment should include the use of intravenously administered oxytocin, manipulative techniques such as uterine massage and, unless contraindicated, intramuscular ergot preparations. Studies have shown that in such cases, the use of Carboprost tromethamine has resulted in satisfactory control of hemorrhage, although it is unclear whether or not ongoing or delayed effects of previously administered ecbolic agents have contributed to the outcome.	**Contraindications**: Hypersensitivity to Carboprost tromethamine Sterile Solution 1. Acute pelvic inflammatory disease 2. Patients with active cardiac, pulmonary, renal or hepatic disease **Side effects:** The adverse effects of carboprost tromethamine Sterile Solution are generally transient and reversible when therapy ends. The most frequent adverse reactions observed are related to its contractile effect on smooth muscle.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	s) Carbetocin 100 mcg/ml Ampoule Carbetocin INN 100 mcg/ml	Prevention of uterine atony after caesarean section.	**Contraindications**: Pre-eclampsia and eclampsia; epilepsy **Side effects:** Nausea, vomiting, abdominal pain, metallic taste; flushing, hypotension, chest pain; dyspnoea; headache, tremor, dizziness; anemia; back pain; pruritus; feeling of warmth, chills; tachycardiaand sweating .	New	BNF-61 Page No-486	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।
		t) Megestrol Acetate 40 mg Tablet Megestrol Acetate BP 40 mg **Appetite stimulant**	Megestrol Acetate is indicated for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of acquired immunodeficiency syndrome.	**Contraindications:** History of hypersensitivity to megestrol acetate or any component of the formulation. Known or suspected pregnancy. **Side effects:** Diarrhea, impotence, rash, flatulence, hypertension, asthenia, insomnia, nausea, anemia, fever, Libido Decreased, dyspepsia, hyperglycemia, headache, Pain, vomiting, pneumonia, urinary frequency.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		u) Iloperidone 2 mg Tablet Iloperidone INN 2 mg **Antipsychotic Drug**	Iloperidone is an atypical antipsychotic agent indicated for the treatment of schizophrenia in adults.	**Contraindications:** Known hypersensitivity to Iloperidone or to any components in the formulation. **Side effects:** Commonly observed adverse reactions (incidence ≥5% and two-fold greater than placebo) were: dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	v) Iloperidone 6 mg Tablet Iloperidone INN 6 mg **Antipsychotic Drug**	Iloperidone is an atypical antipsychotic agent indicated for the treatment of schizophrenia in adults.	**Contraindications:** Known hypersensitivity to Iloperidone or to any components in the formulation. **Side effects:** Commonly observed adverse reactions (incidence ≥5% and two-fold greater than placebo) were: dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		w) Methylprednisolone 40 mg/5ml Vial Injection Methylprednisolone Sodium Succinate USP 53.00 mg eq. to Methylprednisolone 40mg/5ml Vial **Antiasthmatic**	Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions.	**Contraindications**: Patients with known hypersensitivity to the product and its constituents. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura. In premature infants because the formulation contains benzyl alcohol. **Side effects**: Allergic reactions: Allergic or hypersensitivity reactions, anaphylactoid reaction, anaphylaxis, angioedema. Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction.	125 mg/Vial 500 mg/Vial 1 gm/Vial	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		x) Crizotinib 200 mg Capsule Crizotinib INN 200 mg **Anti Cancer**	Crizotinib is a kinase inhibitor, indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA –approved test.	**Contraindications:** None **Side effect:** The most common adverse reactions (≥25%) are vision disorder, nausea, diarrhea, vomiting, edema, and constipation.	New	USFDA	**অনুমোদন করা যেতে পারে।**	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	y) Crizotinib 250 mg Capsule Crizotinib INN 250 mg **Anti Cancer**	Crizotinib is a kinase inhibitor, indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA –approved test.	**Contraindications:** None **Side effect:** The most common adverse reactions (≥25%) are vision disorder, nausea, diarrhea, vomiting, edema, and constipation.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		z) Bortezomib 3.50mg/Vial Injection Bortezomib INN 3.5 mg/ Vial **Anti Cancer**	Bortezomib is a proteasome inhibitor indicated for: 1.Treatment of patients with multiple myeloma 2. Treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy.	**Contraindications:** 1. Patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions. 2. Contraindicated for intrathecal administration. **Side-effects:** Most commonly reported adverse reactions (incidence ≥ 20%) in clinical studies include nausea, diarrhea, thrombocytopenia, neutropenia, peripheral neuropathy, fatigue, neuralgia, anaemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		aa) Rufinamide 200 mg Tablet Rufinamide INN 200 mg **Anticonvulsant**	Rufinamide is an anti-epileptic drug indicated for: Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults.	**Contraindications:** Rufinamide is contraindicated in patients with Familial Short QT syndrome. **Side effects:** In all patients with epilepsy treated with Rufinamide in double-blind, adjunctive therapy studies, the most commonly observed adverse reactions (≥ 10% and greater than placebo) were headache, dizziness, fatigue, somnolence, and nausea.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	ab) Rufinamide 400 mg Tablet Rufinamide INN 400 mg **Anticonvulsant**	Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults	**Contraindications:** Rufinamide is contraindicated in patients with Familial Short QT syndrome. **Side effects:** In all patients with epilepsy treated with Rufinamide in double-blind, adjunctive therapy studies, the most commonly observed adverse reactions (≥ 10% and greater than placebo) were headache, dizziness, fatigue, somnolence, and nausea.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		ac) Erdosteine 300 mg Capsule Erdosteine BP 300 mg **Mucolytic agent**	Symptomatic treatment of acute exacerbations of chronic bronchitis	**Contraindication:** Mucolytics are prescribed to facilitate expectoration by reducing sputum viscosity. In some patients with chronic obstructive pulmonary disease and a chronic productive cough, mucolytics can reduce exacerbations; mucolytic therapy should be stopped if there is no benefit after a 4-week trial. Steam inhalation with postural drainage is effective in bronchiectasis and in some cases of chronic bronchitis. Mucolytics should be used with caution in those with a history of peptic ulceration because they may disrupt the gastric mucosal barrier. **Side effects:** Very rarely nausea, vomiting, diarrhoea, abdominal pain, taste disturbance, headache, rash, and urticaria	New	BNF-61 Page No-203	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	ad) Fludarabine Phosphate 10 mg Tablet Fludarabine Phosphate USP 10 mg **Anti Cancer**	It is a nucleotide metabolic inhibitor indicated as a single agent for the treatment of adult patients with B-cell chronic lymphocytic leukemia (CLL) whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating-agent containing regimen. Studies demonstrating clinical benefit such as prolongation of survival or relief of symptoms have not been performed.	**Contraindication:** None **Side effect:** Most common adverse reactions (incidence > 30%) include myelosuppression (neutropenia, thrombocytopenia and anemia). Fever, weakness, infection, pain, cough and anorexia were also reported as common adverse reactions.	New	USFDA BNF-62 Page No-543	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		ae) Paracetamol 500 mg + Diphenhydramine Hydrochloride 25mg Tablet Paracetamol BP 500 mg + Diphenhydramine HCl BP 25 mg **Anagesic + Antihistamine**	Short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, neuralgia, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.	**Contraindications**: This drug should not be used in neonates or premature infants. Because of the higher risk of antihistamines for infants generally, and for neonates and prematures in particular, antihistamine therapy is contraindicated in nursing mothers. **Side effects:** The following are some of the side effects that are known Drowsiness Blurred vision. Disturbances of the gut such as constipation, nausea, vomiting or abdominal pain. Dry mouth, nose and throat Skin rash. Difficulty in passing urine (urinary retention)	New	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh.	af) Eltrombopag 50 mg Tablet Eltrombopag Olamine INN 63.80 mg eq. to. Eltrombopag 50 mg **Hematopoietic Drug**	Eltrombopag is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Eltrombopag is indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.	**Contraindications:** None **Side effects:** The most common adverse reactions in ITP patients (≥3% and greater than placebo) are: nausea, diarrhea, upper respiratory tract infection, vomiting, increased ALT, myalgia, urinary tract infection, oropharyngeal pain, increased AST, pharyngitis, back pain, influenza, paresthesia, and rash.	New	USFDA BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		ag) Doxorubicin HCl 20mg/10ml Vial Liposomal Injection Doxorubicin HCl USP 20mg/10ml Vial **Anti Cancer**	**Ovarian cancer** After failure of platinum-based chemotherapy. **AIDS-related Kaposi's Sarcoma** After failure of prior systemic chemotherapy or intolerance to such therapy. **Multiple Myeloma** In combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy.	**Contraindications:** Hypersensitivity reactions to a conventional formulation of doxorubicin HCl or the components of Doxorubicin HCl. **Side effects:** Most common adverse reactions (>20%) are asthenia, fatigue,fever, anorexia, nausea, vomiting, stomatitis, diarrhea, constipation, hand and foot syndrome, rash, neutropenia, thrombocytopenia and anemia.	10mg/Vial & 50mg/vial	USFDA BNF-62 Page No-537	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh.	ah) Doxorubicin HCl 50mg/25ml Vial Liposomal Injection Doxorubicin HCl USP 50mg/25 ml Vial **Anti Cancer**	**Ovarian cancer** After failure of platinum-based chemotherapy. **AIDS-related Kaposi's Sarcoma** After failure of prior systemic chemotherapy or intolerance to such therapy. **Multiple Myeloma** In combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy.	**Contraindications:** Hypersensitivity reactions to a conventional formulation of doxorubicin HCl or the components of Doxorubicin HCl. **Side effects:** Most common adverse reactions (>20%) are asthenia, fatigue, fever, anorexia, nausea, vomiting, stomatitis, diarrhea, constipation, hand and foot syndrome, rash, neutropenia, thrombocytopenia and anemia.	10mg/Vial & 50mg/vial	USFDA BNF-62 Page No-537	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		ai) Omalizumab 150mg/Vial Lyophilized Powder for Injection Omalizumab INN 150mg/Vial **Antiasmathic Drug (Monoclonal antibody)**	It is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.	**Contraindications:** Omalizumab should not be administered to patients who have experienced a severe hypersensitivity reaction to Omalizumab. **Side effects:** The most serious adverse reactions are anaphylaxis and malignancies.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		aj) Milnacipran HCl 12.5 mg Tablet Milnacipran HCl INN 12.5 mg **Anti-Depressant**	Milnacipran is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the management of fibromyalgia. Milnacipran is not approved for use in pediatric patients	**Contraindications:** Use of monoamine oxidase inhibitors concomitantly or in close temporal proximity. Use in patients with uncontrolled narrow-angle glaucoma. **Side effects:** The most frequently occurring adverse reactions are nausea, headache, constipation, dizziness, insomnia, hot flush, hyperhidrosis, vomiting, palpitations, heart rate increased, dry mouth, and hypertension.	50mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh.	ak) Peginesatide Acetate 1mg/0.5ml Pre filled Syringe Injection Peginesatide Acetate INN 1mg/0.5ml **Hematopoietic**	Peginesatide Acetate is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis.	**Contraindication:** Uncontrolled hypertension, Serious allergic reactions to Peginesatide. **Side-effect:** The most common adverse events (≥ 10%) are dyspnea, diarrhea, nausea, cough, and arteriovenous fistula site complication.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		al) Bendamustine HCl 25 mg/Vial Lyophilized Powder for Injection. Bendamustine HCl INN 25 mg/Vial **Anti Cancer**	Bendamustine Hydrochloride for Injection is an alkylating drug indicated for treatment of patients with: Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established. Indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab containing regimen.	**Contraindications:** Known hypersensitivity to bendamustine or mannitol. **Side effects:** Most common non-hematologic adverse reactions for Chronic lymphocytic leukemia (frequency ≥15%) are pyrexia, nausea, and vomiting. Most common non-hematologic adverse reactions for non-Hodgkin's lymphoma (frequency ≥15%) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash, and stomatitis.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh.	am) Bendamustine HCl 100mg/Vial Lyophilized Powder for Injection. Bendamustine HCl INN 100 mg/Vial **Anti Cancer**	Bendamustine Hydrochloride for Injection is an alkylating drug indicated for treatment of patients with: Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established. Indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximabcontaining regimen.	**Contraindications:** Known hypersensitivity to bendamustine or mannitol. **Side effects:** Most common non-hematologic adverse reactions for CLL (frequency ≥15%) are pyrexia, nausea, and vomiting. Most common non-hematologic adverse reactions for non-Hodgkin's lymphoma (frequency ≥15%) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash and stomatitis.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		an) Norepinephrine Bitartrate USP 4mg/2ml Ampoule IV Injection Norepinephrine Bitartrate USP 4mg/2ml **Vasoconstrictor sympathomimetics**	For blood pressure control in certain acute hypotensive states (e.g., pheochromocytomectomy,sympathectomy, poliomyelitis, spinal anesthesia, myocardial infarction, septicemia, blood transfusion and drug reactions). As an adjunct in the treatment of cardiac arrest and profound hypotension.	**Contraindication:** Norepinephrine Bitartrate should not be given to patients who are hypotensive from blood volume deficits except as an emergency measure to maintain coronary and cerebral artery perfusion until blood volume replacement therapy can be completed. **Side-effect:** **Body As A Whole**: Ischemic injury due to potent vasoconstrictor action and tissue hypoxia. **Cardiovascular System**: Bradycardia, probably as a reflex result of a rise in blood pressure, arrhythmias. **Nervous System**: Anxiety, transient headache. **Respiratory System**: Respiratory difficulty. **Skin and Appendages**: Extravasation necrosis at injection site.	New	BNF-61 Page No-138	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
19.	Popular Pharmaceuticals Limited	a) Sulindac 150mg Tablet Sulindac BP 150mg **Non streroidal anti-inflammatory drugs**	It is indicated for acute or long-term use in the relief of signs and symptoms of the following: 1. Osteoarthritis 2. Rheumatoid arthritis 3. Ankylosing spondylitis 4. Acute painful shoulder 5. Acute gouty arthritis.	**Contraindications:** Patients known to be allergic to sulindac and those in whom acute asthmatic attacks, urticaria or thinitis have been precipitated by Aspirin or other non-steroidal anti-inflammatory agentsl Sulindac is also contraindicated in patients with a history of active gastro-intestinal bleeding or peptic ulceration. It should not be given to children, pregnant or lactating women. **Side effects:** The most frequent types of adverse reactions occurring with sulindac are gastrointestinal; these include gastrointestinal pain (10%), dyspepsia, and nausea with or without vomiting, diarrhea, constipation, flatulence, anorexia and gastrointestinal cramps. Dermatologic: Rash, pruritus. CNS: Dizziness, headache, nervousness.	100 mg & 200 mg Tablet	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	b) Methotrexate 5mg Tablet Methotrexate USP 5.682 mg eq. to Anhydrous Methotrexate 5mg **Anti-Arthritis**	Methotrexate is used as maintenance therapy for childhood acute lymphoblastic leukaemia. Other uses include choriocarcinoma, and a number of solid tumours. It is used alone or in combination with other anticancer agents in the treatment of breast cancer, epidermoid cancers of the head and neck, advanced mycosis fungoides, and lung cancer, particularly squamous cell and small cell types. Methotrexate is also used in combination with other chemotherapeutic agents in the treatment of advanced stage non-Hodgkin's lymphomas. Methotrexate can be used for Crohn's disease and severe psoriasis. Also used in moderate to severe active rheumatoid arthritis.	**Contraindications**: Hepatic impairment and renal impairment. Methotrexate is contraindicated in pregnant women with psoriasis or rheumatoid arthritis and should be used in the treatment of neoplastic diseases only when the potential benefit outweighs the risk to the fetus. Women of child bearing potential should not be started on methotrexate until pregnancy is excluded and should be fully counseled on the serious risk to the fetus should they become pregnant while undergoing treatment. Because of the potential for serious adverse reactions from methotrexate in breast fed infants, it is contraindicated in nursing mothers. Patients with psoriasis or rheumatoid arthritis with alcoholism, alcoholic liver disease or other chronic liver disease should not receive methotrexate. Patients with psoriasis or rheumatoid arthritis who have overt or laboratory evidence of immunodeficiency syndromes should not receive methotrexate. Patients with psoriasis or rheumatoid arthritis who have preexisting blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia or significant anemia, should not receive methotrexate. Patients with a known hypersensitivity to methotrexate should not receive the drug. **Side effects:** The most frequently reported adverse reactions include ulcerative stomatitis, leukopenia, nausea, and abdominal distress. Other frequently reported adverse effects are malaise, undue fatigue, chills and fever, dizziness	2.5 mg & 10 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited			and decreased resistance to infection. Other adverse reactions are gingivitis, pharyngitis, stomatitis, anorexia, nausea, vomiting, diarrhea, hematemesis, melena, gastrointestinal ulceration and bleeding, enteritis, pancreatitis. Suppressed hematopoiesis causing anemia, aplastic anemia, leukopenia and/or thrombocytopenia. Hypogammaglobulinemia has been reported rarelyPericarditis, pericarial effusion, hypotension, and thromboembolic events. Headaches, drowsiness, blured vision. Aphasia, hemiparesis, paresis and convulsions have also occurred following administration of methotrexate. Following low doses, there have been occasional reports of transient subtle cognitive dysfunction, mood alteration, unusual cranial sensations, leukoencephalopathy, or encephalopathy.There has been case reports of sometimes non-neoplastic diseases. H. simplex, conjenctiovitis, interstitial pneumonitis deaths have been reported, and chronic interstitial obstructive pulmonary disease occasionally occurred, erythematous rashes, pruritus, urticaria, photosensitivity, pigmentary changes, alopecia, ecchymosis, telangiectgasia, acne, furunculosis, erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, skin necrosis, and exfoliative dermatitis, severe nephropathy or renal failure, azotemia, cystitis, hematuria: defective oogenesis or spermatogenesis, transient oligospermia, menstrual dysfunction, vaginal discharge and gynecomestia; infertility, abortion, fetal defects.				

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	c) Pitavastatin 4mg Tablet Pitavastatin Calcium INN 4.192mg eq. to Pitavastatin 4mg **Cholesterol Lowering Drugs**	Patients with primary hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C)	**Contraindications:** Pitavastatin is contraindicated in patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions including rash, pruritus, and urticaria have been reported with pitavastatin. Pitavastatin is contraindicated in patients with active liver disease which may include unexplained persistent elevations of hepatic transaminase levels. **Side effects:** The most frequent adverse reactions (rate ≥2.0% in at least one marketed dose) are myalgia, back pain, diarrhea, constipation and pain in extremity.	2 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		d) Pitavastatin 1mg Tablet Pitavastatin Calcium INN 1.048mg eq. to Pitavastatin 1mg **Cholesterol Lowering Drugs**	Patients with primary hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C)	**Contraindications:** Pitavastatin is contraindicated in patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions including rash, pruritus, and urticaria have been reported with pitavastatin. Pitavastatin is contraindicated in patients with active liver disease which may include unexplained persistent elevations of hepatic transaminase levels. **Side-effect:** The most frequent adverse reactions (rate ≥2.0% in at least one marketed dose) are myalgia, back pain, diarrhea, constipation and pain in extremity.	2 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	e) Rimexolone 1gm/100ml Ophthalmic Suspension Rimexolone (Micronised & Sterile) USP 1gm/100ml **Ophthalmic steroids**	Rimexolone Eye Drops is indicated for the treatment of postoperative inflammation following ocular surgery, for the treatment of anterior uveitis, and for the treatment of corticosteroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe. The inflammation should be of a non-infectious nature. In more serious cases, and if the posterior part of the globe is affected, subconjunctival injection or systemic treatment is recommended.	**Contraindications:** Hypersensitivity to the active substance or any of the excipients. Rimexolone Eye Drops is contraindicated in epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and most other viral diseases of cornea and conjunctiva; mycobacterial infection of the eye; fungal diseases of the eye; acute purulent untreated infections which, like other diseases caused by microorganisms may be masked or enhanced by the presence of the steroid; red eye, where the diagnosis is unconfirmed; and amoebic infections. **Side effects:** Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Ocular adverse reactions occurring in 1 - 5% of patients in clinical studies of Rimexolone 1% ophthalmic suspension included blurred vision, discharge, discomfort, ocular pain, increased intraocular pressure, foreign body sensation, hyperemia and pruritus. Other ocular adverse reactions occurring in less than 1% of patients included sticky sensation, increased fibrin, dry eye, conjunctival edema, corneal staining, keratitis, tearing, photophobia, edema, irritation, corneal ulcer, browache, lid margin crusting, corneal edema, infiltrate, and corneal erosion. Non-ocular adverse reactions occurred in less than 2% of patients.These included headache, hypotension, rhinitis, pharyngitis, and taste perversion.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	f) Zinc 10mg/10ml Injection Zinc Chloride BP 0.0209 gm eq. to Zinc 0.01gm/10ml **Mineral**	Zinc Chloride Injection is intended for use as an additive to compatible intravenous fluids or total parenteral nutrition solutions. It is indicated for the prevention and treatment of zinc deficiency, which may be characterised by growth deterioration, skin lesions, alopecia, impaired reproductive development and function, and delayed or inhibited wound healing.	**Contraindications:** Direct intramuscular (IM) or intravenous (IV) injection is contraindicated as the acidic pH of the injection may cause considerable tissue irritation. It is contraindicated in individuals hypersensitive to any of the ingredients in the preparation. **Side effects:** Direct IM or IV injection may cause considerable tissue irritation and is therefore not recommended. Chronic zinc toxicity in man has not been identified with certainty. Prolonged use of zinc chloride may lead to copper deficiency and anaemia which has reoponded to withdrawal of zinc and symptomatic therapy. Increased serum levels of amylase, lipase and alkaline phosphatase which may indicate pancreatic damage, are commonly reported during zinc therapy. However, insufficient evidence was found for pancreatic damage on either humans or rat studies.		USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	g) Dexmedetomidine 200mcg/2ml Injection Dexmedetomidine HCl INN 0.000236gm eq. to Dexmedetomidine 0.0002gm/2 ml **Sedative-hypnotic Drugs**	Dexmedetomidine HCl for Injection is indicated for: • **Intensive Care Unit Sedation** Dexmedetomidine HCl is indicated for sedation of initially intubated and mechanically ventilated postsurgical patients during treatment in an intensive care setting by continuous IV infusion. The Dexmedetomidine HCl infusion must not exceed 24 hours. Dexmedetomidine HCl has been continuously infused in mechanically ventilated patients prior to extubation, during extubation, and post-extubation. It is not necessary to discontinue. Dexmedetomidine HCl prior to extubation. After extubation, the dose of Dexmedetomidine hydrochloride should be reduced by half. The mean time of continued infusion is approximately 6.6 hours. • **Conscious Sedation:** Dexmedetomidine hydrochloride is indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures by continuous intravenous infusion for the following procedures:	**Contraindications:** None **Side effects:** The most common adverse reactions (incidence greater than 2%) are hypotension, bradycardia, and dry mouth. Adverse reactions associated with infusions greater than 24 hours in duration include ARDS, respiratory failure, and agitation.	New	USFDA	শুধুমাত্র হাসপাতালে সরবরাহ করতে হবে এ শর্তে অনুমোদন করা যেতে পারে।	শুধুমাত্র হাসপাতালে সরবরাহ করতে হবে এ শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দেশনা	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited		• Monitored Anesthesia Care (MAC) with an adequate nerve block and/or local infiltration; and • Awake Fiberoptic Intubation (AFI) with adequate topical preparation of the upper airway with local lidocaine formulations. Due to insufficient safety and efficacy data, Dexmedetomidine hydrochloride is not recommended for use in procedures other than the two listed above. • **Pediatrics:** There have been no clinical studies to establish the safety and efficacy of Dexmedetomidine hydrochloride in pediatric patients younger than 18 years of age. Therefore, Dexmedetomidine hydrochloride should not be used in this population.					
		h) Folic Acid 10mg/2ml Injection Folic Acid BP 10mg/2ml **Vitamin**	Folic acid injection is indicated for the treatment of megaloblastic anemia, where this has been shown to be due to folic acid deficiency either due to inadequate dietary intake, malabsorption or increased utilization, including pregnancy and lactation, hemolytic anemia, hyperthyroidism, exfoliative dermatitis and chronic infection. It is also indicated for prophylaxis during pregnancy and lactation.	**Contraindications:** Folic Acid Injection is contraindicated in patients who may be hypersensitive to it. Although rare, an anaphylactic reaction has been reported. Folic Acid Injection should not be prescribed for megaloblastic anemia due to vitamin B12 deficiency. **Side effects:** Folic Acid Injection appears to be well tolerated, however nausea, flatulence, diarrhoea, irritability and sleep disturbances have been reported uncommonly along with isolated reports of rash and bronchospasm. EEG changes and convulsion have been reported with intravenous therapy. Although rare, an anaphylactic reaction has been reported.	5 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	i) Thiamine 10 mg + Riboflavin 10 mg + Nicotinamide 50 mg + Pantothenic Acid 15 mg+ Pyridoxine HCl 3 mg + Folic Acid 1mg + Cyanocobalamin (1%) 0.015mg + Ascorbic Acid 150mg + Zinc 20mg Capsule Thiamine (Vitamin B1) BP 12.40mg eq. to Thiamine 10 mg + Riboflavin (Vitamin B2) BP 10mg + Nicotinamide BP 50 mg + Calcium Pantothenate BP 16.305mg eq. to Pantothenic Acid 15 mg + Pyridoxine Hydrochloride (Vitamin B6) BP 3mg + Folic Acid BP 1mg + Cyanocobalamin (1%) (Vitamin B12) BP 1.50mg eq. to Vitamin B12 0.015mg + Ascorbic Acid (Vitamin C) BP 150mg + Zinc Sulfate Monohydrate USP 54.90mg eq. to Zinc 20mg **Multivitamin + Mineral**	Vitamin B Complex with Vitamin C and Zinc is indicated for supportive nutritional supplementation in conditions in which the vitamin Bcomplex and vitamin C are requuired prcphylactically and therapeutically. Vitamin deficiencies may be associated with restricted diets, improper food intake, decreased absorption and prolonged stress, infections or chronic fevers, following burns and trauma. Vitamin supplements may be necessary for those on unusual diets, on reducing diets with drastically reduced food selection and also for those with inadequate diets such as alcoholics, the elderly, those with diabetes mellitus, hepatobiliarytract disease, those recovering from surgery and in convalescence.	**Contraindications:** Vitamin B Complex with Vitamin C and Zinc is contraindicated in patients who are hypersensitive to any of the constituents. Adverse effects of zinc include abdominal pain and dyspepsia. Water soluble vitamins seldom cause toxicity in persons with normal renal function. **Side effects:** Adominal pain and dyspepsia. Water soluble vitamins seldom cause toxicity in persons with normal renal function.			প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	j) Pregabalin 50mg + Mecobalamin 0.5mg Capsule Pregabalin INN 50mg + Mecobalamin INN 0.5mg **Neuropathic Anagesic**	Neuropathic pain like, peripheral neuropathies, diabetic neuropathy, vertebral syndrome, nerve compression syndrome, fibromyalgia, post-herpetic neuralgia, post-surgical neuropathy etc.	**Contraindication:** Mecobalamin & Pregabalin are contraindicated in patients who have demonstrated hypersensitivity to these molecules or its ingredients. **Side effects:** Mecobalamin: Generally Mecobalamin is well tolerated. However, a few side effects like GI discomfort & rash may be seen aftger administration of Mecobalamin. Pregabalin**:** The most common adverse effects reported during therapy with pregabalin are dizziness and somnolence. Other common adverse effects include blurred vision, diplopia, increased appetite and weight gain, dry mouth, constipation, vomiting, flatulence, euphoria, confusion, reduced libido, erectile dysfunction, irritability, vertigo, ataxia, tremor, dysarthria, paraesthesia, fatigue, and oedema. Disturbances of attention, memory, coordination, and gait also occur frequently.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		k) Pregabalin 75mg + Mecobalamin 0.5mg Capsule Pregabalin INN 75mg + Mecobalamin INN 0.5mg **Neuropathic Anagesic**	Neuropathic pain like, peripheral neuropathies, diabetic neuropathy, vertebral syndrome, nerve compression syndrome, fibromyalgia, post-herpetic neuralgia, post-surgical neuropathy etc.	**Contraindication:** Mecobalamin & Pregabalin are contraindicated in patients who have demonstrated hypersensitivity to these molecules or its ingredients. **Side effects**: Mecobalamin**:** Generally Mecobalamin is well tolerated. However, a few side effects like GI discomfort & rash may be seen aftger administration of Mecobalamin. Pregabalin**:** The most common adverse effects reported during therapy with pregabalin are dizziness and somnolence. Other common adverse effects include blurred vision, diplopia, increased appetite and weight gain, dry mouth, constipation, vomiting, flatulence, euphoria, confusion, reduced libido, erectile dysfunction, irritability, vertigo, ataxia, tremor, dysarthria, paraesthesia, fatigue, and oedema. Disturbances of attention, memory, coordination, and gait also occur frequently.	new		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Popular Pharmaceuticals Limited	l) Rabeprazole Sodium 20mg/Vial Injection Rabeprazole Sodium INN 20mg/Vial **Antiulcerant- PPI**	It is indicated to 1. Sequential-therapy from oral rabeprazole, e.g. a patient previously on oral rabeprazole who is temporarily unable to take oral medication for any reason. 2. Active duodenal ulcer with bleeding or severe erosions. 3. Active gastric ulcer with bleeding or severe erosions. 4. Short-term treatment of erosive or ulcerative gastroesophageal reflux disease. 5. Prevention of acid-aspiration. 6. Stress-induced mucosal injury in critical care. 7. Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.	**Contraindication:** Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation. **Side effects**: Headache, abdominal pain, diarrhea, dry mouth, dizziness, peripheral edema, hepatic enzyme increase, hepatitis, hepatic encephalopathy, mayalgia, and arthralgia.			প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
20.	UniMed & UniHealth Manufacturers Ltd.	a) Acetylcysteine 100mg/Sachet Effervescent Granules Acetylcysteine BP 0.100g/Sachet **Mucolytic**	For the treatment of adjunctive therapy in respiratory conditions and to reduce the viscosity of non-infective secretions in patients with cystic fibrosis. It is also effective in the treatment of paracetamol overdosage	**Contraindication:** Active peptic ulcer, allergic reaction to acetylcysteine **Side effects:** Rare case of mild gastrointestinal disturbance such as pyrosis, nausea, vomiting diarrhea, as well as itching, urticaria, headache and fever have been reported. Hypersensitivity reaction affecting skin and respiratory organs may occur in some patients. Hydrogen sulfide, resulting from acetylcysteine metabolism, casuses bad breath.	100mg/ml and 200mg/ml Respirator Solution		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & UniHealth Manufacturers Ltd.	b) Acetylcysteine 200mg/Sachet Effervescent Granules Acetylcysteine BP 200 mg/Sachet **Mucolytic**	For the treatment of adjunctive therapy in respiratory conditions and to reduce the viscosity of non-infective secretions in patients with cystic fibrosis. It is also effective in the treatment of paracetamol overdosage	**Contraindication:** Active peptic ulcer, allergic reaction to acetylcysteine **Side effects:** Rare case of mild gastrointestinal disturbance such as pyrosis, nausea, vomiting diarrhea, as well as itching, urticaria, headache and fever have been reported. Hypersensitivity reaction affecting skin and respiratory organs may occur in some patients. Hydrogen sulfide, resulting from acetylcysteine metabolism, casuses bad breath.	100mg/ml and 200 mg/ml Respirator Solution		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Dipyridamole 200mg Modified-Release Capsule Dipyridamole USP 200 mg **Antiplatelet Drugs**	Prevention of atherothrombotic events in peripheral arterial disease, or within 35 days of myocardial infarction, or within 6 months of ischaemic stroke; prevention of artherothrombotic events in acute coronary syndrome without ST-segment elevation and in acute myocardial infarction with ST-segment elevation ; prevention of atherothrombotic and thromboembolic events in patients with atrial fibrillation and for whom warfarin is unsuitable.	**Contraindications:** Active bleeding **Side effects:** Gastro-intestinal effects, dizziness, myalgia, throbbing headache, hypotension, hot flushes and tachycardia; worsening symptoms of coronary heart disease; hypersensitivity reactions such as rash, urticaria, severe bronchospasm and angioedema; increased bleeding during or after surgery; thrombocytopenia reported		BNF-62 Page-154	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & UniHealth Manufacturers Ltd.	d) Silodosin 4mg Capsule Silodosin INN 4 mg **α1a-adrenoceptor antagonist**	Silodosin an alpha-1 adrenergic receptor antagonist is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Silodosin is not indicated for the treatment of hypertension.	**Contraindications:** Patients with Severe renal impairment (CCr < 30 mL/min), Severe hepatic impairment (Child-Pugh score > 10), Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) **Side effects:** Most common adverse reactions (incidence > 2%) are retrograde ejaculation, dizziness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, and nasal congestion.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Silodosin 8mg Capsule Silodosin INN 8 mg **α1a-adrenoceptor antagonist**	Silodosin an alpha-1 adrenergic receptor antagonist is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Silodosin is not indicated for the treatment of hypertension.	**Contraindications:** Patients with Severe renal impairment (CCr < 30 mL/min), Severe hepatic impairment (Child-Pugh score > 10), Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) **Side effects:** Most common adverse reactions (incidence > 2%) are retrograde ejaculation, dizziness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, and nasal congestion.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		f) Eflornithine 11.5% w/w Cream Eflornithine HCl Monohydrate INN 15.00g eq. to 11.500g Eflornithine/100g **Antiprotozoal drug**	An antiprotozoal drug; inhibits the enzyme ornithine decarboxylase in hair follicles. Topical eflornithine can be used as an adjunct to laser therapy for facial hirsutism in women. Eflornithine should be discontinued in the absence of improvement after treatment for 4 months.	**Contraindication:** None **Side effects:** Acne, application site reactions including burning and stinging sensation, rash; *less commonly* abnormal hair texture and growth	New	BNF-62 Page-748	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & UniHealth Manufacturers Ltd.	g) Prazosin 0.50mg Tablet Prazosin HCl BP 0.5476mg eqv. to 0.50mg Prazosin **(Alpha-adrenoceptor blocking drugs) /Antihypertensive drugs**	Prazosin has post-synaptic alpha-blocking and vasodilator properties and rarely causes tachycardia. It may, however, reduce blood pressure rapidly after the first dose and should be introduced with caution. Congestive heart failure Raynaud's syndrome benign prostatic hyperplasia	**Contraindication:** Not recommended for congestive heart failure due to mechanical obstruction (e.g. aortic stenosis) **Side effects:** Alpha-selective alpha blockers include drowsiness, hypotension (notably postural hypotension), syncope, asthenia, dizziness, depression, headache, dry mouth, gastro-intestinal disturbances, oedema, blurred vision, intra-operative floppy iris syndrome (most strongly associated with tamsulosin) rhinitis, erectile disorders (including priapism), tachycardia, and palpitation. Hypersensitivity reactions including rash, pruritus and angioedema have also been reported. Dyspnoea; nervousness; urinary frequency; *less commonly* insomnia, paraesthesia, sweating, arthralgia, eye disorders, tinnitus, and epistaxis; *rarely* pancreatitis, flushing, vasculitis, bradycardia, hallucinations, worsening of narcolepsy, gynaecomastia, urinary incontinence, and alopecia	1mg & 2mg Tablet	BNF-62 Page-113	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		h) Quetiapine 25mg Extended-Release Tablet Quetiapine Fumarate INN 28.80mg eq. to 25.00mg Quetiapine **Antipsychotic Drug**	Schizophrenia; mania, either alone or with mood stabilisers; depression in bipolar disorder; adjunctive treatment in major depressive disorder.	**Contraindication:** None **Side effects:** Dry mouth, constipation, dyspepsia; tachycardia, elevated plasma-triglyceride and -cholesterol concentrations, peripheral oedema; drowsiness, headache, irritability, dysarthria, asthenia; leucopenia, neutropenia; blurred vision; rhinitis; *less commonly* dysphagia, seizures, restless legs syndrome, hyponatraemia, and eosinophilia; *rarely* jaundice and priapism; *very rarely* hepatitis, angioedema, Stevens-Johnson syndrome, and rhabdomyolysis; suicidal behaviour (particularly on initiation) also reported	25mg & 100mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & UniHealth Manufacturers Ltd.	i) Quetiapine 50 mg Extended-Release Tablet Quetiapine Fumarate INN 57.60mg eq. to 50.00mg Quetiapine **Antipsychotic Drug**	Schizophrenia; mania, either alone or with mood stabilisers; depression in bipolar disorder; adjunctive treatment in major depressive disorder.	**Contraindication:** None **Side effects:** Dry mouth, constipation, dyspepsia; tachycardia, elevated plasma-triglyceride and -cholesterol concentrations, peripheral oedema; drowsiness, headache, irritability, dysarthria, asthenia; leucopenia, neutropenia; blurred vision; rhinitis; *less commonly* dysphagia, seizures, restless legs syndrome, hyponatraemia, and eosinophilia; *rarely* jaundice and priapism; *very rarely* hepatitis, angioedema, Stevens-Johnson syndrome, and rhabdomyolysis; suicidal behaviour (particularly on initiation) also reported	25mg & 100mg Tablet	BNF-62 Page-228	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		j) Quetiapine 100mg Extended-Release Tablet Quetiapine Fumarate INN 115.20mg eq. to 100.00mg Quetiapine **Antipsychotic Drug**	Schizophrenia; mania, either alone or with mood stabilisers; depression in bipolar disorder; adjunctive treatment in major depressive disorder.	**-do-**	25mg & 100mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		k) Omega-3 Acid Ethyl Ester 500mg Capsule Omega-3 Acid Ethyl Ester BP 500mg Capsule (containing Eicosapentaenoic Acid, Docosahexaenoic Acid, mixed tocopherols, rosemary extract and ascorbyl palmitate) **(Lipid-regulating drugs)**	Post Myocardial infarction: Adjuvant treatment in secondary prevention after myocardial infarction, in addition to other standard therapy.(e.g. statins, anti-platelet medicinal products, beta-blockers, ACE inhibitors) Hypertriglyceridaemia: Endogenous hypertriglyceridaemia as a supplement to diet when dietary measures alone are insufficient to produce an adequate response-type IV in monotherapy,, -type IIb/III in combination with statins, when control of triglycerides is insufficent.	**Contraindication**: Hypersensitivity to the active substance, to soya or to any of the excipients. **Side effects**: Infection and infestation: Uncommon: gastroenteritis, Uncommon: hypersensitivity, Metabolism and nutrition disorders: Rare: hyperglycaemia, Nervous system disorders: Uncommon: dizziness, dysgeusia. Rare: headache.	1000mg Soft Gelatin Capsule		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & UniHealth Manufacturers Ltd.	l) Clopidogrel 300mg Tablet Clopidogrel Bisulfate USP 391.50mg eq. to 300mg Clopidogrel **Antiplatelet drug**	Prevention of atherothrombotic events in peripheral arterial disease, or within 35 days of myocardial infarction, or within 6 months of ischaemic stroke; prevention of artherothrombotic events in acute coronary syndrome without ST-segment elevation and in acute myocardial infarction with ST-segment elevation , prevention of atherothrombotic and thromboembolic events in patients with atrial fibrillation and for whom warfarin is unsuitable.	**Contraindication:** Active bleeding **Side effects:** Dyspepsia, abdominal pain, diarrhoea; bleeding disorders (including gastro-intestinal and intracranial); less commonly nausea, vomiting, gastritis, flatulence, constipation, gastric and duodenal ulcers, headache, dizziness, paraesthesia, leucopenia, decreased platelets (very rarely severe thrombocytopenia), eosinophilia, rash, and pruritus; rarely vertigo; very rarely colitis, pancreatitis, hepatitis, acute liver failure, vasculitis, confusion, hallucinations, taste disturbance, stomatitis, bronchospasm, interstitial pneumonitis, blood disorders (including thrombocytopenic purpura, agranulocytosis and pancytopenia), and hypersensitivity-like reactions (including fever, glomerulonephritis, arthralgia, Stevens-Johnson syndrome, toxic epidermal necrolysis, lichen planus)	75mg Tablet	BNF-62 Page-153	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		m) Docusate Sodium 0.5% Ear Drops Docusate Sodium BP 0.50g/100ml **Otitis Media**	For the treatment of as an aid in the removal of ear wax.	**Contraindication:** Perforation of the ear drum or inflammation of the ear. **Side effects:** Immune system disorders: hypersensitivity/allergic reaction, Skin disorder: contact dermatitis and allergic skin reaction. General disorder: application dite reaction rarely including transient stinging or irritation may occure, injuries or inflammation in the auditory canal may result in painful symptoms.		BNF-62 Page-702	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & UniHealth Manufacturers Ltd.	n) Dronedarone 400mg Tablet Dronedarone HCl INN 426.40mg eq. to 400mg Dronedarone **Cardiovuscular (Anti-arrhythmia)**	Rapid reversion to sinus rhythm of paroxysmal supraventricular tachycardias, including those associated with accessory conducting pathways (e.g. Wolff-Parkison-White syndrome): aid to diagnosis of broad or narrow complex supraventricular tachycardias: in conjunction with radionuclide myocardial perfusion imaging in patients who cannot exercise adequately or for whom exercise is inappropriate.	**Contraindication:** Liver or lung toxicity associated with previous amiodarone use; second- or third-degree AV block, complete bundle branch block, distal block, sinus node dysfunction, atrial conduction defects, or sick sinus syndrome (unless pacemaker fitted); permanent atrial fibrillation; bradycardia; prolonged QT interval; existing or previous heart failure or left ventricular systolic dysfunction (see also Heart Failure above); haemodynamically unstable patients. **Sideeffects:** Gastrointestinal disturbances, QT-interval prolongation, bradycardia, heart failure, malaise, rash, pruritus, raised serum creatinine; *less commonly* taste disturbance, interstitial lung disease including pneumonitis and pulmonary fibrosis (investigate if symptoms such as dyspnoea or dry cough develop and discontinue treatment if confirmed), erythema, eczema, dermatitis, photosensitivity; *rarely* liver injury (including life-threatening acute liver failure.)	New	BNF-62 Page-93, 94	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		o) Dabigatran Etexilate 110mg Capsule Dabigatran Etexilate Mesilate INN 126.83mg Eq. to 110mg Dabigatran Etexiate **Oral anticoagulants**	A direct thrombin inhibitor is given orally for prophylaxis of venous thromboembolism in adults after total hip replacement or total knee replacement surgery. It is also indicated for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and with at least one of the following risk factors: previous stroke, transient ischaemic attack, or systemic embolism, left ventricular ejection fraction <40%, symptomatic heart failure, age ≥75 years, or age ≥65 years in patients with diabetes, coronary artery disease, or hypertension.	**Contraindication:** Active bleeding' impaired haemostasis. **Side effects:** Nausea, dyspepsia, diarrhoea, abdominal pain, anaemia, haemorrhage. *less commonly* hepatobiliary disorders, vomiting, dysphagia, gastro-intestinal ulcer, gastro-oesophageal reflux, oesophagitis, thrombocytopenia	75mg & 150mg Capsule	BNF-62 Page-148, 149	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & Unihealth Manufacturers Ltd.	p) Warfarin Sodium 1mg Tablet Warfarin Sodium BP 1mg **Oral anticoagulants**	Warfarin Sodium is a vitamin K antagonist indicated for: Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism, Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement, Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such asd stroke or systemic embolization after myocardial infarction.	**Contraindications:** Pregnancy, except in women with mechanical heart valves, Hemorrhagic tendencies or blood dyscrasias, Recent or contemplated surgery of the central nervous system (CNS) or eye, or traumatic surgery resulting in large open surfaces, Bleeding tendencies associated with certain conditions, Threatened abortion, eclampsia, and preeclampsia, Unsupervised patients with potential high levels of non-compliance, Spinal puncture and other diagnostic or therapeutic procedures with potential for uncontrollable bleeding, Hypersensitivity to warfarin or any component of the product, Major regional or lumbar block anesthesia. Malignant hypertension. **Side effects:** Most common adverse reactions are fatal and nonfatal hemorrhage from any tissue or organ.	5mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		q) Warfarin Sodium 2mg Tablet Warfarin Sodium BP 2mg **Oral anticoagulants**	Warfarin Sodium is a vitamin K antagonist indicated for: Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism, Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement, Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such asd stroke or systemic embolization after myocardial infarction.	**Contraindications:** Pregnancy, except in women with mechanical heart valves, Hemorrhagic tendencies or blood dyscrasias, Recent or contemplated surgery of the central nervous system (CNS) or eye, or traumatic surgery resulting in large open surfaces, Bleeding tendencies associated with certain conditions, Threatened abortion, eclampsia, and preeclampsia, Unsupervised patients with potential high levels of non-compliance, Spinal puncture and other diagnostic or therapeutic procedures with potential for uncontrollable bleeding, Hypersensitivity to warfarin or any component of the product, Major regional or lumbar block anesthesia. Malignant hypertension. **Side effects:** Most common adverse reactions are fatal and nonfatal hemorrhage from any tissue or organ.	5mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & Unihealth Manufacturers Ltd.	r) Warfarin Sodium 2.5mg Tablet Warfarin Sodium BP 2.5mg **Oral anticoagulants**	Warfarin Sodium is a vitamin K antagonist indicated for: Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism, Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement, Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such asd stroke or systemic embolization after myocardial infarction.	**Contraindications:** Pregnancy, except in women with mechanical heart valves, Hemorrhagic tendencies or blood dyscrasias, Recent or contemplated surgery of the central nervous system (CNS) or eye, or traumatic surgery resulting in large open surfaces, Bleeding tendencies associated with certain conditions, Threatened abortion, eclampsia, and preeclampsia, Unsupervised patients with potential high levels of non-compliance, Spinal puncture and other diagnostic or therapeutic procedures with potential for uncontrollable bleeding, Hypersensitivity to warfarin or any component of the product, Major regional or lumbar block anesthesia. Malignant hypertension. **Side effects:** Most common adverse reactions are fatal and nonfatal hemorrhage from any tissue or organ.	5mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		s) Tadalafil 2.5mg Tablet Tadalafil INN 2.5mg **Drugs for Erectile Dysfunction**	Erectile dysfunction; pulmonary hypertension.	**Contraindication:** Contraindicated in patients receiving nitrates, in patients in whom vasodilation or sexual activity are inadvisable, or in patients with a previous history of non-arteritic anterior ischaemic optic neuropathy. In the absence of information, manufacturers contra-indicate these drugs in hypotension (avoid if systolic blood pressure below 90 mmHg), recent stroke, unstable angina, and myocardial infarction. also moderate heart failure, uncontrolled arrhythmias, uncontrolled hypertension **Side effects:** Dyspepsia, nausea, vomiting, headache (including migraine), flushing, dizziness, myalgia, back pain, visual disturbances (non-arteritic anterior ischaemic optic neuropathy has been reported—stop drug if sudden visual impairment occurs), and nasal congestion. *Less common* side-effects include painful red eyes, palpitation, tachycardia, hypotension, hypertension and epistaxis. Other side-effects reported rarely include syncope, hypersensitivity reactions (including rash, facial oedema, and Stevens-Johnson syndrome), and priapism. Serious cardiovascular events (including arrhythmia, unstable angina, and myocardial infarction), seizures, sudden hearing loss (discontinue drug and seek medical advice), and retinal vascular occlusion have also been reported. Also increased sweating, abdominal pain, and transient amnesia reported.	5mg, 10mg & 20mg Tablet	BNF-62 Page-525, 526	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & Unihealth Manufacturers Ltd.	t) Valacyclovir 250mg Tablet Valacyclovir HCl USP 278.14mg eq. to 250mg Valacyclovir **Anti-infective-Antiretroviral**	Treatment of herpes zoster; treatment of initial and suppression of recurrent herpes simplex infections of skin and mucous membranes including initial and recurrent genital herpes; reduction of transmission of genital herpes; prevention of cytomegalovirus disease following solid organ transplantation when valganciclovir or ganciclovir cannot be used.	**Contraindications :** **Side effects** : Nausea, vomiting, abdominal pain, diarrhoea, headache, fatigue, rash, urticaria, pruritus, photosensitivity; *very rarely* hepatitis, jaundice, dyspnoea, neurological reactions (including dizziness, confusion, hallucinations, convulsions, ataxia, dysarthria, and drowsiness), acute renal failure, anaemia, thrombocytopenia and leucopenia; on *intravenous infusion*, severe local inflammation (sometimes leading to ulceration), and *very rarely* agitation, tremors, psychosis and fever	500mg and 1000mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		u) Morphine Sulphate 5mg Tablet Morphine Sulphate BP 5mg **Narcotic Anagesic**	Morphine sulfate is indicated for the treatment of acute pain and chronic pain. Morphine is used most widely as post operative analgesia.	**Contra indications:** Known hypersensitivity to morphine, also pancreatitis, cardiac arrhythmias, severe cor pulmonale. **Side effects:** The most common side effects include nausea and vomiting, constipation, dry mouth, and biliary spasm, larger doses produce muscle rigidity, hypotension and respiratory depression.also paralytic ileus, abdominal pain anorexia, dyspepsia, exacerbation of pancreatitis, taste disturbance: hypertension, hypothermia, syncope: bronchospasm, inhibition of cough reflex: restlessnes, seizures, paraesthesia, asthenia, malaise, disorientation, exciation, agitation, delirium, raised intracranial pressure: amenorrhoea: myoclonus, muscle fasciculation, rhabdomyolysis and nystagmus.	10 mg, 30mg & 60 mg CR Tablet & 50 mg/ml Injection		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	UniMed & Unihealth Manufacturers Ltd.	v) Morphine Sulphate 5mg/5ml Oral Solution Morphine Sulphate BP 0.100g/100ml **Narcotic Anagesic**	Morphine sulfate is indicated for the treatment of acute pain and chronic pain. Morphine is used most widely as post operative analgesia.	**Contra indications:** Known hypersensitivity to morphine, also pancreatitis, cardiac arrhythmias, severe cor pulmonale. **Side effects:** The most common side effects include nausea and vomiting, constipation, dry mouth, and biliary spasm, larger doses produce muscle rigidity, hypotension and respiratory depression.also paralytic ileus, abdominal pain anorexia, dyspepsia, exacerbation of pancreatitis, taste disturbance: hypertension, hypothermia, syncope: bronchospasm, inhibition of cough reflex: restlessnes, seizures, paraesthesia, asthenia, malaise, disorientation, exciation, agitation, delirium, raised intracranial pressure: amenorrhoea: myoclonus, muscle fasciculation,rhabdomyolysis and nystagmus.	10 mg, 30mg & 60 mg CR Tablet & 50 mg/ml Injection		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		w) Morphine Sulphate 10mg/5ml Oral Solution Morphine Sulphate BP 0.200g/100ml **Narcotic Anagesic**	Morphine sulfate is indicated for the treatment of acute pain and chronic pain. Morphine is used most widely as post operative analgesia.	-do-	10 mg, 30mg & 60 mg CR Tablet & 50 mg/ml Injection	BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
21.	Drug International Ltd.	a) Dutasteride 0.5 mg + Tamsulosin 0.4mg Tablet Dutasteride INN 0.5 mg + Tamsulosin USP 0.4 mg **Drugs for Urinary Retention**	For the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate	**Contraindication:** known hypersensitivity to dutasteride, other 5 –alpha-reductase inhibitors, tamsulosin hydrochloride or any component of the preparation). Also contraindicated for use in women and children **Side effects**: Allergic reactions, Diziness, Depressed mood, Impotence.	New		ট্যাবলেট ডোজেস ফরমটি নামঞ্জুর করা যেতে পারে।	ট্যাবলেট ডোজেস ফরমটি নামঞ্জুর করা হল।
		b) Acetaminophen 325 mg + Phenylephrine HCl 5 mg Soft Gelatin Capsule Acetaminophen USP 325 mg + Phenylephrine HCl USP 5 mg **Anagesic + Antihistamine**	Temporarily relieves sinus symptoms : sinus pain, headache, nasal & sinus congestion	**Contraindication:** This product is contra-indicted in patients with hypersensitivity to paracetamol, phenylephrine hydrochloride and any other component of the preparation. **Side effect:** Allergic or hypersensitivity reactions may occur very rarely. there have been a few repots of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol			প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
22	Healthcare Pharmaceuticals ltd., Rajendrapur Gazipur	a) Levocetrizine Dihydrochloride 5mg + Montelukast 10mg Tablet Levocetrizine Dihydrochloride INN 5mg + Montilukast Sodium INN 10.38 mg eq. to Montelukast 10mg	For Chronic Allergic conditions like seasonal allergic rhinitis, perennial allergic rhinitis, Rhinitis associated with Asthma	Contraindications: Patients who are hypersensitive to any component of this product or to montelukast sodium, levocetirizine or cetirizine. Patients with completely impaired renal function (anuria). ADR/Undesirable effects: Montelukast & Levocetirizine are generally well tolerated. Common side effects, which might be seen with the combination, are dyspepsia, abdominal pain, rash, dizziness, headache, fatigue, and somnolence. Sometimes, hypersensitivity, irritability, restlessness, insomnia, vomiting and diarrhoea may occur. In rare cases, patients may present with systemic eosinophilia, sometimes presenting with clinical features of consistent with Churg-Strauss Syndrome	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দেশনা	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Healthcare Pharmaceuticals ltd., Rajendrapur Gazipur	b) Dexlansoprazole 30mg Capsule Dexlansoprazole enteric coated pellets 12.5% w/w 240.00mg eq. to 30 mg dexlansoprazole INN **Antiulcerant-PPI**	-Healing of Erosive Esophagitis -Maintaining healing of EE and relief of heartburn - Treating heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD)	**Contraindication:** Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation. The following adverse reactions have been identified during post-approval of Dexlansoprazole. As these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Blood and Lymphatic System Disorders: autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura Ear and Labyrinth Disorders: deafness Eye Disorders: blurred vision. Gastrointestinal Disorders: oral edema, pancreatitis. General Disorders and Administration Site Conditions: facial edema Hepatobiliary Disorders: drug-induced hepatitis Immune System Disorders: anaphylactic shock (requiring emergency intervention), exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fatal) Infections and Infestations: Clostridium difficileassociated diarrhea Metabolism and Nutrition Disorders: hypomagnesemia, hyponatremia Musculoskeletal System Disorders: bone fracture Nervous System Disorders: cerebrovascular accident, transient ischemic attack Renal and Urinary Disorders: acute renal failure. Respiratory, Thoracic and Mediastinal Disorders: pharyngeal edema, throat tightness. Skin and Subcutaneous Tissue Disorders: generalized rash, leukocytoclastic vasculitis **Side Effects:** The most common side effects of Dexlansoprazole include: • diarrhea • abdominal Pain • nausea • common cold • vomiting and • Flatulence	30 mg DR & 60 mg DR Capsule	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Healthcare Pharmaceuticals ltd., Rajendrapur Gazipur	c) Dexlansoprazole 60mg Capsule Dexlansoprazole enteric coated pellets 12.5% w/w 480.00mg eq. to 60 mg dexlansoprazole INN **Antiulcerant - PPI**	-Healing of Erosive Esophagitis -Maintaining healing of EE and relief of heartburn - Treating heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD)	**Contraindication:** Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation. The following adverse reactions have been identified during post-approval of Dexlansoprazole. As these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Blood and Lymphatic System Disorders: autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura. Ear and Labyrinth Disorders: deafness. Eye Disorders: blurred vision. Gastrointestinal Disorders: oral edema, pancreatitis General Disorders and Administration Site Conditions: facial edema Hepatobiliary Disorders: drug-induced hepatitis. Immune System Disorders: anaphylactic shock (requiring emergency intervention), exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fatal) Infections and Infestations: Clostridium difficileassociated diarrhea Metabolism and Nutrition Disorders: hypomagnesemia, hyponatremia Musculoskeletal System Disorders: bone fracture Nervous System Disorders: cerebrovascular accident, transient ischemic attack Renal and Urinary Disorders: acute renal failure Respiratory, Thoracic and Mediastinal Disorders: pharyngeal edema, throat tightness Skin and Subcutaneous Tissue Disorders: generalized rash, leukocytoclastic vasculitis **Side Effects/ADR:** The most common side effects of Dexlansoprazole include: diarrhea, abdominal Pain, nausea, common cold, vomiting and Flatulence.	30 mg DR & 60 mg DR Capsule	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Healthcare Pharmaceuticals ltd., Rajendrapur Gazipur	d) Fosaprepitant 115mg/Vial Injection Fosaprepitant dimeglumine INN 188.00 mg eq. to Fosaprepitant 115mg/Vial **Antiemetic Drug**	Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.	**Contraindication:** Hypersensitivity to the act or any of the other excipients. Coadministration with pimozide, terfinadine, astemizole or cisapride. **Side-effect:** The most common side effects are decreased appetite, headche, hiccups, constipation, dyspesia and fatigue.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Avanafil 50mg Tablet Avanafil INN 50mg **Drugs for Erectile Dysfunction**	It is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction.	**Contraindications:** 1. Patients using any form of organic nitrate is contraindicated. 2. Hypersensitivity to any component of the Avanafil tablet. **Side effects/ADR:** -Most common adverse reactions (greater than or equal to 2%) include headache, flushing, nasal congestion, nasopharyngitis, and back pain.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		f) Avanafil 100mg Tablet Avanafil INN 100mg **Drugs for Erectile Dysfunction**	It is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction.	**Contraindications:** 1. Patients using any form of organic nitrate is contraindicated. 2. Hypersensitivity to any component of the Avanafil tablet. **Side effects/ADR:** -Most common adverse reactions (greater than or equal to 2%) include headache, flushing, nasal congestion, nasopharyngitis, and back pain.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Healthcare Pharmaceuticals ltd., Rajendrapur Gazipur	g) Avanafil 200mg Tablet Avanafil INN 200mg **Drugs for Erectile Dysfunction**	It is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction.	**Contraindications:** 1. Patients using any form of organic nitrate is contraindicated. 2. Hypersensitivity to any component of the Avanafil tablet. **Side effects/ADR:** -Most common adverse reactions (greater than or equal to 2%) include headache, flushing, nasal congestion, nasopharyngitis, and back pain.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
23.	NIPRO JMI Phrma Ltd., Comilla	a) Tolvaptan 15mg Tablet Tolvaptan INN 15mg	It is a selective vasopressin V2-receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia [serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)	**Contraindications:** • Do not administer to patients requiring urgent intervention to raise serum sodium acutely. • Do not use in patients who are unable to sense or to respond appropriately to thirst. • Do not use in patients with hypovolemic hyponatremia. • Do not use with strong CYP 3A inhibitors. • Do not administer to patients who are anuric as no benefit is expected. **Side effects:** Most common adverse reactions (≥5% placebo) are thirst, dry mouth, asthenia, constipation, pollakiuria, or polyurea and hyperglycemia	New	US FDA & BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Tolvaptan 30 mg Tablet Tolvaptan INN 30mg	-do-	-do-	New	USFDA & BNF	**অনুমোদন করা যেতে পারে।**	**অনুমোদন করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	NIPRO JMI Phrma Ltd., Comilla	c) Bedaquiline 100mg Tablet Bedaquiline Fumarate INN 120.896 mg eq. to 100mg Bedaquiline **Antibiotic**	It is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Bedaquiline for use when an effective treatment regimen cannot otherwise be provided. 10 mg tablet is not indicated for the treatment of latent, extra-pulmonary or drug-sensitive tuberculosis.	**Contraindication:** None **Side Effects:** The most common adverse reactions reported in ≥10% of patients treated with Bedaquiline Fumarate are nausea, arthralgia, and headache. Additional adverse events reported in ≥10% of patients treated with it and with a higher frequency than the placebo treatment group are hemoptysis and chest pain.	New	USFDA	শুধুমাত্র MDR-TB (Multi Drug Registance – Tuberculosis) চিকিৎসায় ব্যবহারের ÿ ÿ ত্রে অনুমোদন করা যেতে পারে।	শুধুমাত্র MDR-TB (Multi Drug Registance – Tuberculosis) চিকিৎসায় ব্যবহারের ÿ ÿ ত্রে অনুমোদন করা হল।
		d) Dapagliflozin 10mg Tablet Dapagliflozin Propanediol Monohydrate INN 12.30 mg eq. to 10mg Dapagliflozin **Antidiabetic Drugs**	It reversibly inhibits sodium-glucose co-transporter 2 (SGLT2) in the renal proximal convoluted tubule to reduce glucose reabsorption and increase urinary glucose excretion. It is indicated for use in type 2 diabetes as monotherapy (if metformin not tolerated), or in combination with insulin or other antidiabetic drugs (if existing treatment fails to achieve adequate glycaemic control); dapagliflozin is not recommended in combination with pioglitazone.	**Contraindications:** Contraindicated in ketoacidosis **Side Effects:** Hypoglycaemia (in combination with insulin or sulphonylurea), constipation, dyslipidaemia, back pain, genital infection, urinary-tract infection, dysuria, polyuria, thirst, sweating; *less commonly* nausea, hypotension, dizziness, rash, nocturia, dehydration, hypovolaemia, raised serum creatinine and urea	New	BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
24	Sun Pharmaceutical (Bangladesh) Ltd.	a) Levodopa 200mg + Carbidopa 50mg CR Tablet Levodopa BP 200mg + Carbidopa BP 50mg **CNS - Dopaminergic Drugs (Perkinson' diseases)**	It is indicated in the treatment of the symptoms of idiopathic parkinson's disease, post encephalitic parkinsonism, and symptomatic parkinsonism which may follow injury to the nervous system by carbon monoxide intoxication and manganese intoxication	**Contraindication:** Non selective MAO inhibitors are contraindicated for use with controlled release levodopa and carbidopa preparation. The drug is contraindicated in patients with known hypersensitivity to any component of this drug and in patients with narrow angle glaucoma. Because levodopa may activate a malignant melanoma, Levodopa 200 mg + Carbidopa 50 mg CR Tablet should not be used in patients with suspicious, undiagnosed skin lesions or a history of melanoma. **Side Effects:** In controlled clinical trials, patients predominantly with moderate to severe motor fluctuations.	250 mg + 25 mg Tablet & 100 mg + 10 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Levodopa 100 mg + Carbidopa 25 mg CR Tablet Levodopa BP 100 mg + Carbidopa BP 25 mg **CNS - Dopaminergic Drugs (Perkinson' diseases)**	It is indicated in the treatment of the symptoms of idiopathic parkinson's disease, post encephalitic parkinsonism, and symptomatic parkinsonism which may follow injury to the nervous system by carbon monoxide intoxication and manganese intoxication	**Contraindication:** Non selective MAO inhibitors are contraindicated for use with controlled release levodopa and carbidopa preparation. The drug is contraindicated in patients with known hypersensitivity to any component of this drug and in patients with narrow angle glaucoma. Because levodopa may activate a malignant melanoma, Levodopa 200 mg + Carbidopa 50 mg CR Tablet should not be used in patients with suspicious, undiagnosed skin lessions or a history of melanoma. **Side Effects:** In controlled clinical trials, patients predominantly with moderate to severe motor fluctuations.	250 mg + 25 mg Tablet & 100 mg + 10 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
25	Alco Pharma Ltd. Mirpur, Dhaka	a) Silver sulfadiazine 1gm + Chlorhexidine Gluconate 0.2gm/100gm Cream Silver sulfadiazine USP 1gm + Chlorhexidine Gluconate BP 0.2gm/100gm **Topical Antiinfective (Antibacterial**)	It is indicated in abrasions, cut and wounds, burns, bacterial infections of skin, ulcers (pressure, decubitous, venous), pyoderma, incision and other clean lessions, umbical cord dressing, post-caesarean section, episiotomy, wound dressing and post operative dressing.	**Contraindications:** Pregnancy and breast feeding; sensitive to sulphonamide; not recommended to neonates; Hypersensitive to silver sulfadiazine or any other ingredients in the preparations. **Side Effects:** Widespread extensive application may lead to systemic absorption. In rare cases there could be transient leucopenia. Possibility of Argyria can not be ruled out, though the same is very rare in occurance. Allergic reactions include burning, itching and rashes.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
26	Unimed & UniHealth Manufacturers Ltd.	a) Alfuzosin HCl 2.50 mg Tablet Alfuzosin HCl USP 2.50 mg	Bening prostatic hyperplasia	**Contraindications:** • Hypersensitivity to the active substance or to any of the excipients. • History of orthostatic hypotension. • Combination with other alpha-1 receptorblockers. • Severe hepatic insufficiency. **Adverse Effects:** Cardiac disorders: tachycardia, palpitations, angina pectoris in patients with pre-existing coronary artery disease. Eye disorders: vision abnormal. General disorders and administration site conditions: asthenia, malaise, oedema, chest pain. Gastro-intestinal disorders: nausea, abdominal pain, diarrhoea, dry mouth. Nervous system disorder: faintness/dizziness, vertigo, headache, drowsiness, syncope. Vascular disorders: hypotension (postural), flushing	10mg tablet	BNF 62 Page 516	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Unimed & UniHealth Manufacturers Ltd.	b) Diethyltoluamide (N,N-Dimethyl-3-Methyl Benzamide) 20% lotion Diethyltoluamide USP 20g/100ml	Diethyltoluamide is an insect repellent that is effective against mosquitoes as well as black flies, harvest-bugs or chiggers, midges, ticks, and fleas. It is considered to be of value for personal protection against malaria. It has also been used as a repellent against leeches. It may be applied to skin and clothing.	**Adverse Effects and Precautions** Occasional hypersensitivity to diethyltoluamide has been reported. Diethyltoluamide should not be applied near the eyes, to mucous membranes, to broken skin, or to areas of skin flexion, as irritation or blistering may occur. Systemic toxicity has been reported after application of large topical doses, particularly in children. Hypersensitivity and anaphylaxis has been described in a patient after exposure to diethyltoluamide.Toxic encephalopathy has been noted in children given liberal applications of this compound; seizures have also been reported, and there have been cases of manic psychosis and cardiovascular toxicity (sinus bradycardia and orthostatic hypotension) associated with topical application. An assessment of both published and unpublished data concluded that there had been remarkably few problems considering the wide spread use of diethyltoluamide and that the encephalopathy in children had not been substantiated by detailed surveillance; however, another case analysis did find an association with encephalopathy in children.Toxic reactions, including death, have been reported after the ingestionof large amounts of diethyltoluamide-containing insect repellents.			প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		c) Diethyltoluamide (N,N-Dimethyl-3-Methyl Benzamide) 35% Cream Diethyltoluamide USP 35g/100g	-do-	Do			প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
27.	General Pharmaceuticals Ltd.	a) Methylprednisolone 8mg Tablet Methylprednisolone USP 8mg	Suppression of inflammatory and allergic disorders; Severe Inflammatory Bowel disease (Ulcerative colitis and Crohn's disease); Cerebral Oedema associated with malignancy; Rheumatic Disease	**Contraindications:** Systemic fungal infections. Known hypersensitivity to Methylprednisolone. During prolonged therapy with corticosteroids, adrenal atrophy develops and can persist for years after stopping. Abrupt withdrawal after a prolonged period can lead to acute adrenal insufficiency, Hypotension or death. Withdrawal can also be associated with fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and weight loss. Prolonged courses of corticosteroids increase susceptibility to infections and severity of infections; clinical presentation of infections may also be atypical. Serious infections e.g. Septicaemia and Tuberculosis may reach an advanced stage before being recognised, and Amoebiasis may be activated or exacerbated. Fungal or viral ocular infections may also be exacerbated. Systemic corticosteroids, particularly in high doses, are linked to psychiatric reactions including euphoria, nightmares, insomnia, irritability, mood lability, suicidal thoughts, psychotic reactions, and behavioural disturbances. A serious paranoid state or depression with risk of suicide can be induced, particularly in patients with a history of mental disorder. These reactions frequently subside on reducing the dose or discontinuing the corticosteroid but they may also require specific management. Patients should be advised to seek medical advice if psychiatric symptoms (especially depression and suicidal thoughts) occur and they should also be alert to the rare possibility of such reactions during withdrawal of corticosteroid treatment.	2 mg & 4mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	General Pharmaceuticals Ltd.			**Side-Effects:** Overdosage or prolonged use can exaggerate some of the normal physiological actions of corticosteroids leading to mineralocorticoid and glucocorticoid side-effects.Mineralocorticoid side-effects include hypertension, sodium and water retention, and potassium and calcium loss but these occur only slightly. Glucocorticoid side-effects include diabetes and osteoporosis, which is a danger, particularly in the elderly, as it can result in osteoporotic fractures for example of the hip or vertebrae; in addition high doses are associated with avascular necrosis of the femoral head. Muscle wasting (proximal myopathy) can also occur. Corticosteroid therapy is also weakly linked with peptic ulceration and perforation High doses of corticosteroids can cause Cushing's syndrome, with moon face, striae, and acne; it is usually reversible on withdrawal of treatment, but this must always be gradually tapered to avoid symptoms of acute adrenal insufficiency ***Other side-effects include*: *Gastro-intestinal effects*:** Dyspepsia, Abdominal distension, Acute pancreatitis, Oesophageal Ulceration and candidiasis; ***Musculoskeletal effects*:** muscle weakness, vertebral and long bone fractures, tendon rupture; ***Endocrine effects*:** menstrual irregularities and amenorrhoea, hirsutism, weight gain, hypercholesterolaemia, hyperlipidaemia, negative nitrogen and calcium balance, increased appetite; increased susceptibility to and severity of infection, reactivation of dormant tuberculosis; ***Neuropsychiatric effects*:** psychological dependence, insomnia, increased intracranial pressure with papilloedema in children (usually after withdrawal), aggravation of schizophrenia, aggravation of epilepsy; ***ophthalmic effects*:** glaucoma, papilloedema, posterior subcapsular cataracts, corneal or scleral thinning and exacerbation of ophthalmic viral or fungal disease, increased intra-ocular pressure, exophthalmos				
		b) Methylprednisolone 16mg Tablet Methylprednisolone USP 16mg	-do-	-do-	2 mg & 4 mg Tablet	USFDA BNF	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
1	1) Square Pharmaceuticals Ltd. (Pabna Unit) 2) Beximco Pharmaceuticals Ltd. 3) Beacon Pharmaceuticals Ltd.	a)	Deflazacort 6 mg Tablet Deflazacort INN 6 mg **Endocrine System-Coticosteroids Antiinflammatory and immunosuppressant**	It is a glucocorticoid used as an anti-inflammatory and immunosuppressant. It can be used to treat a wide range of allergic and inflammatory conditions, including severe asthma and rheumatoid arthritis.	**Contraindications:** Hypersensitivity to or any of the ingredients. Patients receiving live virus immunisation. **Side effects:** GI disturbances, musculoskeletal, endocrine, neuropsychiatric, ophthalmic, fluid and electrolyte disturbances; susceptible to infection, impaired healing, hypersensitivity, skin atrophy, striae, telangiectasia, acne, myocardial rupture following recent MI, thromboembolism.		BNF-63	**অনুমোদন করা যেতে পারে।**	**অনুমোদন করা হল।**
2	1) Square Pharmaceuticals Ltd., (Pabna Unit) 2) Ziska Pharmaceuticals Ltd. 3) Beacon Pharmaceuticals Ltd.	a)	Famotidine 10mg + Calcium Carbonate 800mg + Magnesium Hydroxide 165mg Chewable Tablet Famotidine USP 10mg + Calcium Carbonate BP 800mg + Magnesium Hydroxide USP 165mg **Gastrointestinal System-Antacid**	Relieves heartburn associated with acid indigestion and sour stomach.	**Contraindication:** Hypersensitivity to Famotidine, Calcium Carbonate, Magnesium Hydroxide or other acid reducers. Severe renal or hepatic impairment. **ADR/Side effects:** Headache, Constipation, Diarrhea		USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
3	1) Square Pharmaceuticals Ltd. (Pabna Unit) 2) Delta Pharma Ltd.	a)	Bilastine 20mg Tablet Bilastine INN 20mg **Antihistamine**	It is indicated for the Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria	**Contraindications:** Hypersensitivity to the active substance bilastine or to any of the excipients. **Side effects:** Headache, Malaise; Less commonly abdominal pain, diarrhoea, increased appetite, weight gain, thirst, gastritis, prolongation of the QT interval, dyspnoea, anxiety, insomnia, vertigo, dizziness, pyrexia, oral herpes,, tinnitus.		BNF-63	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
4	1) Aristopharma Ltd. 2) Delta Pharma Ltd. Pharma	a)	Dexrabeprazole Sodium 10mg Enteric Coated Tablet Dexrabeprazole Sodium INN 10mg **Gastrointestinal System-Proton Pump Inhibitor**	It is indicated to the heartburn caused by acid-related stomach and throat problems such as acid reflux or gastroesophageal reflux disease (GERD) and erosive esophagitis. It is more effective and tolerable than Rabeprazole.	**Contraindications:** Dexrabeprazole Sodium is contraindicated in patients with known hypersensitivity to Dexrabeprazole Sodium, or to any excipients used in formulation. It is contraindicated in pregnancy and during breast feeding. **Side Effect**: Dexrabeprazole Sodium can cause side effects such as nausea, Vomiting, stomach pain, diarrhea and gas.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
5	1) RAK Pharmaceuticals Ltd., 2) Incepta Pharmaceuticals Ltd. 3) Delta Pharma Ltd. 4) Ziska Pharmaceuticals Ltd. 5) Beacon Pharmaceuticals Ltd.	a)	Linaclotide 145 mcg Capsule Linaclotide INN 0.145 mg **Gastrointestinal Agent**	It is indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C) & chronic idiopathic constipation (CIC).	**Contraindication:** Pediatric patient up to 6 years of age. Patients with known or suspected mechanical gastrointestinal obstruction. **Side Effects:** Diarrhea, abdominal pain, flatulence, abdominal distension.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
6	1) RAK Pharmaceuticals LTD, 2) Incepta Pharmaceuticals Ltd., 3) Delta Pharma Ltd., 4) Ziska Pharmaceuticals Ltd.,	a)	Linaclotide 290 mcg Capsule Linaclotide INN 0.290 mg **Gastrointestinal Agent**	It is indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C) & chronic idiopathic constipation (CIC).	**Contraindication:** Pediatric patient up to 6 years of age. Patients with known or suspected mechanical gastrointestinal obstruction. **Side Effects:** Diarrhea, abdominal pain, flatulence, abdominal distension.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
7	1) Eskayef BD Ltd., Tongi, Gazipur 2) Popular Pharmaceuticals Ltd.,	a)	Parecoxib Sodium 40mg IM/IV injection Parecoxib Sodium INN 40mg **Non-steroidal anti-inflammatory Drugs**	Management of acute post-operative pain	**Contraindications:** History of allergic drug reaction including sulfonamide hypersensitivity & Severe asthma, Nausea & Edema and also NSAIDs contraindication **Side effects:** Hypotension, hypoaesthesia, alveolar osteitis, postoperative anaemia, hypokalaemia, sweating and also NSAIDs side effect.		BNF 63, Page-826	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
8	1) Eskayef BD Ltd., Tongi, Gazipur 2) Delta Pharma Ltd., 3) Ziska Pharmaceuticals Ltd. 4) Beacon Pharmaceuticals Ltd. 5) UniMed & UniHealth 6) Sun Pharma	a)	Dapoxetine 30 mg FC Tablet Dapoxetine INN 30mg **Selective Serotonin Reuptake Inhibitor**	It is indicated for the treatment of premature ejaculation (PE) in men 18 to 64 years of age, who have all of the following: • persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes; and • marked personal distress or interpersonal difficulty as a consequence of PE; and • poor control over ejaculation.	**Contraindications:** Contraindicated in patients with known hypersensitivity to dapoxetine hydrochloride or to any of the excipients. It is also contraindicated in patients with significant pathological cardiac conditions (such as heart failure (NYHA class II-IV), conduction abnormalities (second- or third-degree AV block or sick sinus syndrome) not treated with a permanent pacemaker, significant ischemic heart disease or significant valvular disease. It is contraindicated for concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days of discontinuing treatment with an MAOI. Similarly, an MAOI should not be administered within 7 days after Dapoxetine has been discontinued. It is contraindicated for concomitant treatment with thioridazine, or within 14 days of discontinuing treatment with thioridazine. Similarly, thioridazine should not be administered within 7 days after Dapoxetine has been discontinued. It is contraindicated for concomitant treatment with serotonin reuptake inhibitors [selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs)] or other	New		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
				It is indicated for the treatment of premature ejaculation (PE) in men 18 to 64 years of age, who have all of the following: • persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes; and • marked personal distress or interpersonal difficulty as a consequence of PE; and • poor control over ejaculation.	medicinal/herbal products with serotonergic effects [e.g., L-tryptophan, triptans, tramadol, linezolid, lithium, St. John's Wort (Hypericum perforatum)] or within 14 days of discontinuing treatment with these medicinal/herbal products. Similarly these medicinal/herbal products should not be administered within 7 days after Dapoxetine has been discontinued Dapoxetine is contraindicated for concomitant treatment with potent CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazodone, nelfinavir, atazanavir, etc. Dapoxetine is contraindicated in patients with moderate and severe hepatic impairment. **Side effects:** Most common adverse reactions are headache, dizziness, nausea, diarrhea, insomnia, fatigue, abdominal pain, unusual tiredness and nasal congestion. Serious side effects include fainting and allergy such as rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body and syncope.				
9	1) Eskayef BD Ltd., Tongi, Gazipur 2) Delta Pharma Ltd. 3) Ziska Pharmaceuticals Ltd. 4) UniMed & Unihealth 5) Sun Pharma	a)	Dapoxetine 60 mg FC Tablet Dapoxetine INN 60mg **Selective Serotonin Reuptake Inhibitor**	Do	Do	New		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
10	1) Eskayef BD Ltd., Tongi, Gazipur 2) Beximco Pharmaceuticals Ltd.	a)	Esomeprazole 10mg Powder For Enteric Coated DR Granules for oral Suspension/Sachet Esomeprazole Magnesium Trihydrate Enteric Coated Granule Ph. Grade 193.64mg contains Esomeprazole Magnesium Trihydrate 11.10 mg eq. to 10mg Esomeprazole/Sachet **Antiulcerant-PPI**	Gastroesophageal reflux disease (GERD); risk reduction of NSAIDs associated ulcer; short-term treatment in healing and symptomatic resolution of erosive esophagitis; maintenance of symptom resolution and healing of erosive esophagitis; H. pylori eradication to reduce the risk of duodenal ulcer recurrence; Pathological hypersecretory conditions including Zollinger-Ellison syndrome	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side effects:** The safety of esomeprazole was evaluated worldwide in over 10000 patients (aged 18 - 84 years). In clinical trials the most frequently occurring adverse events were headache, diarrhoea, nausea, flatulence, abdominal pain and constipation. Rarely dermatitis, pruritus, urticaria, dizziness and dry mouth were reported.	Esomeprazole USP 20 mg, 40 mg Tablet, Capsule and 40mg Injection & 20 mg Sachet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
11	1) Eskayef BD Ltd., Tongi, Gazipur 2) Delta Pharma Ltd.	a)	Paracetamol 250mg + Caffeine 65mg + Aspirin 250mg FC Tablet Paracetamol BP 250mg + Caffeine USP 65mg + Aspirin USP 250mg	For the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.	**Contraindications:** Hypersensitivity to the active ingredients or any of the other constituents. Peptic ulceration and those with a history of peptic ulceration; haemophilia, concurrent anti-coagulant therapy; children under 16 years and when breast feeding because of possible risk of Reyes Syndrome. **Side effects:** Side effects are mild and infrequent, but there is a high incidence of gastro-intestinal irritation with slight asymptomatic blood loss. Increased bleeding time. Aspirin may precipitate bronchospasm and induce asthma attacks or other hypersensitivity reactions, such as skin reactions (including angioedema and face oedema) in susceptible individuals. Aspirin may induce gastro-intestinal haemorrhage, occasionally major.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
12	1) Eskayef (BD) Ltd., Tongi, Gazipur 2) General Pharmaceutical Ltd. (Unit-2)	a)	Brinzolamide 1% + Timolol 0.5% ophthalmic suspension Brinzolamide USP 1gm + Timolol USP 0.5gm/100ml	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for monotherapy provides insufficient IOP reduction.	**Contraindication:** * Hypersensitivity to the active substances, or to any of the excipients. * Bronchial asthma, a history of bronchial asthma, or severe chronic obstructive pulmonary disease. * Sinus bradycardia, second or third degree atrioventricular block, overt cardiac failure, or cardiogenic shock * Severe allergic rhinitis and bronchial hyperreactivity: hypersensitivity to other betablockers. * Hyperchloraemic acidosis. * Severe renal impairment * Hypersensitivity to sulphonamides **Site effects:** As with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machines.	New	BNF-61, Page 677 & 678 MHRA	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
13	1) Eskayef (BD) Ltd., Tongi, Gazipur 2) Beacon Pharmaceuticals Ltd.	a)	Levothyroxine Sodium 0.05mg + Liothyronine Sodium 0.0125 mg FC Tablet Levothyroxine Sodium USP 0.05mg + Liothyronine Sodium USP 0.0125mg **Thyroid Supplement**	As replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. This category includes cretinism, myxedema, and ordinary hypothyroidism in patients of any age (children, adults, the elderly), or state (including pregnancy); primary hypothyroidism resulting from functional deficiency, primary atrophy, partial or total absence of thyroid gland, or the effects of surgery, radiation, or drugs, with or without the presence of goiter; and secondary (pituitary), or tertiary (hypothalamic) hypothyroidism	**Contraindication:** Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis, and apparent hypersensitivity to any of their active or extraneous constituents. There is no well documented evidence from the literature, however, of true allergic or idiosyncratic reactions to thyroid hormone. **Side-effect:** During postmarketing surveillance, the following events have been observed to have occured in patients administered Thyrolar (liotrix) : fatigue, sluggishness, increase in weight, alopecia, palpitations, dry skin, urticaria, headache, hyperhidrosis, pruritus, asthenia, increased blood pressure, arthralgia, myalgia, tremor, hypothyroidism, increase in TSH, decrease in TSH	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
14	1) Eskayef BD Ltd., Tongi, Gazipur 2) Delta Pharma Ltd.	a)	Paracetamol 300mg + Chlorzoxazone 250mg FC Tablet Paracetamol BP 300mg + Chlorzoxazone USP 250mg	Paracetamol BP 300mg and Chlorzoxazone USP 250mg tablets are indicated for the relief of severe skeletal muscle spasm and pain associated with such medical and orthopaedic problems as: sprains and strains, myalgias, torticollis, tension headaches, traumatic muscle injuries, low back pain, fibrositis, cervical root and disc syndromes.	**Contra-indication:** Paracetamol BP 300mg and Chlorzoxazone USP 250mg tablets are contra-indicated in patients sensitive to either component. **Side effects:** Occasional patients may develop gastrointestinal disturbances**.** It is possible, in rare instances**,** that chlorzoxazone may have been associated with gastrointestinal bleeding**.** Dizziness, nausea, lightheadedness, malaise, or overstimulation may be noted by an occasional patient. Drowsiness can occur with the use of Paracetamol BP 300mg and Chlorzoxazone USP 250mg and may be additive to drowsiness from the concomitant use of alcohol or other central nervous system depressants**.**	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
15	1) Eskayef BD Ltd., Tongi, Gazipur 2) Incepta Pharmaceuticals Ltd.	a)	Cefixime 100mg + Clavulanic Acid 62.50mg FC Tablet Cefixime Anhydrous USP 111.917mg eq. to Cefixime 100mg + Potassium Clavulanate USP 150.737mg eq. to Clavulanic Acid 62.50mg **Antibiotic- Cephalosporin**	Cefixime- Clavulanic Acid is indicated for the treatment of: - Uncomplicated Urinary Tract Infections - Otitis Media - Pharyngitis and Tonsillitis, is caused by S. pyogenes. - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis - Uncomplicated gonorrhea	**Contraindications:** It is contraindicated in patients with previous history of cholestatic jaundice/liver dysfunction, and hypersensitivity & in patients with known allergy to the cephalosporin group of antibiotics. **Side-effects:** The most frequent side effects seen with Cefixime and Clavulanic Acid are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
16	1) Eskayef BD Ltd., Tongi, Gazipur 2) Incepta Pharmaceuticals Ltd. 3) Delta Pharma Ltd.	a)	Cefixime 200 mg + Clavulanic Acid 125mg FC Tablet Cefixime Anhydrous USP 223.834mg eq. to Cefixime 200mg + Potassium Clavulanate USP 301.474mg eq. to Clavulanic Acid 125mg **Antibiotic- Cephalosporin**	Cefixime- Clavulanic Acid is indicated for the treatment of: - Uncomplicated Urinary Tract Infections - Otitis Media - Pharyngitis and Tonsillitis, is caused by S. pyogenes. - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis - Uncomplicated gonorrhea	**Contraindications:** It is contraindicated in patients with previous history of cholestatic jaundice/liver dysfunction, and hypersensitivity & in patients with known allergy to the cephalosporin group of antibiotics. **Side effects:** The most frequent side effects seen with Cefixime and Clavulanic Acid are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
17	1) Incepta Pharmaceuticals Ltd. 2) Delta Pharma Ltd. 3) Orion Pharma Ltd. Pharma Ltd.	a)	Cefpodoxime 50mg + Clavulanic Acid 31.25 mg/5ml syrup Cefpodoxime Proxetil BP 50mg + Clavulanic Acid BP 31.25mg/5ml **Antibiotic- Cephalosporin**	- Acute bacterial exacerbations of chronic bronchitis -Acute community acquired Pneumonia -Upper and lower respiratory tract infections -Skin and soft tissue infections -Urinary tract infections -Pharyngitis and/or tonsillitis -General gonorrhea (men and women) and rectal gonococcal infections (women) -Acute maxillary sinusitis	**Contraindications:** Cefpodoxime proxetil/ clavulanic acid is contraindicated in patients with hypersensitivity to cefpodoxime proxetil or to clavulanic acid or to any of the excipients of the medicinal product **Side-effects:** **Cefpodoxime** Incidence greater than 1% include #Diarrhea: 7%; Nausea: 3.3%; Vaginal Fungal Infections:1%; Vulvovaginal Infections:1.3%; Abdominal Pain: 1.2%; and Headache : 1% Number of diarrhea or loose stools were dose related: decreasing from 10.4% of patients receiving 800 mg per day to 5.7% for those receiving 200 mg per day. Of patients with diarrhea, 10% had C. difficile organism or toxin in the stool. Other adverse events consists of difficulty breathing or swallowing, Hives, Itching, Mild skin rash, Painful mouth or throat sores, Severe skin rash, Sore throat, Unusual bleeding or bruising, Upset stomach, Vaginal infection, Vomiting, and Wheezing. **Clavulanic Acid** Side effects include bloody diarrhea, bloody urine, painful or difficult urination, unusual weakness, easy bleeding and bruising, confusion, dry mouth, increased urination, chills, body aches, fever, sore throat, headache, seizures, chest pain and irregular heartbeat. These side effects are very rare and do not affect a large amount of users. Treatment should not normally exceed 14 days.	200mg+125mg tablet & 100mg + 62.5mg tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
18	1) Renata Ltd. 2) Incepta Pharmaceuticals Ltd.	a) Drospirenone 3 mg + Ethinylestradiol 0.02 mg Tablet Drospirenone BP 3 mg + Ethinylestradiol BP 0.02 mg **Combined Hormonal Contraceptive**	Estrogen-progestogen combinations act primarily through the mechanism of gonadotropin suppression due to the estrogenic and progestational activity of their components. Although the primary mechanism of action is inhibition of ovulation, alterations in the cervical mucus and the endometrium may also contribute to effectiveness	**Contraindications:** Diabetes and women over forty.History of or actual thrombophlebitis or thromboembolic disorders; history of or actual cerebrovascular disorders; history of or actual myocardial infarction or coronary arterial disease; active liver disease or history of or actual benign or malignant live tumors; history of or known or suspected carcinoma of the breast; history of or known or suspected estrogendependent neoplasia; undiagnosed abnormal vaginal bleeding	Drospirenone BP 3mg + Ethinylestradiol BP 0.03 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
19	1) Beximco Pharmaceuticals Ltd. 2) Beacon Pharmaceuticals Ltd.	a) Fidaxomicin 200 mg Tablet Fidaxomicin INN 200 mg **Antibacterial - Antibiotic**	It is indicated in adults (≥18 years of age) for treatment of Clostridium difficile-associated diarrhea(CDAD)	**Contraindication:** None **Side effects:** The most common adverse reactions are nausea (11%), vomiting (7%), abdominal pain (6%), gastrointestinal hemorrhage (4%), anemia (2%), and neutropenia (2%)	New	USFDA, BNF	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
20	1) Beximco Pharmaceuticals Ltd. 2) Nipro JMI 3) Unimed & UniHealth Manufactures Ltd.	a) Metformin HCl 500mg + Linagliptin 2.5 mg Tablet Metformin HCl BP 500mg+ Linagliptin INN 2.5 mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:**Renal impairrment, metabolic acidosis including diabetic ketoacidosis, hypersensitivity to metformin & linagliptin **Side effects:** • Adverse reactions reported in ≥5% of patients treated with it and more commonly than in patients treated with placebo are nasopharyngitis and diarrhea • Hypoglycemia was more commonly reported in patients treated with the combination of it and SU compared with those treated with the combination of sulfonylurea and metformin. • Pancreatitis was reported more often in patients randomized to linagliptin (1 per 538 person years versus zero in 433 person years for comparator)	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
21	1) Beximco Pharmaceuticals Ltd. 2) Nipro JMI 3) Unimed & Unihealth	a)	Metformin HCl 850 mg+ Linagliptin 2.5 mg Tablet Metformin HCl BP 850 mg+ Linagliptin INN 2.5 mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:**Renal impairrment, metabolic acidosis including diabetic ketoacidosis, hypersensitivity to metformin & linagliptin **Side effects:** • Adverse reactions reported in ≥5% of patients treated with it and more commonly than in patients treated with placebo are nasopharyngitis and diarrhea • Hypoglycemia was more commonly reported in patients treated with the combination of it and SU compared with those treated with the combination of sulfonylurea and metformin. • Pancreatitis was reported more often in patients randomized to linagliptin (1 per 538 person years versus zero in 433 person years for comparator)	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
22	1) Beximco Pharmaceuticals Ltd. 2) Nipro JMI	a)	Metformin HCl 1000mg+ Linagliptin 2.5 mg Tablet Metformin HCl BP 1000mg+ Linagliptin INN 2.5 mg **Antidiabetic**	Do	Do	Do	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
23	1) Beximco Pharmaceuticals Ltd. 2) Unimed & Unihealth	a)	Acetylcysteine 600 mg Dispersible Tablet / Effervisent Tablet Acetylcysteine USP 600 mg **Mucolytic Agent**	Treatment of Chronic bronchopulmonary disease and Acute bronchopulmonary disease	**Contraindications:** It is contraindicated in those patients who are sensitive to it. **Side effects:** Stomatitis, nausea, vomiting, fever, rhinorrhea, drowsiness, clamminess, chest tightness and bronchoconstriction.	100mg/ml and 200 mg /ml Respirator Solution		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম		নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
24	1) Delta Pharma Ltd. 2) Ziska Pharmaceuticals Ltd., 3) Beacon Pharmaceuticals Ltd. 4) NIPRO JMI	a)	Lorcaserin Hydrochloride 10 mg film-coated tablet Lorcaserin HCl Hemihydrate INN 10.40 mg eq. to 10 mg Lorcaserin HCl **Anorectic (Appetite Suppressants)**	It is a serotonin 2C receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes)	**Contraindication:** Pregnancy Category X **Side-effect:** Most common adverse reactions (greater than 5%) in non-diabetic patients are headache, dizziness, fatigue, nausea, dry mouth, and constipation, and in diabetic patients are hypoglycemia, headache, back pain, cough, and fatigue.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
25	1) Delta Pharma Ltd. 2) Beacon Pharmaceuticals Ltd.	a)	Bosutinib 100 mg film-coated tablet Bosutinib Monohydrate INN 103.40 mg eq. to Bosutinib 100 mg **Anticancer**	Bosutinib is a kinase inhibitor indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.	**Contraindication:** Hypersensitivity to Bosutinib. **Side-effect:** Most common adverse reactions (incidence greater than 20%) are diarrhea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anemia, pyrexia, and fatigue.		USFDA	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
26	1) Delta Pharma Ltd. 2) Beacon Pharmaceuticals Ltd.	a)	Bosutinib 500 mg film-coated tablet Bosutinib Monohydrate INN 517.00 mg eqv. to 500 mg Bosutinib **Anticancer**	It is a kinase inhibitor indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.	**Contraindication:** Hypersensitivity to Bosutinib. **Side-effect:** Most common adverse reactions (incidence greater than 20%) are diarrhea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anemia, pyrexia, and fatigue.		USFDA	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
27	1) Delta Pharma Ltd. 2) Beacon Pharmaceuticals Ltd.	a) Tofacitinib 5 mg film-coated tablet Tofacitinib Citrate INN 8.075 mg eq. to Tofacitinib 5 mg **Antirheumatoid arthritis**	Tofacitinib an inhibitor of Janus kinases (JAKs), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Tofacitinib should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.	**Contraindication:** None. **Side-effect:** The most commonly reported adverse reactions during the first 3 months in controlled clinical trials (occurring in greater than or equal to 2% of patients treated with Tofacitinib monotherapy or in combination with DMARDs) were upper respiratory tract infections, headache, diarrhea and nasopharyngitis.		USFDA	অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
28	1) Delta Pharma Ltd. 2) Ziska Pharmaceuticals Ltd. 3) Unimed & Unihealth 4) Beacon Pharmaceuticals Ltd.	a) Dutasteride 0.5 mg + Tamsulosin HCl 0.4 mg Capsule Dutasteride INN 0.5 mg +Tamsulosin HCl INN 0.4 mg **Drugs for Urinary Retention**	It is a combination of dutasteride, a 5 alpha-reductase inhibitor, and tamsulosin, an alpha adrenergic antagonist, indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.	**Contraindication:** • Pregnancy and women of childbearing potential. • Pediatric patients. Patients with previously demonstrated, clinically significant hypersensitivity (e.g., serious skin reactions, angioedema) to dutasteride, other 5 alpha-reductase inhibitors, tamsulosin, or any component of Dutasteride & Tamsulosin HCl. **Side effects:** The most common adverse reactions, reported in ≥1% of subjects treated with coadministered dutasteride and tamsulosin are ejaculation disorders, impotence, decreased libido, dizziness, and breast disorders.	New	USFDA	বিশেষজ্ঞ কমিটির সুপারিশের পরিপ্রেয় তে অনুমোদন করা যেতে পারে।	বিশেষজ্ঞ কমিটির সুপারিশের ভিত্তিতে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
29	1) Orion Pharma Ltd., 2) Nipro JMI	a) Racecadotril 100 mg Capsule Racecadotril INN 100 mg **Antidiarrheals**	Acute watery diarrhoea	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. **Side-effect:** Vomiting, nausea, constipation, abdominal pain, thirst, vertigo & headache.			অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
30	1) Orion Pharma Ltd. 2) Beacon Pharmaceuticals Ltd.	a) Loperamide HCl 2 mg + Simethicone 125 mg Tablet **Antidiarrheal + Antiflatulent**	Relieves symptoms of diarrhea plus bloating, pressure, and cramps	**Contraindications:** This drug should not be used with the following medication because a very serious interaction may occur: pramlintide.If you are currently using the medication listed above, tell your doctor or pharmacist before starting loperamide. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: recent/current antibiotic use, drugs that can cause constipation (e.g., anticholinergic such as belladonna/scopolamine/benztropine, antispasmodics such as glycopyrrolate/oxybutynin, potent narcotic pain medicines such as morphine, certain antihistamines such as diphenhydramine, tricyclic antidepressants such as amitriptyline), cholestyramine, quinidine, ritonavir, saquinavir. **Side effects:** Infrequent side effects of Loperamide & simethicone Oral: Incomplete or Infrequent Bowel Movements**.**		USFDA, BNF	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

2.3.3: Proposed Vaccine for locally manufacture

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	**Incepta Vaccine Limited**	a) Snake Venom Antiserum Injection Snake Venom Antiserum BP 10ml Injection (0.60mg of dried Cobra venom; 0.45mg of dried Common Krait venom; 0.60mg of dried Russell's Viper venom; 0.45mg of dried Sawscaled Viper venom)	Snake Venom antiserum is indicated only for the treatment of envenomation caused by bites of the snake specified as Cobra Common Krait Russell's Viper & Sawscaled Viper.	**Contraindications:** Should be used with extreme caution in subjects with a history of allergic symptoms or hypersensitivity to equine serum. **Side Effects:** Serum sickness reactions sometimes occur. But these usually take a few days to a week, and can be easily treated with oral antihistamines and corticosteroids (for e.g., prednisolone - adults 5 mg/6 hourly; child 0.7mg/kg/day)	New	(Bharat Serums and vaccines Ltd.)	ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক অনুমোদনের জন্য সুপারিশকৃত।	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Tetanus Toxoid, reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Suspension for intramuscular injection Each dose of 0.5 ml contains: Diphtheria Toxoid 2 Lf, Tetanus Toxoid 5 Lf, Acellular Pertussis, Partusis Toxioid (PT) 2.5 mcg Filamentous Haemagglutinin (HFA) 5 mcg, Perfaction (PRN) 3 mcg Fimbriae Types 2 and 3 (FIM) 5 mcg	Adsorbed Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine is indicated for active booster immunization against tetanus, diphtheria and pertussis as a single dose in individuals 11 through 64 years.	**Contraindications:** **Hypersensitivity** A severe allergic reaction (eg, anaphylaxis) after a previous dose of any tetanus toxoid, diphtheria toxoid or pertussis containing vaccine or any other component of this vaccine is a contraindication to administration of DPT vaccine. Because of uncertainty as to which component of the vaccine may be responsible, none of the components should be administered. Alternatively, such	New	USFDA	ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক অনুমোদনের জন্য সুপারিশকৃত।	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

				individuals may be referred to an allergist for evaluation if further immunizations are to be considered. **Encephalopathy** Encephalopathy (eg, coma, prolonged seizures, or decreased level of consciousness) within 7 days of a previous dose of a pertussis containing vaccine not attributable to another identifiable cause is a contraindication to administration of any pertussis containing vaccine. **Side Effects:** DPT vaccine has not been associated with any serious side effects. However, redness, swelling and pain may occur at injection site. These usually start within one day after the vaccination and last from one to three days. Mild to moderate systemic reactions occur frequently following injections of this vaccine. These usually consist of one or more of the following symptoms and signs: temperature elevation 38°C, drowsiness, fretfulness, anorexia, vomiting, irritability, lymph node swelling, Diarrhea, persistent or unusual crying. These symptoms are most frequent during the first 24 hours following vaccine injection and may persist for one to two days.					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Incepta Vaccine Limited	c) Rabies Immune Globulin 1500 IU/ 5 ml Injection Rabies Immune globulin USP (as Equine anti rabies immune Globulin fragments) is supplied as 5 ml liquid preparation contains: Equine Anti Rabies Immune Globulin fragments not less than 300 IU/ml.	Rabies Immune globulin USP (as Equine anti rabies immune globulin fragments) provides passive immunization against rabies for prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or an animal presumed to be rabid. Rabies Immune globulin USP (as Equine anti rabies immune globulin fragments) itself does not constitute an anti rabies treatment and should always be used in conjunction with rabies vaccine.	**Contraindications:** Rabies Immune Globulin should be used with extreme caution in subjects with a history of allergic symptoms or hypersensitivity to equine serum **Side Effects:** None	New	Sanofi Pasteur SA, France Bharat Serums and Vaccines Ltd.	ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক অনুমোদনের জন্য সুপারিশকৃত|	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	GlaxoSmithKline Biologicals SA, Belgium (GlaxoSmithKline Bd. Ltd.)	a) Nimenrix Vaccine 1vial Lypholised powder + 1prefilled syringe with solvent Neisseria Meningititis group A polysaccharide 5 mcg + Neisseria meningitides group C polysaccharide 5 mcg + Neisseria meningitides group W-135 polysaccharide 5 mcg + Neisseria meningitides group Y polysaccharide 5 mcg + Conjugated to tetanus toxoid carrier protein 44 mcg/dose	Active immunization of individuals from 12 months of age against invasive meningococcal diseases caused by Neisseria *meningitides serogroups A, C, W-135 and Y*	**Contraindications:** It should not be administered to subjects with hypersensitivity to the active substances or to any of the excipients contained in the vaccine. **Side effects**: **Very common:** appetite lost, irritability, drowsiness, headache,fever,swelling, pain and redness at injection site, fatigue **Common:** gastrointestinal symptoms (including diarrhoea, vomiting and nausea), injection site haematoma **Uncommon:** insomnia, hypoaesthesia, dizziness, pruritus, rash, myalgia, pain in extremity, malaise, injection site reaction	EMA		ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক অনুমোদনের জন্য সুপারিশকৃত।	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	GlaxoSmithKline Biologicals SA, Belgium (GlaxoSmithKline Bd. Ltd.)	b) Priorix-Tetra Vaccine 1 vial with lypholised powder+1P.F.S with diluent+needle Live attenuated measles virus (Schwarz strain) Ph. Eur not les than $10^{3.0}CCID_{50}$ + Live attenuated mumps virus (RIT 4385 strain) Ph. Eur not les than $10^{4.4}CCID_{50}$ + Live attenuated rubella virus (Wistar RA 27/3 strain) Ph. Eur not les than $10^{3.0}CCID_{50}$ + Live attenuated varicella virus (OKA strain) Ph. Eur not les than $10^{3.3}$PFU/Dose(0.5ml)	Indicated for active immunization in subjects from the age of 9 months onwards up to 12 years of age inclusive against measles, mumps, rubella and varicella.	**Contraindications:** ● Subjects with known hypersensitivity to neomycin or to any other component of the vaccine (for egg allergy) ● Subjects having shown signs of hypersensitivity after previous administration of measles, mumps, and rubella and/or varicella vaccines. ● Pregnant females; Pregnancy should be avoided for three months after vaccination ● subjects with impaired immune function. These include patients with primary or secondary immuno deficiencies **Side effects:** **Very common:** pain and redness at the injection site, fever (rectal ³38°C - £39.5°C; axillary/oral: ³37.5°C - £39°C)* **Common:** irritability, rash, swelling at the injection site, fever (rectal >39.5°C; axillary/oral >39°C)* **Uncommon:** upper respiratory tract infection, lymphadenopathy, parotid swelling, anorexia, nervousness, insomnia, rhinitis, diarrhoea, vomiting, lethargy, malaise, fatigue Rare: otitis media, febrile convulsions, cough, bronchitis	EMA		ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক অনুমোদনের জন্য সুপারিশকৃত।	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
02.	Shantha, India (Sanofi-aventis Bangladesh Limited)	a) Shanchol (Suspension for Oral Cholera Vaccine) Glass vial containing 1.5 mL as a single dose. V.cholerae O1, Inaba El Tor strain phil 6973 formaldehyde killed 600 ELISA Unit (EU) of Lipopolysaccharide (LPS) V.cholerae O1, Ogawa classical strain Cairo 50 heat killed 300 EU of LPS V.cholerae O1, Ogawa classical strain Cairo 50 formaldehyde killed 300 EU of LPS V.cholerae O1, Inaba classical strain Cairo 48 heat killed 300 EU of LPS V.cholerae O139, Strain 4260 B formaldehyde Killed 600 EU of LPS	It is indicated for active immunization against vibrio cholerae	**Contraindications:** Immunization with Shanchol should be delayed in the presence of any acute illness, including acute gastrointestinal illness or acute febrile illness. A minor illness such as mild upper respiratory tract infection is not a reason to postpone immunization. **Side effects:** No side effect for oral uses	India	WHO pre-qualifed. IVI, iccdr,b, BPA endorses officially.	ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক নামঞ্জুরের জন্য সুপারিশকৃত।	প্রয়োজন নাই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
03.	Sanofi Pasteur SA France (Sanofi-aventis Bangladesh Limited,	a) Hexaxim, Suspension for Injection 0.5ml Prefillled Syringe Diphtheria toxoid (D) > 20IU Tetanus toxoid (T) >40IU pertussis (pertussis) toxoid 25µg filamentous haemagglutinin 25µg Inactivated poliomyelitis virus types 1- 40D antigen U types 2- 8D antigen U types 3- 32 D antigen U Haemophilus influenza 10 µg type b polysaccharide (polyribosylribitol phosphate) conjugated to tetanus protein (PRP-T) - 12µg Hepatits B surface antigen (HBsAg) 22-36 µg / dose(0.5ml P.F.S)	Indicated for the primary & booster vaccination of infants against Diphtheria, Tetanus, Pertusis, Hepatitis- B, Polio myelitis and Haemophilus infilus influenza type -B	**ContraIndications:** The infant has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. **Side effects:** Hypersensitivity reaction, Anorexia, Abnormal crying, Vomiting, Rash, fever, Encephalopathy/encephalitis	EMA	Infanrix Hexa Vaccine (GlaxoSmithKline Biologocal SA, Belgium)	ভ্যাকসিন বিশেষজ্ঞ কমিটি কর্তৃক অনুমোদনের জন্য সুপারিশকৃত।	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

2.3.5 Proposed Product for Import (Human)

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	Ebewe Pharma Ges.m.b.H, Austria (Novartis Bangladesh Ltd.)	a) Docetaxel HEXAL **2ml vial** Concentrate for solution for infusion (Infusion solutions have to be prepared with either 0.9% sodium chloride or with 5% glucose and administered as an intravenous infusion. The required volume have to be injected into a 250ml infusion bag) Docetaxel BP 10 mg/ ml	It is used for the treatment of Non-small cell lung cancer, Gastric adenocarcinoma and head and neck cancer	**Contraindications:** Hypersensitivity to the active or to the any of the excipients. Docetaxel must not be used in patients with baseline neutrophil count of <1,500 cells/mm3. Docetaxel must not be used in pregnant or breast-feeding women or in patients with severe liver impairement. **Side effects:** Neutropenia, anemia, dyspnea, constipation, anorexia, nausia, vomiting, diarrhoea etc.	Austria, Germany	80 mg/2 ml & 20 mg/0.5 ml Injection	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Docetaxel HEXAL **8ml vial** Concentrate for solution for infusion (Infusion solutions have to be prepared with either 0.9% sodium chloride or with 5% glucose and administered as an intravenous infusion. The required volume have to be injected into a 250ml infusion bag) Docetaxel BP 10 mg/ ml	-do-	-do-	Austria, Germany	80 mg/2 ml & 20 mg/0.5 ml Injection	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
02.	**Manufacturer:** Novartis Pharma AG, Switzerland. **MAH**: Novartis Europharm Ltd., UK. (Novartis Bangladesh Ltd)	a) SeebriBreezhaler Inhalation Powder, Hard Capsule Glycopyrronium Bromide INN 63 mcg eq. to Glycopyrronium 50 mcg (44 mcg/puff)	It is indicated as once daily maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD)	**Contraindications:** Hypersensitivity to the active substance or to lactose monohydrate & magnesium stearate. **Side effects**: Dry mouth, Insomnia & Gastroenteritis	EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
03.	**Manufacturer:** Novartis Pharma Produktions GmbH, Germany. **MAH:** Novartis Europharm Ltd., UK. (Novartis Bangladesh Ltd)	a) Galvus Met Film-coated tablet Vildagliptin INN 50 mg+Metformin HCl BP 1000 mg	Treatment of type 2 diabetes mellitus patients who are unable to achieve sufficient glycemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets	**Contraindications:** Known hypersensitivity to vildagliptin or metformin hydrochloride or to any of the excipients, renal dysfunction should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials. **Side effects:** Dizziness, headache & Nausea.	EMA	50 mg/500 mg & 50mg/850 mg	প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
04.	**Manufacturer:** Novartis Farmaceutica SA, Spain. **MAH:** Novartis Europharm Ltd., UK. (Novartis Bangladesh Ltd)	a) Exforge HCT 5 mg/160mg/12.5mg Film-coated tablet Amlodipine Besilate BP 6.94 mg(eqv. to 5 mg Amlodipine) + Valsartan USP 160 mg + Hydrochlorothiazide USP 12.5 mg)	It is used for the treatment of essential hypertension	**Contraindication:** Known hypersensitivity to the components of this product or to sulfonamide derivatives, pregnancy, anuria, concomitant use with aliskiren in diabetic type II patients. **Side effects:** Headache, dizziness, abdominal pain & nausea	EMA		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Exforge HCT 10 mg/160mg/12.5mg Film-coated tablet Amlodipine Besilate BP13.88 mg (eqv. to 10 mg Amlodipine) + Valsartan USP 160 mg + Hydrochlorothiazide USP 12.5 mg)	-do-	-do-	-do-		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
	Manufacturer: Novartis Farmaceutica SA, Spain. **MAH:** Novartis Europharm Ltd., UK. (Novartis Bangladesh Ltd)	c) Exforge HCT 5 mg/160mg/25mg Film-coated tablet Amlodipine Besilate BP 6.94 mg (eqv. to 5 mg Amlodipine) + Valsartan USP 160 mg + Hydrochlorothiazide USP 25 mg)	-do-	-do-	-do-		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দেশনা	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
	Manufacturer: Novartis Farmaceutica SA, Spain. **MAH:** Novartis Europharm Ltd., UK. (Novartis Bangladesh Ltd)	d) Exforge HCT 10 mg/160mg/25mg Film-coated tablet Amlodipine Besilate BP 13.88 mg (eqv. to 10 mg Amlodipine) + Valsartan USP 160 mg + Hydrochlorothiazide USP 25 mg)	-do-	-do-	-do-		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		e) Exforge HCT 10 mg/320mg/25mg Film-coated tablet Amlodipine Besilate BP 13.88 mg (eqv. to10 mg Amlodipine) + Valsartan USP 320 mg + Hydrochlorothiazide USP 25 mg)	It is used for the treatment of essential hypertension	**Contraindication:** Known hypersensitivity to the components of this product or to sulfonamide derivatives, pregnancy, anuria, concomitant use with aliskiren in diabetic type II patients. **Side effects:** Headache, dizziness, abdominal pain & nausea	It is used for the treatment of essential hypertension		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
05.	Made for F. Hoffmann La Roche Ltd., Switzerland by Roche SpA, Italy (Roche Bangladesh Ltd)	a) Zelboraf 240 mg Tablet Vemurafenib INN 240 mg	Zelboraf is indicated as monotherapy for the treatment of adult patients with BRAF (BRAF is a human gene that makes a protein called B-Raf) V600 mutation positive unrespectable or metastatic melanoma	**Contraindications:** None **Side effects: Side** effects of Zelboraf include: diarrhea, constipation, decreases appetite, cough, peripheral oedema, fatigue, asthenia, pyrexia, headache, taste disturbance, bells palsy, folliculitis, arthralgia, myalgia, pain in extremities, musculoskeletal pain, arthritis, uveitis, seborrhoeic actinic keratosis, keratosis pilaris, skin papilloma, cutaneous squamous cell carcinoma, basal cell carcinoma, photosensitivity reactions, hyperkeratosis, erythema, alopecia, dry skin, palmar-plantar erythrodysaesthesia, erythema nodosum; less commonly vasculitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, hyper sensitivity reaction, QT-interval prolongation and new primary melanoma also reported.	Switzerland EMEA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
	Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland by Roche Diagnostics GmbH, Mannheim, Germany	b) Perjeta Vials 420 Concentrate Solution for infusion 420mg/14 ml vial (dilute with250ml 0.9% Nacl) Pertuzumab INN 420mg/Vial(30mg/ml)	Perjetainjection for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	**Contraindication:**None **Side effects**: The Most Common (>30%) advers in patients receiving pertuzumab in combination with Trastuzumab and docetaxel, neutropenia, nausea, fatigue, rase, and peripheral neuropathy. The most common (>2%)NCL – CTCAE(verson 3) Grade 3-4 advers reactions were Neutropenia, febrile neuropenia , leukopenia, diarrhea, peripheral , neuropathy, anemia, asthenia, and fatigue. Other significant adverse reactions reported with pertuzumab include left ventricular dysfunction, infution – associated reactions, hypersensitivity reaction and anaphylaxis. Pertuzumab in combination with trastuzumab and anaphylaxis. Pertuzumab in combination with trustuzumab and docetaxel was not associated with increases in the incidence of symptomatic left ventricular systolic dysfunction (LVSD) or decreases in left ventricular ejection fraction (LVEF) compared with placebo in combination with trastuzumab and docetaxel.	Switzerland EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
06.	Catalent Germany Schorndorf GmbH, Germany (GlaxoSmithKline Bd Ltd.)	a) Duodart Capsule 0.5mg/0.4 mg Dutasteride INN 0.5 mg & Tamsulosin hydrochloride INN 0.4 mg **Drugs for Urinary Retention**	For the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate	**Contraindication:** **K**nown hypersensitivity to dutasteride, other 5 – alpha-reductase inhibitors, tamsulosin hydrochloride or any component of the preparation.Also contraindicated for use in women and children **Side effects**: Allergic reactions, Diziness, Depressed mood, Impotence	Germany		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
07.	Glaxo Operations UK Ltd., UK (GlaxoSmithKline Bd Ltd.)	a) Votrient Tablet 400 mg Pazopanib Hydrochloride INN 433.4 mg eq. to 400 mg Pazopanib	Indicated for the treatment of advanced and/or metastatic renal cell carcinoma (RCC)	**Contraindication:**in patients with hypersensitivity to any of the ingredients. **Side effects**: **Very common:** Decreased appetite; Dysgeusia; Hypertension; Diarrhoea, nausea, vomiting, abdominal pain; Hair colour changes; Fatigue; Increased ALT and AST. **Common:** Thrombocytopenia, neutropenia, leucopenia; Hypothyroidism; Headache, dizziness, lethargy, paraesthesia; Hot flush; Epistaxis, dysphonia; Dyspepsia, stomatitis, flatulence, abdominal distension; Abnormal hepatic function, hyperbilirubinaemia; Rash, alopecia, skin hypo/de-pimentation, erythema, pruritus, dry skin, hyperhidrosis; Myalgia, muscle spasms; Proteinuria	EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
	Glaxo Operations UK Ltd., UK (GlaxoSmithKline Bd Ltd.)	b) Revolade Tablet 50 mg Eltrombopag olamine INN 63.80 mg eq. to 50 mg Eltrombopag	Indicated for the treatment of previously treated patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet counts and reduce or prevent bleeding	**Contraindications:** No known contraindications associated with revolade. **Very common:** Headache. **Common:** Insomnia, paraesthesia, cataract, dry eye, nausea, diarrhoea, constipation, upper abdominal pain, hepatobiliary disorders, rash, pruritus, alopecia, arthralgia, myalgia, muscle spasm, bone pain, fatigue, peripheral oedema. **Other serious side effects include:** bleeding after stopping treatment, high platelet counts, risk of blood clots (uncommon), liver (common) and bone marrow problems (rare).	EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
09.	Amgen Manufacturing Limited, USA (GlaxoSmithKline Bd. Ltd.)	a) Xgeva 120 mg/1.7 ml Injection Denosumab INN 120 mg/1.7 ml (70mg/ml) injection for subcutaneous use.	Indicated for the prevention of skeletal related events in patients with bone metastases from soid tumours.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipient. **Side effects**: **Immune system disorder:** Drug hypersensitivity **Metabolism and nutrition disorders**: Hypocalcaemia, Hypophosphatemia **Respiratory, thoracic and mediastinal disorders:** Dyspnoea **Musculoskeletal and connective tissue disorders:** Osteonecrosis of the jaw	USA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
10.	GlaxoSmithKline Ltd,Italy (GlaxoSmithKline Bd. Ltd.)	Hycamtin 4mg IV infusion Powder for concentrate solution for infusion(4mg vial reconstitute with 4ml of W.F.I diluted appropriate volume of the reconstituted solution either 0.9%Nacl or 0.5%glucose) Topotecan 4mg/17ml (1mg/1ml)	for the treatment of: ● metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. ● small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the Phase III study) or at least 90 days (in the Phase II studies) after chemotherapy HYCAMTIN in combination with cisplatin is indicated for the treatment of patients with histologically confirmed Stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy	**Contraindications:** In patients who have a history of severe hypersensitivity reactions to topotecan and/or its excipients in pregnant or breast-feeding already have severe bone marrow depression prior to starting first course, as evidenced by baseline neutrophils less than 1.5 x 109/L and/or a platelet count of less than100 x 109/L **Side effects: Very common**: Infection, Anaemia, febrile neutropenia, leucopenia, neutropenia, Anorexia, Diarrhoea, nausea and vomiting, abdominal pain, constipation and stomatitis, Alopecia, Asthenia, fatigue, pyrexia **Common:** Sepsis, Pancytopenia, Hyperbilirubinaemia **Rare:** Interstitial lung disease	EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
11.	Genzyme Ireland Limited, Ireland (sanofi-aventis Bangladesh Limited) Station Road, Tongi, Gazipur-1710	a) Renvela Powder of suspension in Sachet Sevelamer Carbonate INN 2400 mg (**Note:** Each sachet to be dispersed in 60 ml water)	Hyperphosphataemia in patients on haemodialysis or peritoneal dialysis and patients with chronic kidney disease not on dialysis who have a serum-phosphate concentrartion of 1.78mmol/liter.	**ContraIndications:** Bowel obstruction **Side effect:** Nausea, vomiting, abdominal pain, diarrhoea, dyspepsia, flatulence, also reported intestinal obstruction and perforation, iloeus, pruritus, rash.	EMA	800 mg Tablet	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
12.	Bayer Pharma AG, Germany (sanofi-aventis Bangladesh Limited) Station Road, Tongi, Gazipur-1710)	a) Fludara 10 mg Film-Coated Tablets Fludarabine Phosphate USP 10 mg	Treatment of B-cell chronic lymphocytic leukaemia (CLL) in patients with sufficient bone marrow reserves.	**ContraIndications:** Haemolytic anaemia **Side effects:** Diarrhoea, anorexia, oedema, pneumonia, cough, peripheral neuropathy, visual disturbance, chils, fever, malaise, weakness, rash	CPP Germany UK	50mg/2ml Injection	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
14	Sanofi-Aventis Deutschland GmbH Germany (sanofi-aventis Bangladesh Limited,)	a) Eloxatin 5 mg/ml concentrate for solution for infusion 10 ml vial Oxaoliplatin INN 5.0mg/ ml	Combination with fluorouracil and folinic acid, for the treatment of metastatic co lorectal cancer and adjuvant treatment of colon cancer after resection of the primary tumour.	**Contraindications:** - have a known history of hypersensitivity to oxaliplatin. - are breast feeding. - have myelosuppression prior to starting first course, as evidenced by baseline neutrophils <2x109/l and/or platelet count of <100x109/l. - have a peripheral sensitive neuropathy with functional impairment prior to first course. - have a severely impaired renal function (creatinine clearance less than 30 ml/min **Side effects:** Allergic reactions, occurring mainly during infusion, sometimes fatal. Common allergic reactions include skin rash, particularly urticaria, conjunctivitis, and rhinitis. Common anaphylactic or anaphylactoid reactions, include bronchospasm, angioeodema, hypotension, sensation of chest pain and anaphylactic shock	CPP Germany	5mg/ml powder for soultio for Injection	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
15	Sanofi-Aventis Deutschland GmbH Bruningstrasse 50 D- 65926 Frankfurt am Main Germany (sanofi-aventis Bangladesh Limited, Station Road, Tongi, Gazipur-1710)	a) Eloxatin 5 mg/ml concentrate for solution for infusion 20 ml vial Oxaoliplatin INN 5.0mg/ ml	Combination with fluorouracil and folinic acid, for the treatment of metastatic co lorectal cancer and adjuvant treatment of colon cancer after resection of the primary tumour.	**Contraindications:** - have a known history of hypersensitivity to oxaliplatin. - are breast feeding. - have myelosuppression prior to starting first course, as evidenced by baseline neutrophils <2x109/l and/or platelet count of <100x109/l. - have a peripheral sensitive neuropathy with functional impairment prior to first course. - have a severely impaired renal function (creatinine clearance less than 30 ml/min) **Side effects:** Allergic reactions, occurring mainly during infusion, sometimes fatal. Common allergic reactions include skin rash, particularly urticaria, conjunctivitis, and rhinitis. Common anaphylactic or anaphylactoid reactions, include bronchospasm, angioeodema, hypotension, sensation of chest pain and anaphylactic shock	Germany	5mg/ml powder for soultion for Injection	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
16.	Organon (Ireland) Ltd., Ireland (Nuvista Pharma)	a) Elonva 100 mcg/0.5 ml Solution for Injection Corifollitropin Alfa INN 100 mcg/0.5 ml	Controlled ovarian stimulation (COS) for the development of multiple follicles and pregnancy in women participating in an assisted reproductive technology (ART) program.	**Contraindications:** Ovarian enlargement or cyst; polycystic ovarian syndrome; tumors of hypothalamus, pituitary, ovaries, uterus, or breast; vaginal bleeding of unknown cause; history of ovarian hyper stimulation syndrome. **Side effect:** nausea; headache, fatigue; ovarian hyper stimulation, pelvic pain, breast pain; less commonly vomiting, abdominal distension and pain diarrhea, constipation, dizziness, ovarian torsion; also reported ectopic pregnancy, miscarriage and multiple pregnancies.	EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Elonva 150 mcg/0.5 ml Solution for Injection Corifollitropin Alfa (Organon) INN 150 mcg/0.5 ml	-do-	-do-	Australia and EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
17	Catalent UK Swindon Zydis Ltd., UK (Nuvista Pharma)	a) Saphris 5 mg Sublingual Tablet Asenapine Maleate INN 7.03 mg eq. to 5 mg Asenapine	Treatment of schizophrenia in adults, Treatment of acute manic or mixed episodes associated with bipolar 1 disorder in adults as monotherapy or in combination with lithium or sodium valproate	**Contraindications:** Patients who are hypersensitive to any component of the wafer or to asenapine. **Side effects:** Test disturbance, tongue swelling, glossodynia, anxiety, speech disturbance, dysphagia, transient oral hypoaesthesia and paraesthesia, rhabdomyolysis.	Australia EMA (Brand name change)		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Saphris 10 mg Sublingual Tablet Asenapine Maleate INN 14.06 mg eq. to Asenapine 10 mg	-do-	-do-	Australia EMEA (Brand name change)		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
18.	BIOCODEX 7 avenue Gallieni 94250 GENTILLY France (Beximco Pharmaceuticals Limited, Tongi, Gazipur.)	a) Bioflor 250 mg Sachet *Saccharomyces Boulardii* 250 mg, Lyophilized cells of *Saccharomyces Boulardii*	Acute Diarrhea, Inflammatory Bowel Disease, Antibiotic-Associated Diarrhea, HIV/AIDS- Associated Diarrhea, recurrent Clostridium difficile Infection	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side Effects:** Occasional flatulence, seldom allergic reaction, isolated cases of fungaemia in patients with central venous catheter.	Switzerland		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত্ম	সভার সিদ্ধামন্ত্ম
	BIOCODEX 7 avenue Gallieni 94250 GENTILLY France (Beximco Pharmaceuticals Limited, Tongi, Gazipur.)	b) Bioflor 250 mg Capsule *Saccharomyces Boulardii* 250 mg, Lyophilized cells of *Saccharomyces Boulardii to one capsule*	Acute Diarrhea, Inflammatory Bowel Disease, Antibiotic-Associated Diarrhea, HIV/AIDS- Associated Diarrhea, Recurrent Clostridium difficile Infection	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Side Effects:** Occasional flatulence, seldom allergic reaction, isolated cases of fungaemia in patients with central venous catheter	Switzerland		প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
19.	Novo Nordisk A/S Novo Allé 2880 Bagsværd Denmark (Novo Nordisk Pharma (Pvt.) Ltd, Bangladesh)	a) Tresiba® FlexTouch® 100 units/ml, solution for injection in pre-filled pen. Insulin degludec (produced in *Saccharomyces cerevisiae* by recombinant DNA technology) 1 ml solution contains 100 units insulin degludec (equivalent to 3.66 mg insulin degludec).	Treatment of diabetes mellitus in adults. To improve glycaemic control in adult patients with diabetes mellitus.	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients **Side effects:** Immune system disorders, Hypoglycaemia, Lipodystrophy, Injection site reactions.	Denmark EMA	300 IU/3ml Pencartidge (Isophane) 300 IU/3ml Pencartidge (Regular) 300 IU/3ml Pencartidge (30/70) 300 IU/3ml Pencartidge (50/50)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Tresiba® Penfill® 100 units/ml, solution for injection in cartridge. Insulin degludec (produced in *Saccharomyces cerevisiae* by recombinant DNA technology) 1 ml solution contains 100 units insulin degludec (equivalent to 3.66 mg insulin degludec).	Treatment of diabetes mellitus in adults. To improve glycaemic control in adult patients with diabetes mellitus.	**Contraindications**: Hypersensitivity to the active substances or to any of the excipients **Side effects** Immune system disorders, Hypoglycaemia, Lipodystrophy, Injection site reactions	Denmark EMA	-do-	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
	Novo Nordisk A/S Novo Allé 2880 Bagsværd Denmark (Novo Nordisk Pharma (Pvt.) Ltd, Bangladesh)	c) Tresiba® FlexTouch® 200 units/ml,solution for injection in pre-filled pen. Insulin degludec (produced in *Saccharomyces cerevisiae* by recombinant DNA technology) 1 mL solution contains 200 units insulin degludec (equivalent to 7.32 mg insulin degludec).	Treatment of diabetes mellitus in adults. To improve glycaemic control in adult patients with diabetes mellitus.	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients **Side effects** Immune system disorders, Hypoglycaemia, Lipodystrophy, Injection site reactions	Denmark EMA	300 IU/3ml Pencartidge (Isophane) 300 IU/3ml Pencartidge (Regular) 300 IU/3ml Pencartidge (30/70) 300 IU/3ml Pencartidge (50/50)	অনুমোদন করা যেতে পারে্	অনুমোদন করা হল।
		d) Ryzodeg® Penfill® 100 units/ml, solution for injection in cartridge. Insulin degludec/insulin aspart (produced in *Saccharomyces cerevisiae* by recombinant DNA technology) 1 ml solution contains 100 units insulin degludec/insulin aspart in the ratio 70/30 (equivalent to 2.56 mg insulin degludec and 1.05 mg insulin aspart).	Treatment of diabetes mellitus in adults. To improve glycaemic control in adult patients with diabetes mellitus.	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients **Side effects :** Immune system disorders, Hypoglycaemia, Lipodystrophy, Injection site reactions	Denmark EMA	-do-	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) Ryzodeg® FlexTouch® 100 units/ml, solution for injection in pre-filled pen. Insulin degludec/insulin aspart (produced in *Saccharomyces cerevisiae* by recombinant DNA technology) 1 ml solution contains 100 units insulin degludec/insulin aspart in the ratio 70/30 (equivalent to 2.56 mg insulin degludec and 1.05 mg insulin aspart).	Treatment of diabetes mellitus in adults. To improve glycaemic control in adult patients with diabetes mellitus.	Hypersensitivity to the active substances or to any of the excipients Immune system disorders, Hypoglycaemia, Lipodystrophy, Injection site reactions	Denmark EMA	-do-	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
20.	Manufactured by : Patheon Inc., Canada Released by : Janssen Cilag SpA, Italy UniHealth Ltd.	a) Zytiga 250mg Tablet Abiraterone Acetate INN 250mg	Abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. The treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Women who are or may potentially be pregnant. Severe hepatic impairment. **Side effects:** Very common: Urinary tract infection, hypokalaemia, hypertension, oedema peripheral. Common: hypertriglyceridaemia , dyspepsia, alanine aminotransferase increased, aspartate aminotransferase increased, rash, haematuria, fractures. Uncommon: adrenal insufficiency.	EMA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
21.	Pfizer Manufacturing Belgium NV, Belgium (Janata Traders)	a) Sayana Perss 104mg/0.65 ml Prefilled Injection Medroxyprogesteron Acetate Ph. Eur 104 mg/0.65 ml Injection (Subcutaneous Injection)	Indicated for long term female contraception.	**Contraindications:** It is contraindicated in patients with a known hypersensitivity to medroxyprogesteron e acetate or any of its excipients. It is contraindicated if pregnancy is known or suspected **Side-effects:** Vaginitis, hypersensitivity reaction weight increased, fluid retention, appetitie increase appetitie decrease, headache, dizziness. Convulsion abdominal pain ache, amenorrhea, breast pain, breast cancer may occur.	Belgium		প্রয়োজনীয় ফ্রিসেল সার্টি ফিকো দাখিলের শর্তে অনুমোদন করা যেতে পারে।	প্রয়োজনীয় ফ্রিসেল সার্টি ফিকেট দাখিলেঃ শর্তে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01	ACI Ltd.	a) Colistin Sulphate 5,00,000IU + Doxycycline 100 mg/gm Powder Colistin Sulphate BP 5,00,000 IU/gm + Doxycycline BP 100 mg/gm	Gastrointestinal and respiratory infections caused by micro-organisms sensitive to doxycycline and/or colistin like Bordetella, Campylobacter, Chlamydia, E. coli, Klebsiella, Haemophilus, Mycoplasma, Pasteurella, Rickettsia, Salmonella, Staphylococcus and Streptococcus spp. in calves, goats, poultry, sheep.	**Contraindications**: Do not use in animals with a previous history of hypersensitivity towards tetracyclines. Do not use in ruminant calves. **Side effects**: Discoloration of teeth in young animals or hypersensitivity reactions may occur. Digestive alterations may appear, such as intestinal dybiosis, accumulation of gases or mild diarrhea.	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Levofloxacin Hemihydrate 10.25gm/100 gm Powder Levofloxacin Hemihydrate USP 10.25gm/100gm	Levofloxacin is indicated in the following bacterial infections: Pneumonia, Acute bacterial sinusitis, Acute and chronic bronchitis, Skin infections, Urinary tract infections and Acute pylonephritis.	**Contraindications**: Fluoroquinolones have had a remarkably good safety record. Because these drugs do not alter the anaerobic flora of the gastrointestinal tract, there is minimal disruption of the intestinal bacterial population even when these drugs are administered orally. **Side effects**: There have been no reports of cutaneous resulting from fluoroquinolones usage in the veterinary.	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Oxytetracycline HCl 32 gm + Neomycin Sulphate 32gm/100 gm Powder Oxytetracycline HCl USP 32gm + Neomycin Sulphate BP 32gm/100gm	Broiler chicken, Broiler breeders: Prevention and treatment of colibaccillosis (E.coli) in the early stages of omphalitis and the housing of birds. in the treatment of nonspecific respiratory infections and bacterial enteritis during exposure to stress like during the application of vaccines, pecking and sudden changes in temparature caused by Pasteurella spp, Salmonella spp, Haemophilus spp. Coadjuvante in the treatment of chronic disease and respiratory salmonella.	**Contraindication**: Do not use in female dairy cattle 20 months of age or older. Do not administer to animals with kidney and/or liver dysfunctions. **Side effects**: Renal dysfunction, neurotoxicity and neuromuscular blockade may occur due to overdose.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দেশনা	Contra-indication & Side-effect	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Ref.	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
2.	Popular Pharmaceuticals Ltd.	a) Ketoprofen 500mg Bolus (Vet) Ketoprofen BP 500mg	Ketoprofen bolus is a potent, non-narcotic, non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-pyretic and anti-inflammatory properties. It is indicated for the alleviation of inflammation and pain associated with arthritis and traumatic musculoskeletal injuries. It is also used for the symptomatic treatment of fever. For acute clinical mastitis Ketoprofen bolus is indicated for the alleviation of fever, pain and inflammation in conjunction with primary therapy, including antimicrobials, and supportive therapy. Ketoprofen bolus is also used in the control of mild to moderate pain associated with colic.	The drug should not be used in animals where hypersensitivity to active ingredient.	400 mg Bolus		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) Ciprofloxacin 0.3gm + Dexamethasone 0.1gm/ Eye Drops (Vet) Ciprofloxacin Hydrochloride BP 0.35gm eq. to Ciprofloxacin 0.3gm + Dexamethasone BP 0.10gm/	It may be used against almost all types of bacterial diseases of eye e.g. Acute and chronic keratitis, conjunctivitis and pink eye, ophthalmitis caused by gram-positive & gram-negative bacteria. It is also indicated in chronic anterior uveities, scleritis, episcleritis, myositis and corneal injury from chemical radiation or thermal burns, or penetration of foreign bodies.	Ciprofloxacin should not be used together with the Chloramphenicol, Macrolides or Tetracycline	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

2.3.7 Proposed Product for Import (Veterinary)

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	Vetpharma Laboratories (S) Pte Ltd., Singapore (Advance Animal Science Co.Ltd.)	a) Amocyn-C Powder (vet) Amoxicillin Trihydrate 100 gm + Potassium Clavulanate 25 gm/Kg	Treatment of infections caused by micro-organisms susceptible to amoxicillin and clavulanic acid combination in poultry : Complex chronic respiratory tract infections Gastro-intestinal tract infections Skin and Soft tissue infections		Singapore		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Auflosyn 10% w/v Injection (Vet) Ofloxacin BP 100 gm /1 Litre	It is a broad spectrum bactericidal quinolone oral solution. It is very effective for the treatment and control of poultry respiratory disease and intestinal infections caused by *E.coli, Salmonella, Pseudomonas Aeruginosa, Enterobacteriaceas, Haemophilus influenza, Pasteurella, Mycoplasma and Staphylococcus.*	**Contraindications:** Do not administer to animal with renal impairment, sensitivity towards Quinolones. **Side effects:** GI disturbance include nausea, vomitting, diarrhea, abdominal pain and dyspepsia.	Singapore		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Vetpharma Laboratories (S) Pte Ltd., Singapore (Advance Animal Science Co.Ltd.)	c) Amisyn 10% W/V Solution (Vet) injection Amikacin Sulfate BP 100 gm / 1 Litre	Amikacin has bactericidal action against Escherichia, B*rucella, Calymmatobacterium, Citrobacter, Enterobacter, Francisella, klebsiella, Proteus, Salmonella, Pasteurella, Pseudomonas, Staphylococcus, listeria, Actinomycetes, and Mycoplasmas.*	**Contraindication :** Do not use for treatment in animals which has a history of hypersensitivity and probably in those hypersensitive to other aminoglycosides.It should be avoided in animals with myasthenia gravis and great care is required in animals with parkinsonism and other condition characterized by muscular weakness. Do not administer in pregnant time. **Side effect:** Reversible nephrotoxicity may occur and acute renal failure has been reported, often in associated with the use of other nephrotoxic drugs.	Singapaore		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
02.	Merial Italia spa Italy (Advance Animal Science Co.Ltd.)	a) Gallimune 208 ND + Flu H9 M.E. Vaccine 1000dose/vial Inactivated Avian Influenza Virus, H9N2 strain, ≥ 10HI.U. + Inactivated Newcastle disease virus, Ulster 2C strain, ≥10HI.Ufr(1) + Thiomersal, at most 0.030 mg ,oi excipient q.s 0.3ml/Dose	Inactivated Vaccine in oily adjuvant against Newcastle disease and avian influenza in poultry		Italy (Not Registered in country of origin beacuse Avian Influenza does not exist)		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
03	Merial,France (Advance Animal Science Co.Ltd.)	a) Gallimune Flu H5N9 Vaccine 1000dose/vial Inactivated Avian Influenza virus, H5N9 strain, , ≥ 10HI.U. + Thiomersal, at most 0.030 mg mg ,oi excipient q.s 0.3ml/Dose	Inactivated vaccine in oil adjuvant against avian influenza in poultry		France (Not Registered in country of origin beacuse Avian Influenza does not exist)		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
04.	Merial Laboratorie Porte des Alpes, France (Advance Animal Science Co.Ltd.)	a) Hatchpak Avinew 1000dose/vial Virus Vivant De La Maladie De Newcastle, Souche VG/GA ... 5.5 a 6,7 $log_{10}DIO_{50}$(*) + Newcastle Disease Virus, VG/GA Strain .... 5.5 to 6.7 Log_{10} EID_{50}//dose	Immunization against Newcastle disease in order to reduce mortality and clinical signs linked to Newcastle infection.	**Side effects:** No general reaction or lesion are observed following the administration of one dose of vaccine If noticed any effect or other effect not mentioned in the leaflet please inform vetiarnaiary surgeon	France		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
05.	KBNP INC , Korea **(Tajarat Animal Care)**	a) HIMMVAC Dalguban BEN Plus Oil Vaccine 500,1000 dose/vial Inactivated virus : IBV strain "M41" BP Min. $10^{8.8}$ EID_{50} (10%) + EDSV strain "K11" Min. $10^{9.3}$ EID_{50} (10%) + NDV strain "KBNP-C4152R2L" Min.$10^{10.8}EID_{50}$ BP (10%)/dose(0.5ml)	For the vaccination of healthy chickens as an aid in the preventing Infectious Bronchitis, Egg drop syndrome and Newcastle Disease. The vaccine is indicated for the vaccination of breeding and laying-type chicken flocks pre-immunized against Newcastle disease with live virus vaccine.	**Contraindications:** Do not vaccinate the animals under the conditions as follows: - Under nutritional disorder or have fever. - Stressed or showing any clinical sign of parasite infection, infectious disease. Immunosuppressive condition caused by infection of fungus or bacterial toxin. **Side effect:** At site of injection a swelling the size of a pea may developed. In the majority of this disappears in 2-3 weeks. Anaphylactic reaction or shock. Temporary reducing of feed intake volume.	Korea		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	KBNP INC , Korea **(Tajarat Animal Care)**	b) HIMMVAC Dalguban N Plus Oil Vaccine 500dose, 1000 dose/vial Inactivated virus NDV Strain "KBNP –C4152R2L" Min 10^{10} EID_{50} BP / dose (0.5ml)	The vaccine is indicated for the vaccination of breeding and laying-type chicken flocks pre-immunized against Newcastle Disease with live virus vaccine.	**Contraindication :** Do not vaccinate the animals under the conditions as follows: - Under nutritional disorder or have fever. - Stressed or showing any clinical sign of parasite infection, infectious disease. Immunosuppressive condition caused by infection of fungus or bacterial toxin. **Side effect:** At site of injection a swelling the size of a pea may developed. In the majority of this disappears in 2-3 weeks. Anaphylactic reaction or shock. Temporary reducing of feed intake volume	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	KBNP INC , Korea **(Tajarat Animal Care)**	c) HIMMVAC Dalguban SG9R Live Vaccine 1000dose, 2000dose/vial **Salmonella galinarum 9R at least 2 x 10^7 CFU BP /dose (0.2ml)**	For the active immunization of healthy chickens against Fowl Typhoid.	**Contraindication :** Do not vaccinate the animals under the conditions as follows: - Under nutritional disorder or have fever. - Stressed or showing any clinical sign of parasite infection, infectious disease. Immunosuppressive condition caused by infection of fungus or bacterial toxin. **Side effect:** At site of injection a swelling the size of a pea may be developed. In the majority of this disappears in 2-3 weeks. Anaphylactic reaction or shock. Temporary reducing of feed intake volume.	Korea		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	KBNP INC , Korea **(Tajarat Animal Care)**	d) HIMMVAC Dalguban N + Live Vaccine (1000 dose, 2000dose/Vial) **Newcastle disease virus KBNP – C4152R2L strain BP Min $10^{6.0}$ EID_{50B} BP /dose**	For the active immunization of healthy chickens against Newcastle Disease	**Contraindication :** Do not vaccinate the animals under the conditions as follows: - Under nutritional disorder or have fever. - Stressed or showing any clinical sign of parasite infection, infectious disease. Immunosuppressive condition caused by infection of fungus or bacterial toxin. **Side effect:** At site of injection a swelling the size of a pea may developed. In the majority of this disappears in 2-3 weeks. Anaphylactic reaction or shok. Temporary reducing of feed intake volume.	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
05.	Samyang Anipharm Co. Ltd. Korea **(Tajarat Animal Care)**	a) Peperoxin sol. 100ml & 500ml Pefloxacin BP 100g (as Peflaxacine methanesulfonate 139.6g) /Liter	Chicken : Treatment of CRD, CCRD, Staphylococcus's, Pullorum disease , Fowl typhoid, and Colibacillosis	**Contraindication:** Do not use laying, breeding period. **Side effects:** Continuous using can occur rash.	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) FORCETIL inj 10ml **Tilmicosin Phosphate BP 300mg/ml**	Treatment & prevention of Bovine Respiratory disease or Bovine pneumonia caused by bacteria Pasturella haemolytica & Pasturella multocida.	**Contra indication :** Do not use for milking cows. **Side effect :** Pain & swelling may occur.			অনুমোদন করা যেতে পারে।	দুগ্ধদানকারী গাভীর জন্য ব্যবহার নিষেধ এ শর্তে অনুমোদন করা হল।
06.	Green Cross Veterinary Co Ltd Korea **(Tajarat Animal Care)**	a) Catovita -inj 100 ml Vitamine B12 BP 0.05mg + Taurine BP 37.3mg + Nicotinamide BP 23mg + DL- Methionine BP 18.7mg + Butaphosphan INN 100 mg / ml	(i) Treatment of acute disease & acute metabolic disorder, slight paralysis, anorexia,. decrease in lactating , (ii) Chronic disease , chronic metabolic disorder, promotion of growth of young animal., nutrition deficiency , (iii) Promotion of vitality & resistance of healthy animal (iv) Poultry : Promotion of feed efficiency , weight , vitality , laying performance, egg-shell quality , decrease of mortality, boost resistance in high stress ,	**Contra indication :** Do not use in laying period. **Side effect :** Rapid IV injection may induce a short lasting fainting.			অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
07.	Green Cross Veterinary Products Co. Ltd., Korea (ACI Ltd.)	a) Rabies Live Vaccine, 1dose/vial, 2 dose/vial, 5 dose/vial, 10 dose/vial & 50 dose/vial Rabies virus (ERA strain) .... More than $10^{3.5}$ LD_{50}/0.03 ml BP /Dose	Prevention of rabies in animals	**Contraindications**: When the animal are under following conditions, avoid or postpone the vaccination, because side effect or poor immune response may be expected: Environmental exchanges like long distance transfer and feed change, Fever, Parasite infection or malfunction & disease signs like cough, diarrhea, dullness, dermatitis etc. **Side Effect**: Reddish color and little pain may occur at the injected site.	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Green Cross Veterinary Products Co. Ltd., Korea (ACI Ltd.)	b) IB1 Live Vaccine 500 & 1000 doses/vial Infectious bronchitis virus (H-120 strain) more than $10^{5.0}$ EID_{50}/Dose + Newcastle disease virus (B1 strain) more than $106.^{5}$ EID_{50} BP /Dose	Active immunization against infectious Bronchitis and Newcastle disease.	**Contraindications**: Do not use in animals of the following conditions, animals that has early history of shock or hypersensitivity associated with this vaccine, animals with fever or malfunction, animal that infected with contagious disease or parasites and animal that immune-suppressed by fungal or bacterial toxin. **Side effects**: Depending on health status of vaccinated flock, vaccine reaction such as anorexia, coughing and sneezing, could be observed. If those things are observed, consult with veterinarian for prescription of antibiotics or nutritional supplements.	Korea		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Green Cross Veterinary Products Co. Ltd., Korea (ACI Ltd.)	c) Newcastle Disease Lasota Live Vaccine 500 & 1000 doses/vial Newcastle Disease Virus (LaSota Strain) more than $10^{5.0}$ EID_{50} BP /Dose	Prevention of Newcastle disease in Chickens	**Contraindications**: Do not use in animals of the following conditions, animals that has early history of shock or hypersensitivity associated with this vaccine, animals with fever or malfunction, animal that infected with contagious disease or parasites and animal that immune-suppressed by fungal or bacterial toxin. **Side effects**: Depending on health status of vaccinated flock, vaccine reaction such as anorexia, coughing and sneezing, could be observed. If those things are observed, consult with veterinarian for prescription of antibiotics or nutritional supplements.	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Green Cross Veterinary Products Co. Ltd., Korea (ACI Ltd.)	d) Infectious Bursal Disease Live Vaccine 500 & 1000 Doses/vial Tissue culture attenuated infectious bursal disease virus BP 20% /Dose	Recommended for prevention of infectious bursal disease in Chickens	**Contraindications**: Do not use in animals of the following conditions, animals that has early history of shock or hypersensitivity associated with this vaccine, animals with fever or malfunction, animal that infected with contagious disease or parasites and animal that immune-suppressed by fungal or bacterial toxin. **Side effects**: Depending on health status of vaccinated flock, vaccine reaction such as anorexia, coughing and sneezing, could be observed. If those things are observed, consult with veterinarian for prescription of antibiotics or nutritional supplements.	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
08.	Biomune Company, USA (ACI Ltd.)	a) Vectormune HVT AIV Vaccine 1000, 2000 & 4000 doses/vial Avian Influenza-Marek's disease vaccine, H5 subtype, Serotype 3, min 3020 PFU's through expiration Cryoprotectant No. 1..55% Cryoprotectant No 2..25% USP / Dose	Recommended for use in day old chicks as an aid in the prevention of avian influenza, due to H5 type viruses and marek's disease caused by Marek's disease virus.	**Contraindications:** No contraindications are known. **Side effects**: Reddish color and little pain may occur at the injected site.	USA		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Vectormune HVT NDV & Rispens Vaccine 1000, 2000 & 4000 doses/vial Marek's disease Newcastle disease virus at least 2474 PFU's through expiration Marek's disease Rispens CV1988 strain at least 1206 PFU's through expiration Cryoprotectant No. 1 + HVT and Rispens CV1988 strains 50-90% Cryoprotectant No 2 10-50% USP /Dose	It is recommended for in ovo vaccination in 18 to 19 days old embryonated eggs and for subcutaneous vaccination in day old chicks as an aid in the prevention of Newcastle disease and very virulent marek's disease.	**Contraindication:** No contraindications are known. **Side Effect**: Reddish color and little pain may occur at the injected site.	USA		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
09.	Ceva Phylaxia Veterinary Biologicals Co. Ltd. Hungary (ACI Ltd.)	a) Cevac Transmune Vaccine 1000, 2000, 2500, 4000 & 5000 doses/vial Avian infectious bursal disease virus strain Winterfield 2512, G-61 min. 0.1 CID_{50} USP /Dose	Active immunization of healthy 18 day old chicken embryos and healthy day old chicks against the disease caused by classical and very virulent strains of infectious bursal disease (IBD) or Gumboro disease virus.	**Contraindications**: It is not recommended to use this vaccine if chicken embryos or day old chicks come from breeder flocks not receiving IBD vaccine before the onset of lay. Chicken embryos less than 18 days old shall not be injected. **Side effects**: Reddish color and little pain may occur at the injected site.	Hungary		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
10.	Intervet International B.V., Netherlands (Bengal Overseas Ltd.)	a) Nobilis Influenza H5 Vaccine 1000,2000doses/vial Avian Influenza Type A, Subtype H5N2 inducing ≥3.32 log_2 HI units /dose	It is used for active immunization of healty poultry as an aid in the prevention of Avian Influenza type A sybtype H5	**Contraindications**: No **Side effects**: In healthy animal no clinical reaction.slight transient reaction at the site of injection.	Netherlands (Not Registered in country of origin)		অনুমোদন করা যেতে পারে।	মাঠ পর্য ায়ে পরী ামূলক ব্যবহারের ফলাফল অসমেন্তাষজনক বিধায় অনুমোদনের সুপারিশ স্থগিত করা হল।
11.	Bioveta, a.s., Czech Republic (Eon Animal Health Products Ltd.)	a) Ornibur Intermediate Plus Vaccine 200,500,1000dose/vial Virus bursitidis infectiosae avium strain IBDV OP-1, min. $10^{4.0}$ $TCID_{50}$ – max. $10^{5.2}$ $TCID_{50}$Ph Eur/dose	Preventive vaccination of chickens from the seventh day of age in flocks endangered with very virulent strains of infectious bursitis virus.	**Contraindications**: Only healthy animals should be vaccinated. Do not use in animas that are showing signs of disease **Side effects**:Not known	Czech Republic		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
	Bioveta, a.s., Czech Republic (Eon Animal Health Products Ltd.)	b) Ornimix Clone B1 + H120 Vaccine 200,500,1000dose/vial Virus bronchitidis infectiosae avium, strain IBV H120 min. $10^{3.0}$ EID_{50} – max. $10^{4.8}$ $EIID_{50}$ + Paramyxovirus pseudopestis avium, strain NDV B1 min. $10^{6.0}$ EID_{50} – max. $10^{7.}$ $EIID_{50}$Ph.Eur/ dose	For active immunization of fowl against Newcastle avian disease and infectious bronchitis of Massachusetts type. For prevention of infection and mortality caused by Newcastle disease virus and by infectious bronchitis virus.	**Contraindications**: Only healthy animals should be vaccinated. Do not use in animas that are showing signs of disease **Side effects**:Not known	Czech Republic		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
13.	Laboratorios Hipra S.A., Spain (Nasco Agro Product)	a) Hipraviar-S Vaccine 1000dose/vial Live Newcastle Disease Virus, strain La Sota $10^{6.5}$ – $10^{8.5}$ EID_{50B}BP/dose	To prevent Newcastle disease.	**Contraindications**: Not in dossier **Side effects:** Respiratory symptoms may occur in vaccinated birds at 5-7days post vaccination**.**	Spain		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Avisan Multi Vaccine 1000dose/bottle Inactivated Infectious bronchitis virus, inactivated, strain H52 .. HAI : 2^{6}-2^{8} + Newcastle disease virus, inactivated, La Sota strain HAI 2^{4}-2^{6} + Egg drop syndrome virus, inactivated, Adenovirus 127 strain HAI 2^{7}-2^{9}/ $_{B}$BP dose(0.5ml)	Active immunization of future layer chicks as of 16 weeks of age for protection against the virus of Newcastle disease, the egg drop syndrome 76 virus and against a drop in production and quality of laying caused by the Massachusetts serotype of Avian infectious bronchitis virus.	**Contraindications**: Not in dossier **Side effects:** Microscopic lession at the injection site (lymphoid proliferation, inflammatory reaction on the day following the administration and the granulomatous inflammation), which disappear by 7days after vaccination.	Spain		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
14.	Shinil Bio-gen Co. Ltd., Korea (Pharma & Firm)	a) Mytil Solution **Tilmicosin Phosphate USP 150 gm/Litre**	For the treatment of the bacterial diseases caused by the below pathogens susceptible to Tilmicosin. Chicken : Mycoplasma gallisepticum and Mycoplasma synoviae	**Contraindications**: Not to be used automatically powered syringes or to be given intravenously as fatalities may result.Tilmicosin has been shown to be fatal in swine (when Injected), non human primates and potentially fatal in horses. **Side effects:** If administered IM, a local tissue reaction may occur resulting in trim loss. Edema may be noted at the site of subcutaneous injection.	Korea	100 gm/Litre & 250 gm/Litre Locally Available	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Shinil Bio-gen Co. Ltd., Korea (Pharma & Firm)	b) Sulfaprim Solution Sulphamethoxazole USP 200 gm + Trimethoprim USP 40 gm/Litre	For the prevention and treatment of the bacterial disease caused by pathogens susceptible to sulfamethoxazole and trimethoprim in swine and poultry. Swine: Pleuropneumoia, Atropin rhiniits, pasterullosis and collibacilosis. Poultry- Collibacilosis, Myco-plasmosis, Haemophilus infection and pasterullosis.	**Contraindication**: Should not be used in dogs and horses showing marked liver parenchymal damage, blood dyscrasias. **Side effect: in Dogs** – vomiting, anorexia, diarrhea, fever, hemolytic anemia, urticaria, facial swelling, poludipsia, polyuria and cholestasis. **In cats** – anorexia, leucopenia and anemias. **In Horses-** diarrhea development in some horses.	Korea	Sulphamethoxazole 200 mg + Trimethoprim 40 mg/ml Solution for Intramuscular Injection	**প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।**	**প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।**
		c) Norfloxacin Combi Solution Norfloxacin USP 45 gm + Sulfamethoxypyridazine 45 gm Ph Eur + Trimethoprim USP 9 gm + Phenylbutazone USP 12.50 gm/Litre	For the prevention and treatment of diseases caused by pathogens susceptible to Norfloxacin, Sulfamethoxypyridazine and trimethoprim Poultry- CRD, Colibacilosis, Salmonellosis and bacterial enteritis.	**Contraindication**: Do not administer to chickens producing eggs for human consumption. Do not combine with Tetracycline or Erythromycin. **Side effects:** Vomiting, diarrhea, dizziness, drowsiness, blurred vision, joint stiffness, or muscle pain. Side effects other than those listed may occur.	Korea		**প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।**	**প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামন্ত	সভার সিদ্ধামন্ত
15.	Dae Sung Microbiological Labs, Korea (Vital BD Ltd.)	a) DS ND Lasota Chicken Vac New Castale Disease virus, La Sota Strain 60% SPGA or skim milk 40% Penicillin 800 IU/ml **Streptomycin Sulfate 3 mg/ml**	For the prevention or decrease of Newcastle Disease in poultry		Korea		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
		b) DS ND Killed Vac. 500,1000,2000,2.500,5000 doses ND Virus (Lasota Strain of Choriollantonic fluid ad aminotic fluid 40% Formalin 0.1% Saline 26.6% Aluminium Hydroxide Gel 33.3%	For the prevention or decrease of Newcastle Disease in poultry		Korea		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
16.	Dong Bang Co. Ltd. Korea Planet Pharma, Dhaka	a) Dino Plus 10ml vial Cloprostenol Sodium BP 250 mcg/ml solution for injection	It is induces luteolysis of functional corpora lutea with return to oestrus in most cows in 2-4 days	**Contraindications:** Do not use in pregnant animal when abortion or induced parturition is not the objective. Do not administer intravenously. Do not use in mares suffering from acute or sub acute disorders of the gastrointestinal or respiratory system. **Side effects:** Induce abortion in pregnant animal.	Korea		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
17.	ICA International Chemicals (Pty) Ltd., South Africa (RDS&T Solution)	a) Virukill Solution Poly Dimethylammonium Chloride BP 120gm/Liter	Disinfectant for Livestock	**NO**	South Africa		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
18.	Merial,INC USA Advance Animal Science Co. Ltd.	a) Recombitek C4 Vaccine 25x1mlvialwith 25x1ml sterile water diluen **Each dose of vaccine contains:** Canary Pox/Canine distemper virus recombinant, at least $10^{6.4}CCID_{50}$ Canine adenovirus (CAV2), at least $10^{4.3}CCID_{50}$ Canine parvovirus, at least $10^{3.3}CCID_{50}$ Parainfluenza type 2 virus, at least $10^{3.9}CCID_{50}$ Gentamicin, at most 30 mcg/ml	Prevention against canine distemper, adenoviruses, parvovirosis & parainfluenza type 2 respiratory infection in dog.	**Contraindication:** None **Side effect & Toxicity :** Vaccine may exceptionally reveal a state of hypersensitivity. In such case symptomatic treatment should be provided.	USA		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
		b) Purevax Feline 4 Vaccine 10x1ml,25x1m lwith10x1ml,25x1ml diluents **Each dose of vaccine contains:** Feline Rhinotracheitis Virus, at least $10^{4.9}TCID_{50}$ Calicivirus, at least $10^{4.7}TCID_{50}$ Panleukopenia virus, at least $10^{4.0}TCID_{50}$ Chlamydia Psittaci, at least $10^{2.5}ELD_{50}$	For prevention against feline rhinotracheitis, calci, panleukopenia & Chlamydia psittaci disease in cat.	**Contraindications:** None **Side effect & Toxicity:** Vaccine may cause inflammatory or hypersensitivity reaction.	USA		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**
		c) Trovac AIV H5 Vaccine 1000dose /vial 2000d0se/vial **Each dose of vaccine contains:** Fowl pox vectored avian influenza recombinant virus, strength $\geq 10^{2.2}TCID_{50}$	To prevent avian influenza (H5) and fowl pox infection in poultry	**Contraindication:** None **Side effect & Toxicity :** None	USA		**প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।**	**প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
19.	Vetpharm Laboratories (S) Pte. Ltd., Singapore Advance Animal Science Co. Ltd.	a) Caninethic Plus Tablet Febantel 150 mg + Pyrantel Pamoate 150 mg + Praziquantel 50 mg	Remedy for roundworm and tapeworm in dogs	**Contraindications:** It should not be used during the first two third of gestation, should be used strictly in accordance with dosage and should not be administered concurrently with other antihelminthics. **Side effects:** Adverse effect with caninethic plus may be common but usually mild and transient. Headache, diarrhea, dizziness, drowsiness, malaise, abdominal discomfort, nausea and vomiting have been reported most frequently. Hypersensitivity reactions such as fever, urticaria, pruritic skin rashes and eosinophilia can occur.	Singapore		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
	Vetpharm Laboratories (S) Pte. Ltd., Singapore Advance Animal Science Co. Ltd.	b) Amisyn-C 120 Water Soluble Powder Each 1000 gm contains: Amikacin Sulfate 120 gm + Colistin Sulfate 2500 MIU	Treatment of infections caused by severe gram negative microorgaism susceptible to amikacin sulfate and colistin sulfate combination in poultry. Use also when infections are resistant to other aminoglycosides, Salmonellosis, Collibacillosis, Pasteurellosis	**Contraindications:** Do not use for treatment in animals which has a history of hypersensitivity and probably in those hypersensitive to other aminoglycosides. It should be avoided in animals with myasthenia gravis, and great care is required in animals with parkinsonism and other conditions characterized by muscular weakness. Do not administer in pregnant time. **Side effects:** Can produce irreversible cumulative ototoxicity affecting both the cochlea and the vesitibular system. Reversible nephrotoxicity may occur and acute renal failure has been reported. Electrolyte disturbances have occurred. Neurotoxicity has occurred with both peripheral neuropathies and central symptoms being reported including encephalopathy, confusion, lethargy, hallucinations, convulsion, and mental depression.	Singapore		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
20.	Samu Median Co. Ltd., Korea (Dream Trading Corporation)	a) Genta LA Injection (50 ml Vial) Gentamicin Sulfate USP 250 mg/ml	Cattle : for treatment of mastitis, endometritis, cystitis, nephritis, dermatitis, shipping fever, brucellosis, hemorrahagic septicemia, bacterial diarrhea and various bacterial disease Swine : for treatment of neonatal diarrhea, dysentery, pneumonia, enteritis, erysipelas, coli-diarrhea, salmonella diarrhea, atrophic rhinitis and various bacterial disease. Chicken : for treatment of CRD, CCRD, infectious coryza, colibacillosis, staphylococcosis, bacterial diarrhea and various bacterial disease.	**Contraindications:** Not to contact with eyes and skin at the time of handing and if contacted, wash immediately with clean water. **Side-effects:** Use of over dosage than recommended or by unapproved routes of administration may result in illegal residues in edible tissues and/or in milk	Korea		অনুমোদন করা যেতে পারে।	**অনুমোদন করা হল।**

2.3.8 Proposed Product for Import (Medical Devices & Others)

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শনা	Contraindication & Side-effect	FSC/CPP	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	Genzyme Biosurgery , USA (Sanofi-aventis Bangladesh Limited)	a) Synvisc- One Hylan G-F 20 Hylan G –F 20 8.0 mg/ ml 6ml /10ml borosilicate glass syringe	Relieves pain caused by osteoarthritis of the knee	**Contraindications:** •If venous or lymphatic stasis is present in the relevant limb, Synvisc- One should not be injected into the joint. • Synvisc- One should not be used in infected or severely inflamed joints or in patients having skin diseases or infections in the area of the injection site. **Side-effect:** Rash, hives, itching, fever, nausea, headache, dizziness, chills, muscle cramps, paresthesia, peripheral oedema. malaise, respiratory difficulties, flushing, and facial swelling.	USA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	পদটির প্রয়োজনীয়তা বিবেচনা করে অনুমোদন করা হল।
		b) Seprafilm 5" x 3" (12.7 x 7.62 cm) Seprafilm® Adhesion Barrier (membrane) is a sterile, bioresorbable, translucent adhesion barrier composed of two anionic polysaccharides, sodium hyaluronate (HA) and carboxymethylcellulose (CMC). Together, these biopolymers have been chemically modified with the activating agent 1-(3-dimethylaminopropyl) -3-ethylcarbodiimide hydrochloride (EDC).	Indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder.	**Contra indications:** There are no known contraindications associated with the uses of Seprafilm. **Side effect:** The placement of Seprafilm under the abdominal wall incision did not affect wound healing or surgical site infection rates. In addition, there was no statistical difference between groups in the incidence of either abdominopelvic abscess or pulmonary embolism.	USA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	পদটির প্রয়োজনীয়তা বিবেচনা করে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
02.	B.Braun Surgical S.A., Rubi (Barcelona), Spain (Asia Pacific Medicals Ltd.)	a) Safil Multifilament aborable synthetic PGA suture	Use in all surgical intervention	**Side effects**: May cause allergic and inflammation	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Novosyn Multifilament aborable synthetic PGLA suture	Use in all surgical intervention	**Side effect**: May cause allergic and inflammation	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Premilene Monofilament non Absorbable Polypropylene suture	Use as Skin closer(intra/sub/skin) in Cardiac Surgery,Hernia repair.	**Side effect**: May cause allergic and inflammation	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		d) Monoplus Monofilament absorbable synthetic PDO (Polydioxanone) suture	Use in all surgical intervention	**Side effect**: May cause allergic and inflammation	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শনা	Contraindication & Side-effect	FSC/CPP	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
03.	B.Braun Melsungen AG, Germany (Asia Pacific Medicals Ltd.)	a) Perifix Catheters for epidural Anesthesia	Use in epidural Anesthesia	**Side effect**: May cause allergic and inflammation	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Pencan (25Gx1" 0.5x25mm) Needle for Spinal anesthesia	Use in Spinal Anesthesia	**Side-effect**: May cause allergic and inflammation	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Spinocan (18Gx3" 1./3x75mm) Needle for Spinal anesthesia	Use in Spinal Anesthesia	**Side effect**: May cause allergic and inflammation	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
04.	Yongcheng City Science and Technology Development Factory, China (Suntouch Trading)	a) Suncon Medical Adhesive A homologue of ά-cyanoacrylate	Suncon Medical Adhesive is intended for application to bond approximated skin edges of wounds from surgical incisions and thoroughly cleansed lacerations, as well as to repair ruptured internal organs, sinus tracts, and fractured bones, where suture procedures could be difficult to apply.	***Contraindications:*** Do not use on wound of active infection, gangrene, or wounds of decubitus etiology. Do not use on mucosal surfaces or across mucocutaneous junctions. Do not use on patients with a known hypersensitivity to cyanoacrylate. Do not use on patients suffering gross obesity	China	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	পদটির প্রয়োজনীয়তা বিবেচনা করে অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Contraindication & Side-effect	FSC/CPP	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
05.	S.AAlcon Couvreur N.V Belgium Globex Marketing Co Ltd	a) DisCoVisc ™ Opthalmicviscosurgical Device Sodium Hyaluronate BP 16.5 mg/ 1 ml syringe	DisCoVisc (OVD) is indicated for use during surgery in the anterior segment of the eye. It is designed to create and maintain space, to protect the corneal endothelium and other intra-ocular tissues and to maipulate tissues during surgery. It may also be used to coat intraocular lenses and instruments during cataract extraction and IOL insertion	**Contraindications:** At present, there are no known contraindications to the use of DisCoVisc (OVD). **Side effects:** DisCovisc ophthalmic Viscosurgical Device (OVD) was very well tolerated in nonclinical and clinical studies. A transient rise in intraocular pressure may be expected due to the presence of sodium hyaluronate, which has been shown to effect such a rise. Other events which have been reported infrequently with use of viscoelastics in intra-ocular surgical procedures include postoperative inflammatory reaction, infection and corneal edema/cloudiness. Their relationship to use of viscoelastics has not been established	Belgium USA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
06.	Aeon Astron Europe B.V., The Netherlands GM Healthcare Pvt. Ltd.	a) Ologen Collagen Matrix Collagen Matrix	Glaucoma: Ologen Collagen Matrix is primary designed to create the subconjuctival space and modulate the wound healing physiologically for trabeculectomy, non-penetrating deep sclerotomy, bleb revision of drainage implantation surgery. The host tissue collagen matrix interaction may optimize and stabilize the structure and composition of ocular tissues, creating a mature bleb structure and prevent scar formation.	**Side effects** : N/A **Contraindications** : Ologen Collagen Matrix is contraindicated in patients with known hypersensivitivy to porcine collagen	EMEA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শনা	Contraindication & Side-effect	FSC/CPP	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
07	Nipro Corporation 3-9-3 Honjo-Nishi, Kita-Ku Osaka, Japan (JMI Hospital Requisite Mfg. Limited)	a) Single Patient Dialysis Machine SURDIAL-55 Haemo dialysis machine	Use for Dialysis		Japan	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Single Patient Dialysis Machine SURDIAL-55 Plus Haemo dialysis machine	Use for Dialysis		Japan	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Single Patient Dialysis Machine DIAMAX Haemo dialysis machine	Use for Dialysis		Japan	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
08	Nipro Diagnostic Inc, USA (JMI Hospital Requisite Mfg. Limited)	a) TRUEbalance Blood Glucose Monitoring System Blood Glucose measuring device	To measure the blood glucose		USFDA export certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) TRUEresult Blood Glucose Monitoring System Blood Glucose measuring device	To measure the blood glucose		USFDA export certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) TRUEresult twist Blood Glucose Monitoring System Blood Glucose measuring device	To measure the blood glucose		USFDA export certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		d) TRUEresult Blood Glucose test Strips Blood Glucose test Strips	To measure the blood glucose		USFDA export certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		e) TRUEbalance Blood Glucose test Strips Blood Glucose test Strips	To measure the blood glucose		USFDA export certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শনা	Contraindication & Side-effect	FSC/CPP	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
09	Nipro Thailand Corporation Ltd., Thailand (JMI Hospital Requisite Mfg. Limited)	a) Arterial Venous Fistula Needle Venous Fistula Needle	To transfer blood from body to dialysis machine		Thailand	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
10	Nipro Corporation 3-9-3 Honjo-Nishi, Kita-Ku Osaka, Japan (JMI Hospital Requisite Mfg. Limited)	a) Synthetic Hollow Fiber Dialyzer Hollow Fiber Dialyzer	Use as artificial Kidney during dialysis.		Japan	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		b) Polyethersulfone Hollow Fiber (PUREMA) Dialyzer Hollow Fiber Dialyzer	Use as artificial Kidney during dialysis.		Japan	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		c) Triacetate Hollow Fiber Dialyzer Hollow Fiber Dialyzer	Use as artificial Kidney during dialysis.		Japan	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
11	Shandong Zibo ShanChuan Medical Instrument Co. Ltd., China Hossain Traders, Dhaka	a) Infusion Sets with Burette Infusion Sets with Burette			China	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

৩। নিমণবর্ণি ত Dutasteride 0.5 mg & Tamsulosin 0.4 mg Capsule ঔষধটির Safety, Efficacy and Usefullness এর বিষয়ে মতামতসহ প্রতিবেদন প্রদানের জন্য ঔষধ নিয়ন্ত্রণ কমিটির ২৪০ তম সভায় (১) অধ্যাপক এম এ সালাম, ইউরোলজি বিভাগ, বঙ্গবন্ধু শেখ মুজিব মেডিকেল বিশ্ববিদ্যালয়, (২) মেজর জেনারেল এইচ আর হারুন্নন, কনসালটেন্ট সার্জন, বাংলাদেশ আর্মি, ডিজিএমএস অফিস, ঢাকা ক্যান্টনমেন্ট এবং (৩) অধ্যাপক আনোয়ারুল ইসলাম, ইউরোলজি বিভাগ, বঙ্গবন্ধু শেখ মুজিব মেডিকেল বিশ্ববিদ্যালয় এর সম্বনয়ে একটি কমিটি গঠন করা হয়। উক্ত কমিটি ঔষধটি সম্পর্কে নিমণবর্ণি ত মতামত প্রদান করিয়াছেঃ

1. Several research works studied the effectiveness and safety of the combination of the Dutasteriod 0.5 mg and Tamsulosin 0.4 mg in a single capsule presentation and found it to be safer and more effective than that of any single molecule inpatients with LUTS from BPH.
2. The Urologists of Bangladesh have already been practicing the combination therapy using the drugs as separate capsules.
3. FDA of US Government has approved the Dutasteride 0.5 mg and Tamsulosin 0.4 mg in a single capsule presentation combination in June 14th 2010
4. Currently the Dutasteriod 0.5 mg and Tamsulosin 0.4 mg in a single capsule presentation combination is available all over the world.

Considering the above facts, the committee recommends the combination of Dutasteriod 0.5 mg and Tamsulosin 0.4 mg in a single capsule presentation.

The committee also emphasizes on the fact that the manufacturers should follow the appropriate manufacturing technology to ensure and preserve the efficacy and quality of both of the pharmaceutical product.

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দে শন	Status (New Molecule/ Existing)	আবেদনকারী প্রদত্ত BNF or USFDA Reference	টেকনিক্যাল সাব-কমিটির ৫৭ তম সভার মতমত	
	Ziska Pharmaceuticals Ltd.	a) **Dutasteride 0.5 mg & Tamsulosin 0.4 mg Capsule** Dutasteride INN 0.5 mg & Tamsulosin hydrochloride INN 0.4 mg **Drugs for Urinary Retention**	For the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

3.1 ঔষধ নিয়ন্ত্রণ কমিটির ২৪১ তম সভার সিদ্ধামত্ম মোতাবেক পুনর্মূল্যায়নের জন্য উপস্থাপন করা হইলঃ

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনিরিক নাম	নির্দে শন	Status (New Molecule/Existing)	আবেদনকারী প্রদত্ত USFDA or MHRA Reference	টেকনিক্যাল সাব-কমিটির ৫৯ তম সভার সিদ্ধামত্ম	সভার সিদ্ধামত্ম
01.	Sun Pharmaceutical (Bangladesh) Ltd.	1) **Dapoxetine 30 mg Tablet** Dapoxetine Hydrochloride INN 33.60 mg eq. to Dapoxetine 30 mg **Selective Serotonin Reuptake Inhibitor**	Treatment of premature ejaculation in men 18-64 years	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		2) **Dapoxetine 60 mg Tablet** Dapoxetine Hydrochloride INN 67.20 mg eq. to Dapoxetine 60 mg **Selective Serotonin Reuptake Inhibitor**	Treatment of premature ejaculation in men 18-64 years	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
		3) **Pregabalin 75 mg Extended Release Tablet** Pregabalin INN 75 mg	Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.	25mg, 50, 75 mg, 100mg, 150mg, 300 mg capsule		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
02.	Sharif Pharmaceuticals Ltd.	1) **Racecadotril 100 mg Capsule** **Racecadotril INN 100 mg**	Acute symptomatic watery diarrhoea	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
03.	Beximco Pharmaceuticals Ltd.	1) **Vitamin C 1000mg + Zinc 10mg Chewable Tablet** **Ascorbic Acid USP 1030.928 eqv. to Vitamin C 1000 mg + Zinc Sulfate Monohydrate USP 27.500 mg eq. to Zinc 10 mg**	This formulation is indicated - Increased risk with respect to infectious Disease, Colds. To meet a higher requirement for vitamin C and Zinc, for example in smokers, in infectious disease or wound healing.	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

৪। **টেকনিক্যাল সাব-কমিটির বিবিধ আলোচনাঃ**

মেসার্স রেডিয়েন্ট বিজনেস কনসোর্টি য়াম লিমিটেড প্রতিষ্ঠানটLatex Condom নামীয় পদটি M/s Unidus Corporation, China হতে আমদানীর নিমিত্তে রেজিস্ট্রেশনের জন্য আবেদন করেছে।

দেশে বিদেশ হতে ঔষধ প্রশাসন অধিদপ্তরের অনুমোদনবিহীন আমদানীকৃত বিভিন্ন প্রকারের Condom অনিয়ন্ত্রিতভাবে বিক্রয় হচ্ছে। জন্ম নিয়ন্ত্রণের লক্ষ্যে ব্যবহৃত আমদানীকৃত সকলপ্রকার Condom-এর নিরাপত্তা বিধান করা আবশ্যক। অনুমোদনবিহীন Condom ব্যবহারে স্বাস্থ্য ঝুঁকি থাকে। দেশে M/s Essential Drug Company Limited নামীয় প্রতিষ্ঠান Condom জাতীয় পদটি শুধুমাত্র Family Planning এ সরবরাহের নিমিত্তে উৎপাদন করে থাকে।

উক্ত পদটির ব্যাপক চাহিদার পরিপ্রেক্ষিতে রেডিয়েন্ট বিজনেস কনসোর্টি য়াম লিমিটেড কর্তৃক রেজিস্ট্রেশনের জন্য আবেদিত পদটির বিষয়ে টেকনিক্যাল সাব-কমিটির সদস্যগণ বিসত্মারিত আলোচনা শেষে রেজিস্ট্রেশন প্রদানের প ÿ ÿ মত প্রকাশ করেন।

টেকনিক্যাল সাব-কমিটির সুপারিশঃ মেসার্স রেডিয়েন্ট বিজনেস কনসোর্টি য়াম লিমিটেড কর্তৃক আবেদিত M/s Unidus Corporation, China এর Latex Condom নামীয় পদটি আমদানীর নিমিত্তে রেজিস্ট্রেশন প্রদান করা যেতে পারে।

বিষয়টির উপর বিসত্মারিত আলোচনাক্রমে টেকনিক্যাল সাব-কমিটির সুপারিশ অনুমোদন করা যেতে পারে বলে সদস্যগণ মত প্রকাশ করেন।

সভার সিদ্ধামত্মঃ টেকনিক্যাল সাব-কমিটির সুপারিশ অনুমোদন করা হল।

৫। বিবিধ আলোচনাঃ

৫.১। **ছয়টি ভ্যাকসিন জাতীয় পদের অনুমোদন প্রসঙ্গে।**

সভার আলোচনাঃ ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক সভাকে অবহিত করেন যে, ভ্যাকসিন জাতীয় পদের মূল্যায়নের নিমিত্তে সংশিস্নষ্ট বিষয়ে বিশেষজ্ঞদের সমন্বয়ে স্মারক নং ডিএ/এডমিন-৯৯/১০/৩১৩০, তারিখঃ ১৪/০৩/২০১২ এবং স্মারক নং ডিএ/এডমিন-৯৯/১০/৩১৩১, তারিখঃ ১৪/০৩/২০১২ মোতাবেক যথাক্রমে Expert Committee for Clinical study and Toxicology of Vaccines and Bio-Products এবং Expert Committee for Chemistry and Manufacturing of Vaccines and Bio-Products নামীয় দু'টি কমিটি গঠন করা হয়েছে। বিগত ১০/১০/২০১৩ তারিখে উক্ত কমিটিদ্বয়ের সভা অনুষ্ঠিত হয়। উক্ত সভায় স্থানীয়ভাবে উৎপাদনের জন্য ০৩ (তিন)টি এবং আমদানীর জন্য ০৩ (তিন) টি মোট নিমণবর্ণি ত৬ (ছয়) টি ভ্যাকসিনের যাবতীয় ডকুমেন্টসমূহ পর্য ালোচনা ও মূল্যায়নপূর্ব কঅনুমোদনের জন্য সুপারিশ করা হয়।

Proposed Vaccine for locally manufacture (Unintroduced) :

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Indication	Contra-indication & Side effect	Status (New Molecule/ Existing)	USFDA, BNF or MHRA Reference	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	সভার সিদ্ধামত্ম
03	**Incepta Vaccine Limited**	a) Measles and Rubella Virus Vaccine Live	Each dose of 0.5 ml contains: Live attenuated Measles Virus not less than 1000 $CCID_{50}$ Live attenuated Rubella Virus not less than 1000 $CCID_{50}$	Measles and Rubella Virus Vaccine Live is indicated for simultaneous immunization against measles and rubella in persons 15 months of age or older. A second dose of Measles and Rubella Virus Vaccine Live or monovalent measles vaccine is recommended. Infants who are less than 15 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin; the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunization programs are logistically difficult, and in population groups in which natural measles infection may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 15 months of age. There is some evidence to suggest that infants immunized at less than one year of age may not develop sustained antibody levels when later reimmunized. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization. **Non-Pregnant Adolescent and Adult Females:** Immunization of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed. Women of childbearing age should be advised not to become pregnant for three months after vaccination and should be informed of the reason for this precaution. **Postpartum Women:** It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period. Rubella Vaccine (live) is those expected to follow administration of the monovalent vaccines given	**Contraindications:** • As with other Measles and Rubella Vaccine (Live) should not be administered to subjects with either known hypersensitivity to the active substances or to any of the excipients. • vaccines, the administration of this vaccine should be postponed in subjects suffering from acute severe febrile illness. • Do not give Measles and Rubella Virus Vaccine Live to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination. • Contraindicated to patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease. • Contraindicated to individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems. **Side Effects:** The adverse reactions associated with the use of Measles and Rubella Vaccine (live) is those expected to follow administration of the monovalent	**New**	Serum Institute of India	ডিসিসি এর অনুমোদনের জন্য সুপারিশকৃত	অনুমোদন করা হল।

				separately. The measles vaccine may cause within 24 hours of vaccination mild pain and tenderness at the injection site. In most cases, they spontaneously resolve within two to three days without further medical attention. A mild fever can occur in 5-15% of vaccinees 7 to 12 days after vaccination and last for 1-2 days. Rash occurs in approximately 2% of recipients, usually starting 7-10 days after vaccination and lasting 2 days. The mild side effects occur less frequently after the second dose of a measles containing vaccine and tend to occur only in person not protected by the first dose. Encephalitis has been reported following measles vaccination at a frequency of approximately one case per million doses administered although a causal link is not proven. The rubella component may commonly result in joint symptoms manifested as arthralgias (25%) and arthritis (10%) among adolescent and adult females that usually last from a few days to 2 weeks. However, such adverse reactions are very rare in children and in men receiving MMR vaccine (0%-3%). Symptoms typically begin 1-3 weeks after vaccination and last 1 day to 2 weeks. These transient reactions seem to occur in non-immunes only, for whom the vaccine is important. Low-grade fever and rash, lymphadenopathy, myalgia and paraesthesiae are commonly reported. Thrombocytopenia is rare and has been reported in less than 1 case per 30000 doses administered. Anaphylactic reactions are also rare. Clinical experience has exceptionally recorded isolated reactions involving the CNS. These more serious reactions have however, not been directly linked to vaccination.	vaccines given separately. The measles vaccine may cause within 24 hours of vaccination mild pain and tenderness at the injection site. In most cases, they spontaneously resolve within two to three days without further medical attention. A mild fever can occur in 5-15% of vaccinees 7 to 12 days after vaccination and last for 1-2 days. Rash occurs in approximately 2% of recipients, usually starting 7-10 days after vaccination and lasting 2 days. The mild side effects occur less frequently after the second dose of a measles containing vaccine and tend to occur only in person not protected by the first dose. Encephalitis has been reported following measles vaccination at a frequency of approximately one case per million doses administered although a causal link is not proven. The rubella component may commonly result in joint symptoms manifested as arthralgias (25%) and arthritis (10%) among adolescent and adult females that usually last from a few days to 2 weeks. However, such adverse reactions are very rare in children and in men receiving MMR vaccine (0%-3%). Symptoms typically begin 1-3 weeks after vaccination and last 1 day to 2 weeks. These transient reactions seem to occur in non-immunes only, for whom the vaccine is important. Low-grade fever and rash, lymphadenopathy, myalgia and paraesthesiae are commonly reported. Thrombocytopenia is rare and has been reported in less than 1 case per 30000 doses administered. Anaphylactic reactions are also rare. Clinical experience has exceptionally recorded isolated reactions involving the CNS. These more serious reactions have however, not been directly linked to vaccination.				

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Indication	Contra-indication & Side effect	Status (New Molecule/ Existing)	USFDA, BNF or MHRA Reference	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	সভার সিদ্ধামত্ম
	Incepta Vaccine Limited	b) Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	Each 0.5 ml dose of vaccine contains 4 µg each of meningococcal A, C, Y, and W-135 polysaccharides conjugated to approximately 48 µg of diphtheria toxoid protein carrier.	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine is indicated for active immunization of individuals 9 months through 55 years of age for the prevention of invasive meningococcal disease caused by N meningitidis serogroups A, C, Y and W-135. This vaccine is not indicated for the prevention of meningitis caused by other microorganisms or for the prevention of invasive meningococcal disease caused by N meningitidis serogroup B.	**Contraindications:** Known hypersensitivity to any component of Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine including diphtheria toxoid, or a life-threatening reaction after previous administration of a vaccine containing similar components are contraindications to vaccine administration. Known history of Guillain-Barre syndrome is a contraindication to vaccine administration. Known hypersensitivity to dry natural rubber latex is a contraindication to vaccine administration. **Side Effects:** Common (≥10%) solicited adverse events in infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormalcrying, drowsiness, appetite loss, vomiting, and fever. Common (≥10%) solicited adverse events in individuals 2 through 55 years of age were injection site pain, redness, induration, and swelling; anorexia and diarrhea. Other common solicited adverse events were irritability and drowsiness (2-10 years of age), headache, fatigue, malaise, and arthralgia (11-55 years of age).	New	USFDA, BNF-62,	ডিসিসি এর অনুমোদনের জন্য সুপারিশকৃত	অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Indication	Contra-indication & Side effect	Status (New Molecule/ Existing)	USFDA, BNF or MHRA Reference	ভ্যাকসিন বিশেষজ্ঞ কমিটির মতামত	সভার সিদ্ধামত্ম
	Incepta Vaccine Limited	c) Cholera Vaccine (Inactivated, Oral)	Each oral dose of vaccine (1.5 ml) contains: 1. V. cholerae O1 Inaba E1 Tor strain Phil 6973 formaldehyde killed- 600 Elisa Units (EU) of lipopolysaccharide (LPS) 2. V.cholerae O1 Ogawa classical strain Cairo 50 heat killed- 300 EU of LPS 3. V.cholerae O1 Ogawa classical strain Cairo 50 formaldehyde killed- 300 EU of LPS 4. V.cholerae O1 Inaba classical strain Cairo 48 heat killed- 300 EU of LPS 5. V.cholerae O139 strain 4260B formaldehyde killed- 600 EU of LPS	Cholera vaccine is indicated for active immunization against Vibrio cholerae. The vaccine can be administered to anyone above the age of 1 year. Data for the safety and efficacy of the vaccine in infants (less than 1 year of age) is not available. The earliest onset of protection can be expected 7-10 days after the completion of the primary series of vaccine.	**Contraindications:** Cholera vaccine should not be administered to subjects with either known hypersensitivity to any component of the vaccine, or having shown signs of hypersensitivity after previous administration of the vaccine. Formaldehyde is used during the manufacturing process and trace amount may be present in the final product. Caution should be taken in subjects with known hypersensitivity to formaldehyde. As with all products, the possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. As with other vaccines, immunization with the Cholera vaccine should be delayed in the presence of any acute illness, including acute gastrointestinal illness or acute febrile illness. A minor illness such as mild upper respiratory tract infection is not a reason to postpone immunization. **Side Effects:** The following adverse events are known to occur with Cholera vaccine use. Acute Gastroenteritis, Diarrhea, Fever, Vomiting, Abdominal pain, Itching, Rash, Nausea, Weakness, Cough, Vertigo, Dryness of mouth, Oral ulcer (rare), Sore throat (rare) and Yellowing of urine (rare). It has been observed that the incidence of adverse events is less after the second dose as compared to the first.	New	Shantha Biotechnics Limited, India	ডিসিসি এর অনুমোদনের জন্য সুপারিশকৃত	অনুমোদন করা হল।

Proposed Vaccine for Import (Unintroduced):

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Indication	Contraindications & Side effects	Status (New Molecule/ Existing)	USFDA, BNF or MHRA Reference	Opinion of Vaccine Expert Committee.	সভার সিদ্ধামত্ম
1	Merck Sharp & Dohme Corp. Sumneytown Pike P.O. Box 4 West Point, Pennsylvania 19486-0004 USA **Local Agent : Janata Traders**	RotaTeq • Solution for Oral Administration	Rotavirus vaccine, live, oral, pentavalent Active Ingredients: G1 Reassortant: ≥2.2 $X10^6$ IU/dose G2 Reassortant: ≥2.8 $X10^6$ IU/dose G3 Reassortant: ≥2.2 $X10^6$ IU/dose G4 Reassortant: ≥2.0 $X10^6$ IU/dose P1 Reassortant: ≥2.3 $X10^6$ IU/dose	RotaTeq is an oral pentavalent vaccine indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, G4, and G-serotypes that contain P1A[8] (e.g., G9). RotaTeq may be administered as early as six weeks of age.	**Contraindications:** Individuals who develop symptoms suggestive of hypersensitivity after receiving a dose of RotaTeq should not receive further doses of RotaTeq. Individuals with Severe Combined Immunodeficiency Disease (SCID). Cases of gastroenteritis associated with vaccine virus have been reported post-marketing in infants with SCID. **Side Effects:** The vaccine is generally well tolerated. The Common side effects are: Elevated temperature (17%), Vomiting (6-7%), Diarrhea (10-11%), Pyrexia, Anaphylactic reaction, Urticaria, angioedema may occur vut very minimum.	New	Approved in USA, Canada, Australia, France, Germany, UK, Netherlands, Switzerland, Singapore, Italy, India and other 102 countries. **(FSC-USA)**	ভ্যাকসিন সংরক্ষণ ও বিতরণে তাপমাত্রা ২-৮ ডিঃ সেঃ ব্যবসহা নিশ্চিতকরণ সাপেক্ষে **ডিসিসি এর অনুমোদনক্রমে** রেজিস্ট্রেশন দেয়া যেতে পারে।	অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Indication	Contraindications & Side effects	Status (New Molecule/ Existing)	USFDA, BNF or MHRA Reference	Opinion of Vaccine Expert Committee.	সভার সিদ্ধামত্ম
2	Merck Sharp & Dohme Corp. Sumneytown Pike P.O. Box 4 West Point, Pennsylvania 19486-0004 USA **Local Agent : Janata Traders**	**Gardasil** • 0.5 mL Single-Dose Prefilled Syringe • 0.5 mL Single-Dose vial	Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine. Active Ingredients: Type 6 L1 Protein: 20µg Type 11 L1 Protein: 40µg Type 16 L1 Protein: 40µg Type 18 L1 Protein: 20µg	GARDASIL is a vaccine indicated in girls and women 9 through 45 years for the prevention of cervical, vulvar, vaginal, and anal cancer; precancerous or dysplastic lesions; genital warts; and infections caused by Human Papillomavirus (HPV). GARDASIL is indicated to prevent the following diseases: • Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16 and 18 • Genital warts (condyloma acuminata) caused by HPV types 6 and 11 And infections and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18: • Cervical intraepithelial neoplasia (CIN) grade 2/3 and Cervical adenocarcinoma in situ (AIS) • Cervical intraepithelial neoplasia (CIN) grade 1 • Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3 • Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3 • VIN grade 1 and VaIN grade 1 • Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3. GARDASIL also provides protection in girls and women 9 through 26 years of age against HPV 31-, 33-, 52- and 58-related CIN (grades 1, 2, 3) or AIS. GARDASIL is indicated in boys and men 9 through 26 years of age for the prevention of external genital lesions and infection and the following diseases caused by HPV types included in the vaccine: • Anal cancer caused by HPV types 16 and 18	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients of the vaccine. Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL should not receive further doses of GARDASIL. **Side effects:** Gardasil is generally save vaccine. Very Few cases observed vaccine related side effects such as fever, nausea, vomiting pyrexia, injection site pain, swelling redness are co mmon.	New	Approved in USA, Canada, Australia, France, Germany, UK, Netherlands, Switzerland, Singapore, Italy, India and other 102 countries. **(FSC-USA)**	ভ্যাকসিন সংরক্ষণ ও বিতরণে তাপমাত্রা ২-৮ ডিঃ সেঃ ব্যবসহা নিশ্চিতকরণ সাপেক্ষে **ডিসিসি এর অনুমোদনক্রমে** রেজিস্ট্রেশন দেয়া যেতে পারে।	অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Indication	Contraindications & Side effects	Status (New Molecule/ Existing)	USFDA, BNF or MHRA Reference	Opinion of Vaccine Expert Committee.	সভার সিদ্ধামন্ত
3	Merck Sharp & Dohme Corp. Sumneytown Pike P.O. Box 4 West Point, Pennsylvania 19486 USA **Local Agent : Janata Traders**	**Pneumovax-** 0.5 ml Vial	Pneumococcal Polysaccharide Vaccine Each 0.5ml dose of vaccine contains 25mcg of each polysaccharide type. Pneumococcal Polysaccharide vaccine serotype – 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F & 33F	PNEUMOVAX 23 is indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine. Effectiveness of the vaccine in the prevention of pneumococcal pneumonia and pneumococcal bacteremia has been demonstrated in controlled trials in South Africa and France and in case-controlled studies. PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.	**Contraindications:** Hypersensitivity to any component of the vaccine. Epinephrine injection (1:1000) must be immediately available should an acute anaphylactoid reaction occur due to any component of the vaccine. **Side Effects:** The most common side effects reported in >10% of subject vaccinated with Pneumovax 23 in clinical trials were: Injection site pain,/seroness/tenderness, injection site swelling/ in duration headache, Injection site erythema, asthenia, fatigue and myalgia	New	Approved in USA, Canada, Australia, France, Germany, UK, Netherlands, Switzerland, Singapore, Italy, India and other 101 countries. **(FSC - USA)**	ভ্যাকসিন সংরক্ষণ ও বিতরণে তাপমাত্রা ২-৮ ডিঃ সেঃ ব্যবসহা নিশ্চিতকরণ সাপেক্ষে **ডিসিসি এর অনুমোদনক্রমে** রেজিস্ট্রেশন দেয়া যেতে পারে।	অনুমোদন করা হল।

উক্ত ভ্যাকসিনসমূহের আবেদন ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব কমিটির সভা অনুষ্ঠিত হওয়ার পর দাখিল করা হয়, ফলে আবেদনগুলো ২৭/০৬/২০১৩ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সভায় উপস্থাপন করা সম্ভব হয়নি।

এমতাবস্থায়, আবেদিত ভ্যাকসিনসমূহের প্রয়োজনীয়তার কথা বিবেচনা করে সভার সিদ্ধামেত্মর জন্য উপস্থাপন করা হয়। সভায় বিসত্মারিত আলোচনা করে উলিস্নখিত ভ্যাকসিনসমূহের অনুমোদনের বিষয়ে সদস্যগণ একমত পোষণ করেন।

সভার সিদ্ধামত্মঃ উলিস্নখিত স্থানীয়ভাবে উৎপাদনের জন্য ০৩ (তিন) টি এবং আমদানীর জন্য ০৩(তিন) টি ভ্যাকসিনের আবেদন অনুমোদন করা হল।

৫.২। হার্ব াল জাতীয় পদের অনুমোদন প্রসঙ্গে।

সভার আলোচনাঃ বাংলাদেশ ফার্মেসী কাউন্সিল-এর প্রতিনিধি জনাব নাসের শাহরিয়ার জাহেদী সভাকে অবহিত করেন যে, দেশে হার্ব ালঔষধ Advisory কমিটি কর্তৃক সুপারিশের ভিত্তিতে হার্ব াল জাতীয় পদে রেজিস্ট্রেশন প্রদান করা হচ্ছে যা ঔষধ নিয়ন্ত্রণ অধ্যাদেশ-১৯৮২ এর পরিপন্থী। উক্ত অধ্যাদেশ মোতাবেক যে কোন ঔষধের রেজিস্ট্রেশন ঔষধ নিয়ন্ত্রণ কমিটির সুপারিশ ব্যাতিরেকে অনুমোদন করা যায় না। এক্ষেত্রে উলিস্নখিত Advisory কমিটি ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব কমিটি হিসেবে কাজ করতে পারে। ইতোমধ্যে ঔষধ প্রশাসন অধিদপ্তর কর্তৃক রেজিস্ট্রেশন প্রদানকৃত হার্ব াল ঔষধসমূহ ঔষধ নিয়ন্ত্রণ কমিটিতে উপস্থাপনপূর্ব ক অনুমোদন করিয়ে নেয়া যেতে পারে। সভায় বিষয়টির উপর বিসত্মারিত আলোচনা হয় এবং উক্ত প্রসত্মাবনার সাথে সদস্যগণ একমত প্রকাশ করেন।

সভার সিদ্ধামত্মঃ

(K) ঔষধ (নিয়ন্ত্রণ) অধ্যাদেশ ১৯৮২-এর ৫(২) ধারা মোতাবেক ঔষধ নিয়ন্ত্রণ কমিটির সুপারিশ ব্যাতিরেকে কোন হার্ব াল জাতীয় পদের রেজিস্ট্রেশন প্রদান করা যাবে না।

(L) বিদ্যমান Advisory কমিটি হার্ব াল জাতীয় নতুন ঔষধ মূল্যায়ণের ÿ ÿ ত্রে ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটি হিসেবে কাজ করবে।

(M) ইতোমধ্যে ঔষধ প্রশাসন অধিদপ্তর কর্তৃক রেজিস্ট্রেশন প্রদানকৃত হার্ব াল ঔষধসমূহ ঔষধ নিয়ন্ত্রণ কমিটিতে মূল্যায়নের/সুপারিশের জন্য উপস্থাপন করতে হবে।

৫.৩। ঢাকা বিশ্ববিদ্যালয়ের ফার্মেসী অনুষদের ডীন এবং বাংলাদেশ ফার্ম াসিউটিক্যাস সোসাইটির প্রতিনিধিকে ঔষধ নিয়ন্ত্রণ কমিটির সদস্য হিসেবে অমত্মর্ভু ক্তকরণ প্রসঙ্গে।

সভার আলোচনাঃ বাংলাদেশ ফার্মেসী কাউন্সিল-এর প্রতিনিধি জনাব নাসের শাহরিয়ার জাহেদী সভাকে অবহিত করেন যে, ডীন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয় এবং প্রতিনিধি, বাংলাদেশ ফার্ম াসিউটিক্যালস্ সোসাইটি, ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটিতে সদস্য হিসেবে অমত্মর্ভু ক্ত আছেন। নতুন ঔষধ মূল্যায়ণের ÿ ÿ ত্রে ঢাকা বিশ্ববিদ্যালয়ের ফার্মেসী অনুষদের ডীন এবং বাংলাদেশ ফার্ম াসিউটিক্যাল সোসাইটির প্রতিনিধি গুরম্নত্বপূর্ণ ভূমিকা পালন করতে পারেন।

তিনি উলিস্নখিত দু'জন পেশাজীবী বিশেষজ্ঞকে ঔষধ নিয়ন্ত্রণ কমিটির সদস্য হিসেবে অমত্মর্ভুক্ত করার প্রসত্মাব করেন। উক্ত প্রসত্মাব সদস্যগণ সমর্থন করেন।

সভার সিদ্ধামত্মঃ ঢাকা বিশ্ববিদ্যালয়ের ফার্মেসী অনুষদের ডীন এবং বাংলাদেশ ফার্মাসিউটিক্যালস্ সোসাইটির প্রতিনিধিকে ঔষধ নিয়ন্ত্রণ কমিটির সদস্য হিসেবে অমত্মর্ভুক্ত করারসিদ্ধামত্ম গৃহীত হয়।

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

মেজর জেনারেল মোঃ জাহাংগীর হোসেন মলিস্নক
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ও
সদস্য-সচিব
ঔষধ নিয়ন্ত্রণ কমিটি।

এম এম নিয়াজ উদ্দিন
সচিব
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
ও
সভাপতি
ঔষধ নিয়ন্ত্রণ কমিটি।