ঔষধ নিয়ন্ত্রণ কমিটির ৩০ এপ্রিল ২০১৯ তারিখে অনুষ্ঠিত ২৫০ তম সভার কার্যবিবরণী

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্বাস্থ্য সেবা বিভাগের সচিব জনাব মোঃ আসাদুল ইসলাম এঁর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৫০ তম সভা বিগত ৩০ এপ্রিল ২০১৯ তারিখ দুপুর ২.০০ ঘটিকায় মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

সভায় কমিটির নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জেষ্ঠ্যতার ক্রমানুসারে নয়)ঃ

১. অধ্যাপক ডাঃ মোঃ ইসমাইল খান, উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয়, চট্টগ্রাম।
২. জনাব সুভাষ চন্দ্র সরকার, অতিরিক্ত সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা।
৩. জনাব আব্দুল ওহাব খান, যুগ্মসচিব (ঔষধ প্রশাসন), স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা।
৪. অধ্যাপক মীর মিজবাহ উদ্দিন, ফার্মাকোলজী বিভাগ, বঙ্গবন্ধু শেখ মুজিব মেডিকেল বিশ্ববিদ্যালয়, শাহবাগ, ঢাকা।
৫. অধ্যাপক ড. এস. এম. আবদুর রহমান, ডীন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়।
৬. অধ্যাপক ডাঃ মোঃ টিটো মিঞা, মেডিসিন বিভাগ, ঢাকা মেডিকেল কলেজ।
৭. অধ্যাপক ডাঃ জাকির হোসাইন গালিব, চর্ম ও যৌন রোগ বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
৮. অধ্যাপক ড. সীতেশ চন্দ্র বাছার, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ফার্মেসী কাউন্সিল, ঢাকা।
৯. অধ্যাপক সেলিম রেজা, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ফার্মাসিউটিক্যাল সোসাইটি, ঢাকা।
১০. ডাঃ মোঃ শফিউর রহমান, সহকারী পরিচালক (হাসপাতাল-১), স্বাস্থ্য অধিদপ্তর, মহাখালী, ঢাকা।
১১. ডাঃ মোঃ ফরহাদুল আলম, চীফ ভেটেরিনারি অফিসার, সিভি হসপিটাল, প্রাণি সম্পদ অধিদপ্তর, ঢাকা।
১২. ডাঃ ইশরাত জাহান, সহকারী অধ্যাপক, গাইনী এন্ড অবসটেট্রিক্স বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
১৩. ডাঃ মোঃ জামাল উদ্দিন চৌধুরী, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ মেডিকেল এসোসিয়েশন, ঢাকা।
১৪. কবিরাজ কৃষ্ণকান্ত রায়, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ইউনানী আয়ুর্বেদিক বোর্ড, ঢাকা।
১৫. মেজর জেনারেল মোঃ মোস্তাফিজুর রহমান, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।

পর্যবেক্ষক ঃ

১. ডাঃ মোমেনুল হক, বিশেষজ্ঞ প্রতিনিধি, উপদেষ্টা, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা এবং ব্যবস্থাপনা পরিচালক, জেনারেল ফার্মাসিউটিক্যালস্ লিঃ।
২. জনাব আবদুল মোক্তাদির, বিশেষজ্ঞ প্রতিনিধি, সিনিয়র সহসভাপতি, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা এবং ব্যবস্থাপনা পরিচালক, ইনসেপ্টা ফার্মাসিউটিক্যালস্ লিঃ।
৩. জনাব মোঃ আবদুর রাজ্জাক, মেডিকেল ডিভাইস বিশেষজ্ঞ, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা এবং ব্যবস্থাপনা পরিচালক, জেএমআই সিরিঞ্জেস এন্ড মেডিকেল ডিভাইসেস লিঃ, কুমিল্লা।

সভার আলোচ্যসূচীঃ

ক। ঔষধ নিয়ন্ত্রণ কমিটির ১৬ই এপ্রিল ২০১৮ তারিখে অনুষ্ঠিত ২৪৯তম সভার কার্যবিবরণী নিশ্চিতকরণ প্রসঙ্গে ।
খ। WHO কর্তৃক Prequalified Medicine আমদানীর জন্য রেজিস্ট্রেশন এর বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।
গ। কোন ঔষধের রেজিস্ট্রেশনের আবেদন ঔষধ নিয়ন্ত্রণ কমিটির সভায় নামঞ্জুর করা হলে তা পরবর্তী পর পর দুটি ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন না করার বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।
ঘ। ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক নির্ধারিত রেফারেন্সবিহীন কোন ঔষধের রেজিস্ট্রেশনের জন্য আবেদন মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন করার বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।
ঙ। হিউম্যান Fixed Dose Combination (FDC) ঔষধের রেজিস্ট্রেশনের প্রয়োজনীয়তা পূণঃমূল্যায়ন প্রসঙ্গে ।
চ। ফার্মাসিউটিক্যালস প্রডাক্টের Ethical Promotion-এর বিষয়ে একটি নীতিমালা প্রণয়ন প্রসঙ্গে।
ছ। প্যারাসিটামল কম্বিনেশন ঔষধের বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।
জ। WHO কর্তৃক স্বীকৃত হিউম্যানের জন্য নির্দেশিত Access, Watch & Reserve group এর অ্যান্টিবায়োটিকের মধ্যে ভেটেরিনারি চিকিৎসার জন্য রেজিস্ট্রেশনভুক্ত অ্যান্টিবায়োটিকসমূহের প্রয়োজনীয়তা পুণঃমূল্যায়ন প্রসঙ্গে।

ঝ। মানবদেহেরে জন্য ক্ষতিকর Olaquindox (VET) Growth Promoter-এর রেজিস্ট্রেশন বাতিলকরণ প্রসঙ্গে।

ঞ। স্থানীয়ভাবে উৎপাদনের জন্য ৩৩৮টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।

ট। আমদানীর জন্য ৩৪টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ঠ। স্থানীয়ভাবে উৎপাদনের জন্য ০৩টি ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ড। আমদানীর জন্য ৩৯টি ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব-কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।

ঢ। আমদানীর জন্য ১৫টি মেডিকেল ডিভাইসের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

ণ। বিবিধ ঃ মেসার্স নোভারটিস বাংলাদেশ লিঃ কর্তৃক আবেদনের পরিপ্রেক্ষিতে ১৬টি ভেটেরিনারি ঔষধের রেজিস্ট্রেশন বাতিলকরণ প্রসঙ্গে।

সভার আলোচনা ও সিদ্ধান্ত ঃ

সভাপতি উপস্থিত সকলকে স্বাগত জানিয়ে সভার কার্যক্রম শুরু করেন। অতঃপর তিনি ঔষধ প্রশাসনর অধিদপ্তরের পরিচালক (চলতি দায়িত্ব) জনাব মোঃ রুহুল আমিন-কে আলোচ্য সূচী অনুযায়ী বিষয়সমূহ উপস্থাপন করার জন্য আহবান করেন।

জনাব মোঃ রুহুল আমিন সভাকে অবহিত করেন যে, ইতোমধ্যে ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির নিম্নবর্ণিত তিনটি সভা অনুষ্ঠিত হয় ঃ

টেকনিক্যাল সাব-কমিটির সভা ঃ

১. বিগত ১০ জুলাই ২০১৮ তারিখে সকাল ১১.০০ ঘটিকায় হিউম্যান ও ভেটেরিনারি মেডিসিন মূল্যায়নের নিমিত্তে ঔষধ প্রশাসন অধিদপ্তরের সভা কক্ষে একটি সভা অনুষ্ঠিত হয়।

২. বিগত ১৭ অক্টোবর ২০১৮ তারিখে সকাল ১০.৩০ ঘটিকায় মেডিকেল ডিভাইস মূল্যায়নের নিমিত্তে ঔষধ প্রশাসন অধিদপ্তরের সভা কক্ষে একটি সভা অনুষ্ঠিত হয়।

৩. বিগত ১৭ অক্টোবর ২০১৮ তারিখে সকাল ১১.০০ ঘটিকায় হিউম্যান ও ভেটেরিনারি মেডিসিন মূল্যায়নের নিমিত্তে ঔষধ প্রশাসন অধিদপ্তরের সভা কক্ষে একটি সভা অনুষ্ঠিত হয়।

ক) ঔষধ নিয়ন্ত্রণ কমিটির ২৪৯তম সভার কার্যবিবরণী নিশ্চিতকরণ প্রসঙ্গে।

বিগত ১৬ এপ্রিল, ২০১৮ তারিখে অনুষ্ঠিত ঔষধ নিয়ন্ত্রণ কমিটির ২৪৯তম সভার কার্যবিবরণী সভায় উপস্থাপন করা হয়।

অধ্যাপক মীর মিজবাহ উদ্দিন, ফার্মাকোলজী বিভাগ, বঙ্গবন্ধু শেখ মুজিব মেডিকেল বিশ্ববিদ্যালয় বলেন যে, বিগত সভার কার্যবিরণীতে "সিলডেনাফিল সাইট্রেট ঔষধটির আবিষ্কারক নোবেল পুরষ্কার পেয়েছেন" তথ্যটি সঠিক নয়। কার্যবিবরণী হতে উক্ত তথ্যটি বাদ দেওয়ার জন্য তিনি প্রস্তাব করেন। অন্যান্য সকল তথ্যাদি যথাযথভাবে লিপিবদ্ধ করা হয়েছে বলে উপস্থিত সদস্যগণ মত প্রকাশ করেন।

প্রস্তাবিত সংশোধনীসহ সর্বসম্মতিক্রতে ২৪৯তম সভার কার্যবিবরণী নিশ্চিত করা হয়।

খ) WHO কর্তৃক Prequalified Medicine আমদানীর জন্য রেজিস্ট্রেশন এর বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।

টেকনিক্যাল সাব কমিটির সভার আলোচনা ঃ

প্রচলিত নিয়মানুযায়ী আমদানীকৃত ঔষধের রেজিস্ট্রেশন প্রদানের ক্ষেত্রে উন্নত ০৭(সাত)টি দেশ যথা-যুক্তরাষ্ট, যুক্তরাজ্য, সুইজারল্যান্ড, জার্মানী, ফ্রান্স, জাপান ও অস্ট্রেলিয়া-এর এবং EMA-এর ফ্রি সেল সার্টিফিকেট/Certificate of Pharmaceuticals Product গ্রহণ করা হয়ে থাকে।

দেশে যেসব ঔষধ উৎপাদন করা হয় না এবং উন্নত বিশ্বে যেসব ঔষধ প্রয়োজন হয় না, দেশের জরুরী প্রয়োজনে WHO কর্তৃক Prequalified সেসকল Medicine-এর আমদানী রেজিস্ট্রেশন প্রদানের বিষয়ে Case to Case বিবেচনা করা যেতে পারে।

এন্টি-ম্যালেরিয়ার ঔষধসমূহ উন্নত দেশ যেমন-আমেরিকায় প্রয়োজন হয় না বিধায় তারা গবেষণা করে না। কিন্তু যখন পর্যটনের মাধ্যমে তাঁদের দেশে ম্যালেরিয়া রোগটি বিস্তার লাভ করে, তখন ইউএসএ-তে এন্টি-ম্যালেরিয়ার ঔষধ নিয়ে গবেষণা করা হয়। তাই যেসব রোগের প্রাদুর্ভাব শুধু বাংলাদেশসহ পার্শ্ববর্তী দেশে রয়েছে, সেসব রোগের ঔষধের আমদানীর ক্ষেত্রে WHO কর্তৃক Prequalified Medicine আমদানীর জন্য রেজিস্ট্রেশন প্রদান করা যেতে পারে।

টিবি রোগের ঔষধ বর্তমানে দেশে অনুদান হিসেবে পাওয়া গেলেও ভবিষ্যতে এসকল ঔষধ ক্রয় করতে হবে। অনুদানের এসব ঔষধ ক্রয়ের ক্ষেত্রে WHO কর্তৃক Prequalified Medicine আমদানীর শর্ত দেওয়া হয়ে থাকে। তাই দেশে পর্যাপ্ত পরিমানে উৎপাদন না হলে, দেশের প্রয়োজনে WHO কর্তৃক Prequalified Medicine আমদানীর রেজিস্ট্রেশন অনুমোদন দেওয়া প্রয়োজন।

টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত ঃ

দেশে পর্যাপ্ত পরিমানে উৎপাদন না হলে, দেশের প্রয়োজনে WHO কর্তৃক Prequalified Medicine আমদানীর রেজিস্ট্রেশন Case to Case বিবেচনাপূর্বক অনুমোদন দেওয়া যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

দেশে পর্যাপ্ত পরিমানে উৎপাদন না হলে, দেশের প্রয়োজনে WHO কর্তৃক Prequalified Medicine আমদানীর রেজিস্ট্রেশন Case to Case বিবেচনাপূর্বক অনুমোদন দেওয়া যেতে পারে।

গ) কোন ঔষধের রেজিস্ট্রেশনের আবেদন ঔষধ নিয়ন্ত্রণ কমিটির কোন সভায় নামঞ্জুর করা হলে তা পরবর্তী পর পর দু'টি ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন না করার বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ ঃ

টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ

সভায় বিষয়টি নিয়ে বিস্তারিত আলোচনা করে সিদ্ধান্ত হয় যে, কোন ঔষধের রেজিস্ট্রেশনের আবেদন ঔষধ নিয়ন্ত্রণ কমিটির সভায় নামঞ্জুর করা হলে তা পরবর্তী পরপর দু'টি ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন করা হবে না।

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

কোন ঔষধের রেজিস্ট্রেশনের আবেদন ঔষধ নিয়ন্ত্রণ কমিটির সভায় নামঞ্জুর করা হলে তা পরবর্তী পরপর দু'টি ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন করা হবে না।

ঘ) ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক নির্ধারিত রেফারেন্সবিহীন কোন ঔষধের রেজিস্ট্রেশনের জন্য আবেদন মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন করার বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ।

টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ

ঔষধ নিয়ন্ত্রণ কমিটির ২৪১ তম সভায় সিদ্ধান্ত গৃহীত হয় যে, স্থানীয়ভাবে ঔষধ উৎপাদনের জন্য আবেদন বিবেচনার ক্ষেত্রে USFDA, UK-MHRA কর্তৃক অনুমোদনের তথ্য/রেফারেন্স অথবা BNF এ অন্তর্ভুক্তির রেফারেন্স দাখিল করতে হবে। অনেক আবেদনকারী প্রতিষ্ঠান উল্লিখিত রেফারেন্স ব্যতীত আবেদন দাখিল করে থাকেন। এ পরিপ্রেক্ষিতে সভায় বিস্তারিত আলোচনা হয়।

সভায় সর্বসম্মতিক্রমে নিম্নলিখিত সিদ্ধান্ত গৃহিত হয় ঃ

১. দেশে উৎপাদনের ক্ষেত্রে কোন ঔষধের রেজিস্ট্রেশন মূল্যায়নের লক্ষ্যে রেফারেন্স হিসেবে USFDA, UKMHRA, EMA এবং BNF-এ অন্তর্ভুক্তির রেফারেন্স বিবেচনা করা যেতে পারে।

২. External use (Topical preparation), sweetner ও mouth wash জাতীয় ঔষধের আবেদন মূল্যায়নের ক্ষেত্রে উক্ত রেফারেন্স না থাকলেও মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির (ডিসিসি) এর সভায় উপস্থাপন করা যেতে পারে।

৩. জনস্বার্থে জরুরী প্রয়োজনে যে কোন রেফারেন্সবিহীন ঔষধ মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির (DCC) সভায় উপস্থাপন করা যেতে পারে।

৪. ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক নির্ধারিত রেফারেন্স ছাড়া অন্যান্য ঔষধ মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন না করার মতামত প্রদান করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

১. দেশে উৎপাদনের ক্ষেত্রে **কোন ঔষধের রেজিস্ট্রেশন মূল্যায়নের ক্ষেত্রে রেফারেন্স হিসেবে USFDA, UKMHRA, EMA এবং BNF-এ অন্তর্ভুক্তির রেফারেন্স বিবেচনা করা হবে।**

২. **External use (Topical preparation), sweetner ও mouth wash জাতীয় ঔষধের আবেদন মূল্যায়নের ক্ষেত্রে উক্ত রেফারেন্স না থাকলেও মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির (ডিসিসি) এর সভায় উপস্থাপন করা হবে।**

৩. **জনস্বার্থে জরুরী প্রয়োজনে যে কোন রেফারেন্সবিহীন ঔষধ মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির (DCC) সভায় উপস্থাপন করা হবে।**

৪. **ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক নির্ধারিত রেফারেন্স ছাড়া অন্যান্য ঔষধ মূল্যায়নের নিমিত্তে ঔষধ নিয়ন্ত্রণ কমিটির সভায় উপস্থাপন করা হবে না।**

ঙ) হিউম্যান Fixed Dose Combination জাতীয় বিভিন্ন ঔষধের রেজিস্ট্রেশনের প্রয়োজনীয়তা পূণঃমূল্যায়ন প্রসঙ্গে।

টেকনিক্যাল সাব কমিটির ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভার আলোচনা ও সিদ্ধান্তঃ

জাতীয় ঔষধনীতি-২০১৬ এবং ঔষধ নিয়ন্ত্রণ কমিটির ২৪৬তম সভার সিদ্ধান্ত মোতাবেক ইতঃপূর্বে নিবন্ধিত এন্টিবায়োটিকসহ বিভিন্ন Fixed Dose Combination জাতীয় ৫৬৫(পাঁচশত পয়ষট্টি)টি হিউম্যান ঔষধের প্রয়োজনীয়তা পূণঃমূল্যায়নের নিমিত্তে সভায় উপস্থাপন করা হয় (Annex-A)। সভায় বিস্তারিত আলোচনাক্রমে নিম্নলিখিত সিদ্ধান্ত গৃহীত হয় :

১. Human Fixed Dose Antibiotic combination:

টেকনিক্যাল সাব-কমিটির সভার সিদ্ধান্তঃ

সভায় এন্টিবায়োটিক কম্বিনেশনসমূহ নিয়ে বিস্তারিত আলোচনা শেষে সর্বসম্মতিক্রমে নিম্নলিখিত দুটি ঔষধের রেজিস্ট্রেশন বাতিলের সুপারিশ করে।

1. Benzyl Penicillin 1 Lac IU + Procaine Penicillin 3 Lac IU Injection
2. Benzyl Penicillin 2 Lac IU + Procaine Penicillin 6 Lac IU Injection

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নলিখিত দুটি অ্যান্টিবায়োটিক কম্বিনেশন জাতীয় ঔষধের রেজিস্ট্রেশন বাতিলের সিদ্ধান্ত গৃহীত হয়:

1. Benzyl Penicillin 1 Lac IU + Procaine Penicillin 3 Lac IU Injection
2. Benzyl Penicillin 2 Lac IU + Procaine Penicillin 6 Lac IU Injection

২. Human Fixed Dose combination products Other than Antibiotic

টেকনিক্যাল সাব-কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ

সভায় এন্টিবায়োটিক ব্যতীত অন্য কম্বিনেশনসমূহ নিয়ে বিস্তারিত আলোচনা শেষে সর্বসম্মতিক্রমে নিম্নলিখিত ঔষধগুলির রেজিস্ট্রেশন বাতিল করার সুপারিশ করা হয়।

a) Caffeine 100mg + Ergotamine Tartrate 2mg Suppository
b) Niacin 500mg + Simvastatin 20mg Extended Tablet
c) Diclofenac Sodium 50mg + Misoprostol 200mcg Tablet
d) Diclofenac Sodium 75mg + Misoprostol 200 mcg Tablet

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নলিখিত ঔষধগুলির রেজিস্ট্রেশন বাতিলের সিদ্ধান্ত গৃহীত হয়:

a) **Caffeine 100mg + Ergotamine Tartrate 2mg Suppository**
b) **Niacin 500mg + Simvastatin 20mg Extended Tablet**
c) **Diclofenac Sodium 50mg + Misoprostol 200mcg Tablet**
d) **Diclofenac Sodium 75mg + Misoprostol 200 mcg Tablet**

৩. **Anesthetic** কম্বিনেশন ঔষধের বিষয়ে বিশেষজ্ঞগণের সুপারিশের বিষয়ে আলোচনা ঃ

টেকনিক্যাল সাব-কমিটির বিগত ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নলিখিত কম্বিনেশনসমূহের প্রয়োজনীয়তা পূণঃমূল্যায়নের নিমিত্তে (ক) বিভাগীয় প্রধান, এনেসথেশিওলজি বিভাগ, ঢাকা মেডিকেল কলেজ এবং (খ) বিভাগীয় প্রধান, এনেসথেশিওলজি বিভাগ, শহীদ সোহ্‌রাওয়ার্দী মেডিকেল কলেজ -এর মতামত গ্রহণ করার সিদ্ধান্ত গৃহীত হয় :

List of Human Combination Products other than Antibiotic Preparation (Anesthetic)		
Sl.	**Generic Name with Strength**	**DCC**
1.	Bupivacaine 5 mg + Dextrose 320 mg/ ml Injection	DCC210
2.	Bupivacaine 20 mg + Dextrose 320 mg/4 ml Injection	DCC210
3.	Bupivacaine 20 mg + Dextrose 320 mg/ml Injection	DCC001
4.	Dextrose 75 mg + Lidocaine Hydrochloride 50 mg/ml Injection	DCC211

বিশেষজ্ঞগণের সুপারিশের ভিত্তিতে টেকনিক্যাল সাব-কমিটির ১৭ অক্টোবর ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয় ঃ

Anesthetic কম্বিনেশনসমূহের প্রয়োজনীতা পূণঃমূল্যায়নের বিষয়ে বিশেষজ্ঞদের সুপারিশ	**টেকনিক্যাল সাব-কমিটির সুপারিশ**
অধ্যাপক ডাঃ মোঃ মোজাফ্‌ফর হোসেন, বিভাগীয় প্রধান, এনেসথেশিওলজি বিভাগ, ঢাকা মেডিকেল কলেজ, ঢাকা এবং অধ্যাপক ডাঃ এবিএম মাকসুদুল আলম, বিভাগীয় প্রধান, এনেসথেশিওলজি বিভাগ, শহীদ সোহ্‌রাওয়ার্দী মেডিকেল কলেজ, শেরেবাংলা নগর, ঢাকা সমন্বয়ে গঠিত বিশেষজ্ঞগণ সর্বসম্মতিক্রমে নিম্নোক্ত মতামত প্রদান করেছেন ঃ ক) Bupivacaine 20 mg + Dextrose 320 mg/4ml Injection বহাল রাখার সুপারিশ করেছেন। খ) নিম্নবর্ণিত ০৩টি পদের রেজিস্ট্রেশণ বাতিল করার সুপারিশ করেছেন। 1. Bupivacaine 5 mg + Dextrose 320 mg/ml Injection 2. Bupivacaine 20 mg + Dextrose 320 mg/ml Injection 3. Dextrose 75 mg + Lidocaine Hydrochloride 50 mg/ml Injection	বিশেষজ্ঞগণের সুপারিশ মোতাবেক সর্বসম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয় ঃ ১। Bupivacaine 20 mg + Dextrose 320 mg/4 ml Injection ঔষধটি রেজিস্ট্রেশন বহাল রাখা যেতে পারে। ২। নিম্নবর্ণিত ০৩ (তিন) টি পদের রেজিস্ট্রেশন বাতিল করা যেতে পারেঃ a) Bupivacaine 5 mg + Dextrose 320 mg/ ml Injection, b) Bupivacaine 20 mg + Dextrose 320 mg/ml Injection, c) Dextrose 75 mg + Lidocaine Hydrochloride 50 mg/ml Injection

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা/সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বসম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

১। Bupivacaine 20 mg + Dextrose 320 mg/4 ml Injection ঔষধটি রেজিষ্ট্রেশন বহাল রাখা হয়।

২। নিম্নবর্ণিত ০৩ (তিন) টি পদের রেজিস্ট্রেশন বাতিল করা হয় ঃ

a) Bupivacaine 5 mg + Dextrose 320 mg/ ml Injection,
b) Bupivacaine 20 mg + Dextrose 320 mg/ml Injection,
c) Dextrose 75 mg + Lidocaine Hydrochloride 50 mg/ml Injection

৪. **Antiplatelet কম্বিনেশন ঔষধের বিষয়ে বিশেষজ্ঞগণের সুপারিশের বিষয়ে আলোচনা ঃ**

টেকনিক্যাল সাব-কমিটির বিগত ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নলিখিত কম্বিনেশনসমূহের প্রয়োজনীয়তা পূণঃমূল্যায়নের নিমিত্তে (ক) অধ্যাপক ডাঃ মোঃ আবদুল ওয়াদুদ চৌধুরী, কার্ডিওলজি বিভাগ, ঢাকা মেডিকেল কলেজ, ঢাকা এবং (খ) অধ্যাপক ডাঃ মোঃ আফজালুর রহমান, পরিচালক, জাতীয় হৃদরোগ ইন্সটিটিউট, শেরে বাংলানগর, ঢাকা-এর মতামত গ্রহণ করার সিদ্ধান্ত গৃহীত হয় :

List of Human Combination Products other than Antibiotic Preparation (Antiplatelet)		
Sl.	**Generic Name with Strength**	
1.	Aspirin 75 mg + Clopidogrel 75 mg Capsule	DCC228
2.	Aspirin 75 mg + Clopidogrel 75 mg Tablet	DCC228

বিশেষজ্ঞগণের সুপারিশের ভিত্তিতে টেকনিক্যাল সাব-কমিটির ১৭ অক্টোবর ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয় ঃ

Antiplatelet কম্বিনেশনসমূহের প্রয়োজনীয়তা পূণঃমূল্যায়নের বিষয়ে বিশেষজ্ঞদের সুপারিশ	**টেকনিক্যাল সাব-কমিটির আলোচনা ও সুপারিশ**
ক) অধ্যাপক ডাঃ মোঃ আবদুল ওয়াদুদ চৌধুরী এর মতামত ঃ Aspirin + Clopidogrel fixed dose combination should be continued. However it should be checked whether the Bangladeshi companies are adhering to good manufacturing practices guideline. খ) অধ্যাপক ডাঃ মোঃ আফজালুর রহমান এর মতামত ঃ To date, Aspirin plus Clopidogrel combination formulations are not available in the USA and UK. However, they have been marketing in France, Russia, India and some European countries. **Recommendations:** ➢ Aspirin separately and Clopidogrel separately available all over the world and it is tested. ➢ Aspirin 75mg + Clopidogrel 75mg either Capsule or Tablet is available only limited	Antiplatelet কম্বিনেশন জাতীয় ঔষধের বিষয়ে বিশেষজ্ঞগণের মতামতের উপর সভায় বিস্তারিত আলোচনা হয়। ডাঃ জুলফিকার আলী লেলিন বলেন যে, ঔষধটি দীর্ঘদিন যাবৎ চিকিৎসকের প্রেসক্রিপশন মোতাবেক রোগিরা ব্যবহার করছেন। এর কোন বিরূপ প্রতিক্রিয়া সম্পর্কে কোন তথ্য পাওয়া যায় নাই। এছাড়া আমাদের দেশে Clopidogrel রেজিসটেন্স রোগিদের চিহ্নিত করা সম্ভব হয় না। তাই তিনি Aspirin 75 mg + Clopidogrel 75 mg Capsule/Tablet ঔষধ দুটি বহাল রাখার পক্ষে মতামত প্রদান করেন। অধ্যাপক ডাঃ টিটু মিয়া বলেন যে Aspirin ও Clopidogrel পৃথকভাবে অনুমোদিত রয়েছে। Clopidogrel রেজিসটেন্স রোগিদের ক্ষেত্রে Aspirin 75 mg + Clopidogrel 75 mg Capsule/Tablet এর কম্বিনেশন ব্যবহার করা উচিত নয়। পৃথকভাবে থাকলে ঔষধটির যৌক্তিক ব্যবহার নিশ্চিত করা সম্ভব হবে। সভার পর্যবেক্ষক জনাব আবদুল মোক্তাদির, ব্যবস্থাপনা পরিচালক, ইনসেপ্টা ফার্মা লিঃ বলেন যে, Clopidogrel রেজিসটেন্স কিনা

Antiplatelet কম্বিনেশনসমূহের প্রয়োজনীয়তা পূণঃমূল্যায়নের বিষয়ে বিশেষজ্ঞদের সুপারিশ	**টেকনিক্যাল সাব-কমিটির আলোচনা ও সুপারিশ**
number of countries of the world. So ➢ In our country, either the combination formulation of Aspirin plus Clopidogrel can be stopped Or May remain available if the individual pharmaceutical company can certify about its efficacy.	তা যাচাইপূর্বক ব্যবস্থাপত্র প্রদান করা সংগত হবে বলে তিনি মত প্রকাশ করেন। সভার সদস্যগণ Aspirin 75 mg + Clopidogrel 75 mg Capsule/Tablet ঔষধ ০২ (দুই) টির রেজিস্ট্রেশন বহাল রাখার পক্ষে মতামত প্রদান করেন। **বিশেষজ্ঞগণ সুপারিশের ভিত্তিতে নিম্নবর্ণিত পদগুলোর রেজিস্ট্রেশন বহাল রাখার সুপারিশ করা হয় ঃ** 1. Aspirin 75 mg + Clopidogrel 75 mg Capsule এবং 2. Aspirin 75 mg + Clopidogrel 75 mg Tablet

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা/সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নবর্ণিত পদগুলোর রেজিস্ট্রেশন বহাল রাখা হয় ঃ

1. Aspirin 75 mg + Clopidogrel 75 mg Capsule এবং
2. Aspirin 75 mg + Clopidogrel 75 mg Tablet

৫. **Antipsychotic কম্বিনেশন ঔষধের বিষয়ে বিশেষজ্ঞগণের সুপারিশের বিষয়ে আলোচনা ঃ**

টেকনিক্যাল সাব-কমিটির বিগত ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নলিখিত কম্বিনেশনসমূহের প্রয়োজনীতা পূণঃমূল্যায়নের নিমিত্তে (ক) বিগ্রেডিয়ার জেনারেল ডাঃ মোঃ আজিজুল ইসলাম, বিভাগীয় প্রধান, সাইক্রিয়াটিক বিভাগ, কম্বাইন্ড মিলিটারী হসপিটাল, ঢাকা ক্যান্টনমেন্ট, ঢাকা এবং (খ) পরিচালক, জাতীয় মানসিক স্বাস্থ্য ইন্সটিটিউট ও হাসপাতাল, শেরেবাংলা নগর, ঢাকা-এর মতামত গ্রহণ করার সিদ্ধান্ত গৃহীত হয় :

List of Human Combination Products other than Antibiotic Preparation (Antipsychotic)		
Sl.	**Generic Name with Strength**	**DCC**
1.	Fluphenazine Hydrochloride 1.5 mg + Nortriptyline 30 mg Tablet	DCC238
2.	Fluphenazine Hydrochloride 500 mcg + Nortriptyline 10 mg Tablet	DCC238
3.	Isopropamide 5 mg + Trifluoperazine 1 mg Tablet	DCC238
4.	Isopropamide 5 mg + Trifluoperazine 2 mg Tablet	DCC238
5.	Isopropamide 7.5 mg + Trifluoperazine 2 mg Tablet	DCC238

বিশেষজ্ঞগণের প্রদত্ত সুপারিশের ভিত্তিতে টেকনিক্যাল সাব-কমিটির ১৭ অক্টোবর ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয় ঃ

বিশেষজ্ঞগণের সুপারিশ	**টেকনিক্যাল সাব-কমিটির সুপারিশ**
(ক) বিগ্রেডিয়ার জেনারেল ডাঃ মোঃ আজিজুল ইসলাম, বিভাগীয় প্রধান, সাইক্রিয়াটিক বিভাগ, কম্বাইন্ড মিলিটারী হসপিটাল, ঢাকা ক্যান্টনমেন্ট, ঢাকা এবং (খ) পরিচালক, জাতীয় মানসিক স্বাস্থ্য ইন্সটিটিউট ও হাসপাতাল, শেরেবাংলা নগর, ঢাকা সর্বসম্মতক্রমে নিম্নোক্ত মতামত প্রদান করেছেন ঃ মানষিক রোগ বিষয়ক জাতীয় ও আন্তর্জাতিক বই এবং জার্নালসহ সংশ্লিষ্ট বৈজ্ঞানিক প্রকাশনা পর্যালোচানার করে পদগুলোর	বিশেষজ্ঞগনের সুপারিশ মোতাবেক পদগুলির প্রয়োজনীয়তার পক্ষে কোন বিজ্ঞানভিত্তিক প্রমান বা সুপারিশ না থাকায় সভায় নিম্নলিখিত **Antipsychotic কম্বিনেশনসমূহ বাতিল করার সুপারিশ করা হয়ঃ** 1. Fluphenazine HCL 1.5 mg + Nortriptyline 30 mg Tablet 2. Fluphenazine HCL 500 mcg + Nortriptyline 10 mg Tablet

প্রয়োজনীয়তার পক্ষে কোন বিজ্ঞানভিত্তিক প্রমান বা সুপারিশ পাওয়া যায়নি। এছাড়া সাধারণত কম্বিনেশন ড্রাগের পার্শ্বপ্রতিক্রিয়া বেশী এবং পার্শ্বপ্রতিক্রিয়া হলে কোন ড্রাগের কারণে তা হয়েছে নির্ধারন করা কঠিন হয়ে পড়ে। তাঁরা সংশ্লিষ্ট বিষয়ে পদক্ষেপ গ্রহণের জন্য সুপারিশ করেন।	3. Isopropamide 5 mg + Trifluoperazine 1 mg Tablet 4. Isopropamide 5 mg + Trifluoperazine 2 mg Tablet 5. Isopropamide 7.5 mg + Trifluoperazine 2 mg Tablet

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বসম্মতিক্রমে নিম্নবর্ণিত পদগুলোর রেজিস্ট্রেশন বাতিল করা হল :

1. Fluphenazine HCL 1.5 mg + Nortriptyline 30 mg Tablet
2. Fluphenazine HCL 500 mcg + Nortriptyline 10 mg Tablet
3. Isopropamide 5 mg + Trifluoperazine 1 mg Tablet
4. Isopropamide 5 mg + Trifluoperazine 2 mg Tablet
5. Isopropamide 7.5 mg + Trifluoperazine 2 mg Tablet

৬. ভিটামিন কম্বিনেশন ঔষধের বিষয়ে বিশেষজ্ঞগণের সুপারিশের বিষয়ে আলোচনা ঃ

টেকনিক্যাল সাব-কমিটির বিগত ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভায় সর্বসম্মতিক্রমে ভিটামিন জাতীয় কম্বিনেশনসমূহ পূণঃমূল্যায়নের নিমিত্তে নিম্নলিখিত সদস্যদের নিয়ে কমিটি গঠন গ্রহণ করার সিদ্ধান্ত গৃহীত হয় :

নং	নাম ও পদবী	
১.	অধ্যাপক ডাঃ মোঃ ইসমাইল খান, ফার্মাকোলজি বিভাগ ও উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয়, চট্টগ্রাম।	আহবায়ক
২.	অধ্যাপক ডাঃ মোঃ টিটো মিঞা, মেডিসিন বিভাগ, ঢাকা মেডিকেল কলেজ।	সদস্য
৩.	ডাঃ মুশতাক হোসেন, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ মেডিকেল এসোসিয়েশন, ঢাকা।	সদস্য
৪.	ডাঃ মোমেনুল হক, বিশেষজ্ঞ প্রতিনিধি, ব্যবস্থাপনা পরিচালক, জেনারেল ফার্মাসিউটিক্যালস্ লিঃ	সদস্য
৫.	জনাব আবদুল মোক্তাদির, বিশেষজ্ঞ প্রতিনিধি, ব্যবস্থাপনা পরিচালক, ইনসেপ্টা ফার্মা লিঃ।	সদস্য
৬.	নায়ার সুলতানা, পরিচালক (চলতি দায়িত্ব), ঔষধ প্রশাসন অধিদপ্তর	সদস্য-সচিব

বিশেষজ্ঞগণের প্রদত্ত নিম্নোক্ত সুপারিশের ভিত্তিতে টেকনিক্যাল সাব-কমিটির ১৭ অক্টোবর ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয় ঃ

বিশেষজ্ঞগণের সুপারিশ	টেকনিক্যাল সাব-কমিটির সুপারিশ
ঔষধ প্রশাসন অধিদপ্তর কর্তৃক ইতঃপূর্বে অনুমোদিত ভিটামিন ও মিনারেলস জাতীয় কম্বিনেশন প্রডাক্ট এর প্রয়োজনীয়তা পূণঃমূল্যায়নের নিমিত্তে ১৩-০৯-২০১৮ তারিখে অনুষ্ঠিত বিশেষজ্ঞ কমিটির সভায় ১০৭ (একশত সাত)টি কম্বিনেশন প্রডাক্ট সভায় উপস্থাপন করা হয়। উল্লিখিত ১০৭ টি কম্বিনেশন প্রোডাক্ট এর মধ্যে বিশেষজ্ঞগণ ৪৫(পঁয়তাল্লিশ)টি ভিটামিন ও মিনারেলস কম্বিনেশন-এর প্রয়োজনীয়তা রয়েছে মর্মে মতামত প্রকাশ করেন এবং ৬২(বাষট্টি)টি ভিটামিন ও মিনারেলস কম্বিনেশন-পদ প্রয়োজন নেই বলে মতামত প্রদান করেন।	সভায় সর্বসম্মতিক্রমে নিম্নলিখিত সিদ্ধান্ত গৃহীত হয় : ভিটামিন জাতীয় কম্বিনেশনসমূহ পূণঃমূল্যায়নের নিমিত্তে বিশেষজ্ঞদের সমন্বয়ে গঠিত কমিটির সুপারিশ মোতাবেক ঔষধ প্রশাসন অধিদপ্তর কর্তৃক ইতঃপূর্বে অনুমোদিত ১০৭ (একশত সাত)টি ভিটামিন ও মিনারেলস জাতীয় কম্বিনেশন ঔষধের (Annex-B) মধ্যে বিশেষজ্ঞ কমিটির মতামতের ভিত্তিতে ৪৫টি ভিটামিন ও মিনারেলস জাতীয় কম্বিনেশন ঔষধের (Annex-C) রেজিস্ট্রেশন বহাল রাখা যেতে পারে এবং ৬২(বাষট্টি)টি ভিটামিন ও মিনারেলস জাতীয় কম্বিনেশন ঔষধের (Annex-D) রেজিস্ট্রেশন বাতিল সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

ইতঃপূর্বে অনুমোদিত ১০৭(একশত সাত)টি কম্বিনেশন প্রডাক্ট (Annex-B) এর মধ্যে

রেজিষ্ট্রেশন বহাল রাখার হল ঃ ৪৫ টি (Annex-C)

রেজিষ্ট্রেশন বাতিল করা হল ঃ ৬২ টি (Annex-D) ।

৭. **ইলেকট্রোলাইট কম্বিনেশন ঔষধের বিষয়ে বিশেষজ্ঞগণের সুপারিশের বিষয়ে আলোচনা ঃ**

টেকনিক্যাল সাব-কমিটির বিগত ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভায় কমিটির সদস্যগণ সর্বসম্মতিক্রমে ইলেকট্রোলাইট জাতীয় কম্বিনেশনসমূহের প্রয়োজনীয়তা পূণঃমূল্যায়নের নিমিত্তে নিম্নলিখিত সদস্যদের নিয়ে কমিটি গঠন গ্রহণ করার সিদ্ধান্ত গৃহীত হয়:

নং	নাম ও পদবী	
১.	মেজর জেনারেল মোঃ আবদুল আলী মিয়া, কনসালটেন্ট ফিজিশিয়ান জেনারেল, বাংলাদেশ আর্মড ফোর্সেস মেডিকেল সার্ভিসেস	আহবায়ক
২.	ডাঃ মোমেনুল হক, বিশেষজ্ঞ প্রতিনিধি, ব্যবস্থাপনা পরিচালক, জেনারেল ফার্মাসিউটিক্যালস্ লিঃ	সদস্য
৩.	অধ্যাপক ডাঃ মোঃ টিটো মিঞা, মেডিসিন বিভাগ, ঢাকা মেডিকেল কলেজ।	সদস্য
৪.	ডাঃ তাহমিদ আহমেদ, সিনিয়র ডিরেক্টর আইসিডিডিআরবি, মহাখালী, ঢাকা	সদস্য
৫.	নায়ার সুলতানা, পরিচালক (চলতি দায়িত্ব), ঔষধ প্রশাসন অধিদপ্তর	সদস্য-সচিব

বিশেষজ্ঞগণের প্রদত্ত সুপারিশের ভিত্তিতে টেকনিক্যাল সাব-কমিটির ১৭ অক্টোবর ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয় ঃ

বিশেষজ্ঞগণের সুপারিশ	টেকনিক্যাল সাব-কমিটির সুপারিশ
বিশেষজ্ঞ কমিটির ২৭-০৮-২০১৮ তারিখে অনুষ্ঠিত সভায় ক) ৩৩টি এ্যামাইনো এসিড ও ইলেকট্রোলাইট কম্বিনেশন পদ যাচাইবাছাইপূর্বক ২৪ টি পদের রেজিস্ট্রেশন বহাল এবং ০৯(নয়)টি পদের রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়। খ) নিম্নবর্ণিত ঔষধগুলো স্থানীয়ভাবে উৎপাদনের উদ্যোগ গ্রহণের সুপারিশ করেন ঃ (1) Zinc Acetate 25mg Capsule (2) Zinc Acetate 50mg Capsule (3) Penicillamine 125mg Tablet (4) Dextrose 5% + Sodium Chloride 0.45% IV Infusion, (5) (Dextrose Hydrous 4.25mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml;	সভায় সর্বসম্মতিক্রমে নিম্নলিখিত সিদ্ধান্ত গৃহীত হয় : ক) ইলেকট্রোলাইট জাতীয় কম্বিনেশনসমূহের প্রয়োজনীয়তা পূণঃমূল্যায়নের নিমিত্তে গঠিত কমিটির সুপারিশ মোতাবেক ঔষধ প্রশাসন অধিদপ্তর কর্তৃক ইতঃপূর্বে অনুমোদিত ৩৩(তেত্রিশ)টি ইলেকট্রোলাইট কম্বিনেশন যাচাইবাছাইপূর্বক ২৪ (চব্বিশ)টি জেনেরিকের রেজিস্ট্রেশন বহাল ০৯(নয়)টি বাতিল করার সুপারিশ করেন (Annex-E)। খ) বিশেষজ্ঞ কমিটির সুপারিশের ভিত্তিতে নিম্নবর্ণিত ০৭টি পদ (১-৭) স্থানীয়ভাবে উৎপাদনের উদ্যোগ গ্রহণের জন্য বাংলাদেশ ঔষধ শিল্প সমিতিকে অনুরোধ করা যেতে পারে ঃ **1.** Zinc Acetate 25mg Capsule **2.** Zinc Acetate 50mg Capsule **3.** Penicillamine 125mg Tablet **4.** Dextrose 5% + Sodium Chloride 0.45% IV Infusion,

বিশেষজ্ঞগণের সুপারিশ	টেকনিক্যাল সাব-কমিটির সুপারিশ
(6) (Dextrose Hydrous 2.50mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml; (7) (Dextrose Hydrous 1.5mg + Sodium lactate-4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml	**5.** (Dextrose Hydrous 4.25mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml; **6.** (Dextrose Hydrous 2.50mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml; **7.** (Dextrose Hydrous 1.5mg + Sodium lactate-4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml টেকনিক্যাল সাব কমিটির সভায় নিম্নবর্ণিত পদ দু'টি উৎপাদন ও সরবরাহের ব্যবস্থা গ্রহণের জন্য প্রস্তাব করা হয়। **8.** Fat soluble Vitamin + Water soluble Vitamin IV Infusion & **9.** Trace Elements IV Infusion

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্ত ঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

ক) ইলেকট্রোলাইট জাতীয় কম্বিনেশনসমূহের মধ্যে ইতঃপূর্বে অনুমোদিত ৩৩টি ইলেকট্রোলাইট কম্বিনেশন যাচাইবাছাইপূর্বক ২৪ টি জেনেরিকের রেজিস্ট্রেশন বহাল ০৯ টি বাতিল করা হল **(Annex-E)**।

খ) বিশেষজ্ঞগণের সুপারিশ মোতাবেক নিম্নবর্ণিত ০৭টি পদ (১-৭) স্থানীয়ভাবে উৎপাদনের উদ্যোগ গ্রহণের জন্য বাংলাদেশ ঔষধ শিল্প সমিতিকে অনুরোধ করা যেতে পারে ঃ

১. Zinc Acetate 25mg Capsule
২. Zinc Acetate 50mg Capsule
৩. Penicillamine 125mg Tablet
৪. Dextrose 5% + Sodium Chloride 0.45% IV Infusion,
৫. (Dextrose Hydrous 4.25mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml;
৬. (Dextrose Hydrous 2.50mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml;

৭. (Dextrose Hydrous 1.5mg + Sodium lactate- 4.48mg + Calcium- 3.5mg + Magnesium Chloride-5.08mg +Magnesium -0.5mg + Sodium chloride-5.38 mg + Calcium chloride-25.7mg + Chloride-96 + Lacrate-40mg)/100ml

টেকনিক্যাল সাব কমিটির সভার সুপারিশ মোতাবেক নিম্নবর্ণিত পদ দু'টি উৎপাদন ও সরবরাহের উদ্যোগ গ্রহণের জন্য প্রস্তাব করা হয়।

৮. Fat soluble Vitamin IV Infusion + Water soluble Vitamin IV Infusion &

৯. Trace Elements IV Infusion

৯। **বাতিলের জন্য সুপারিশকৃত ঔষধসমূহ, উহার কাঁচামাল এবং মোড়ক সামগ্রী প্রসঙ্গেঃ**

ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক বাতিলের জন্য সুপারিশকৃত মওজুদকৃত ও বাজার থেকে প্রত্যাহারকৃত হিউম্যান ঔষধ, ঔষধের কাঁচামাল এবং মোড়ক সামগ্রী আগামী ০৩ মাসের মধ্যে ধ্বংস করে ঔষধ প্রশাসন অধিদপ্তরকে অবহিত করার জন্য নির্দেশ প্রদান করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ

ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক বাতিলকৃত ঔষধসমূহ বাজার থেকে প্রত্যাহারের জন্য সংশ্লিষ্ট প্রতিষ্ঠানকে ঔষধ প্রশাসন অধিদপ্তর নির্দেশ প্রদান করবে। প্রত্যাহারকৃত ঔষধ, মওজুদকৃত ঔষধ, মওজুদকৃত ঔষধের কাঁচামাল এবং মোড়ক সামগ্রী আগামী ০৩ মাসের মধ্যে ধ্বংস করে ঔষধ প্রশাসন অধিদপ্তরকে অবহিত করতে হবে।

চ। ফার্মাসিউটিক্যালস প্রডাক্টের Ethical Promotion-এর বিষয়ে একটি নীতিমালা প্রণয়ন প্রসঙ্গে।

টেকনিক্যাল সাব-কমিটির গত ১০ জুলাই ২০১৮ অনুষ্ঠিত সভায় ফার্মাসিউটিক্যালস প্রডাক্টের **Ethical Promotion**-এর বিষয়ে ঔষধ প্রশাসন অধিদপ্তর, বাংলাদেশ মেডিকেল এসোসিয়েশন, বিএমআরসি, বাংলাদেশ ঔষধ শিল্প সমিতির সাথে সমন্বয় করে একটি নীতিমালা প্রণয়ন করার লক্ষ্যে সদস্যগণ অভিমত ব্যক্ত করেন।

টেকনিক্যাল সাব কমিটির সিদ্ধান্তঃ

ফার্মাসিউটিক্যালস প্রডাক্টের Ethical Promotion-এর বিষয়ে ঔষধ প্রশাসন অধিদপ্তর, বাংলাদেশ মেডিকেল এসোসিয়েশন, বিএমআরসি, বাংলাদেশ ঔষধ শিল্প সমিতির সাথে সমন্বয় করে একটি নীতিমালা প্রণয়নের সুপারিশ করেন।

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্তঃ টেকনিক্যাল সাব-কমিটির সুপারিশ মোতাবেক সভায় সর্বসম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

ফার্মাসিউটিক্যালস প্রডাক্টের Ethical Promotion-এর বিষয়ে ঔষধ প্রশাসন অধিদপ্তর, বাংলাদেশ মেডিকেল এসোসিয়েশন, বিএমআরসি, বাংলাদেশ ঔষধ শিল্প সমিতির সাথে সমন্বয় করে একটি নীতিমালা প্রণয়নের সুপারিশ করা হয়।

ছ) **প্যারাসিটামল কম্বিনেশন বিষয়ে আলোচনা ও সিদ্ধান্ত গ্রহণ:** টেকনিক্যাল সাব-কমিটির বিগত ১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত সভায় নিম্নবর্ণিত প্যারাসিটামল কম্বিনেশন পদগুলোর বিষয়ে আলোচনা হয়।

I. Paracetamol 500mg + Caffeine 65mg Tablet
II. Paracetamol 325mg + Tramadol Hydrochloride 37.5mg Tablet

জনাব এম মোসাদ্দেক হোসেন, প্রতিনিধি, বাংলাদেশ ফার্মেসী কাউন্সিল বলেন যে, ঔষধ দুটি UK-MHRA কর্তক অনুমোদিত বিধায় রেজিস্ট্রেশন বহাল রাখা যেতে পারে।

দেশে প্যারাসিটামল ৫০০ মিঃগ্রাঃ ট্যাবলেটের মূল্য প্রতিটি ০.৮০ টাকা কিন্তু প্যারাসিটামল ৫০০ মিঃ গ্রাঃ + ক্যাফেইনের ৬৫ মি.গ্রাঃ ট্যাবলেট- এর মূল্য ২.৫০ টাকা। কম্বিনেশনের কারণে ঔষধটির মূল্য বৃদ্ধি পেয়েছে। বিভিন্ন মহল থেকে এ বিষয়ে প্রশ্ন উত্থাপিত হয় যাতে ঔষধ প্রশাসন ও ঔষধ শিল্পের ভাবমূর্তি ক্ষুণ্ন হয়।

টেকনিক্যাল সাব কমিটির সুপারিশঃ উপরোক্ত ঔষধ দুটি UK-MHRA কর্তৃক অনুমোদিত বিধায় ঔষধ দু'টির রেজিস্ট্রেশন বহাল রাখা যেতে পারে এবং ঔষধ প্রশাসন অধিদপ্তর কর্তৃক প্যারাসিটামল কম্বিনেশন ঔষধের মূল্য যৌক্তিকভাবে নির্ধারণের লক্ষ্যে ঔষধ শিল্প সমিতি সংশ্লিষ্টদের সাথে মত বিনিময় করতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সভার আলোচনা ও সিদ্ধান্তঃ

সভার সদস্য সচিব বলেন যে, দেশে প্যারাসিটামল ৫০০ মিঃগ্রাঃ ট্যাবলেটের মূল্য প্রতিটি ০.৮০ টাকা কিন্তু ক্যাফেইন যুক্ত প্যারাসিটামল ট্যাবলেটের মূল্য ২.৫০ টাকা। এ পর্যায়ে সভাপতি মহোদয় বাংলাদেশ ঔষধ শিল্প সমিতির মতামত জানতে চান।

বাংলাদেশ ঔষধ শিল্প সমিতির সিনিয়র সহসভাপতি জনাব মোক্তাদির বলেন যে, প্যারাসিটামলের সর্বোচ্চ খূচরা মূল্য ১৯৯৪ সালে সরকার কর্তৃক নির্ধারণ করা হয়। প্রতি বছরের মূল্য স্ফিতি বিবেচনায় নিলে বর্তমানে প্যারাসিটামল ৫০০ মিলি. গ্রাম ট্যাবলেট এর মূল্য দাড়াবে ৩.০০ টাকা। তিনি আরও বলেন যে, বিগত সময়ে সরকার কর্তৃক পদটির মূল্য পূণঃমূল্যায়ণ করা হয়নি। তিনি ঔষধ নিয়ন্ত্রণ কমিটির সভায় ঔষধটির Safety ও Efficacy নিয়ে আলোচনা করার এবং মূল্যের বিষয়ে ঔষধ মূল্য নির্ধারণ কমিটিতে আলোচনা করার প্রস্তাব করেন।

বাংলাদেশ ঔষধ শিল্প সমিতির উপদেষ্টা ডাঃ মোঃ মোমেনুল হক বলেন যে, প্যারাসিটামল ঔষধের মূল্য সমন্বয় করার জন্য মূল্য নির্ধারণ কমিটিতে আলোচনা করার প্রস্তাব করেন।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ

প্যারাসিটামল কম্বিনেশন ঔষধ দুটি UK-MHRA কর্তৃক অনুমোদিত বিধায় ঔষধ দু'টির রেজিস্ট্রেশন বহাল রাখা হল এবং প্যারাসিটামল ঔষধের মূল্য সমন্বয় করার জন্য ঔষধের মূল্য নির্ধারণ কমিটিতে আলোচনা করা হবে।

জ) WHO কর্তৃক স্বীকৃত হিউম্যানের জন্য নির্দেশিত Access, Watch & Reserve group এর এন্টিবায়োটিকের মধ্যে ভেটেরিনারি চিকিৎসার জন্য রেজিস্ট্রেশনভুক্ত এন্টিবায়োটিকসমূহের প্রয়োজনীয়তা পুণঃমূল্যায়ন প্রসঙ্গে।

১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সভার আলোচনাঃ

সভায় সদস্যগণ অভিমত ব্যক্ত করেন যে, বর্তমানে বিশ্বে Antibiotic Resistance (AMR)-এর কারনে প্রতি বছর প্রায় সাত লক্ষ লোক মারা যাচ্ছে। এমন অবস্থা চলতে থাকলে আগামী ২০৫০ সালে ১০(দশ) মিলিয়ন মানুষ AMR-এর কারনে মারা যাবে। এমতাবস্থায়, বিশ্ব স্বাস্থ্য সংস্থা (WHO) Antimicrobial Resistance প্রতিরোধ করার নিমিত্তে এর ব্যবহার নিয়ন্ত্রণ করার লক্ষ্যে এন্টিবায়োটিক সমূহকে তিনটি ভাগে ভাগ করেছে; যথা- Access, Watch & Reserve group নামে অভিহিত।

সভায় আরও উল্লেখ করা হয় যে, বিগত ১৬ এপ্রিল ২০১৮ তারিখে ঔষধ প্রশাসন অধিদপ্তরে বিশ্ব স্বাস্থ্য সংস্থার প্রতিনিধিদের উপস্থিতিতে Antimicrobial Resistance বিষয়ক মতবিনিময় সভায় মৎস্য/প্রাণীদের জন্য হিউম্যান এন্টিবায়োটিক এর ব্যবহার বন্ধ করার বিষয়ে সিদ্ধান্ত গৃহীত হয়। ভেটেরিনারি ঔষধ হিসেবে এসকল এন্টিবায়োটিক অনুমোদন থাকার ফলে এর অপব্যবহারের কারণে তা মানবদেহে স্থানান্তরের সম্ভাবনা রয়েছে। এতে মানবদেহে ব্যাক্টেরিয়াগুলো এসকল এন্টিবায়োটিকের ক্ষেত্রে প্রতিরোধী হয়ে উঠার সমূহ সম্ভাবনা বিরাজমান। এছাড়া Food and Agriculture Organization (FAO) এসব Antibiotic ভেটেরিনারি চিকিৎসায় ব্যবহারে বিষয়ে উদ্বেগ প্রকাশ করেছে। বিশ্ব স্বাস্থ্য সংস্থা (WHO) কর্তৃক হিউম্যানের জন্য নির্দেশিত Reserve group Antibiotic-এর মধ্যে Colistin-এর সাথে যেসব ভেটেরিনারী ঔষধের কম্বিনেশন ঔষধ প্রশাসন অধিদপ্তর কর্তৃক রেজিস্ট্রেশনভুক্ত রয়েছে তাদের রেজিস্ট্রেশনের প্রয়োজনীয়তা পূণঃমূল্যায়ন করার জন্য সভায় উপস্থাপন করা হয়।

এছাড়া ভেটেরিনারী ঔষধের মধ্যে বিশ্ব স্বাস্থ্য সংস্থা (WHO) কর্তৃক স্বীকৃত হিউম্যানের জন্য নির্দেশিত Access এবং Watch Group Antibiotic-এর নিম্নবর্ণিত কম্বিনেশনের প্রয়োজনীতা পূণঃমূল্যায়নের নিমিত্তে সভায় উপস্থাপন করা হয়।

Veterinary Antibiotic Combination Preparation (Access Group)

SL No	Generic Name	DCC No
1.	Amoxicillin 1.25 gm + Cloxacillin 1.25 gm/vial Injection	DCC 237
2.	Amoxicillin Trihydrate 10% + Bromhexine Hydrochloride 2% + Vitamin A 500000 IU/KG Powder	DCC 209
3.	Amoxicillin Trihydrate 5% + Cyproheptadine Hydrochloride 1% + Guaiphenesin 3.5% + Lysozyme Hydrochloride 1% + Vitamin A 2500% Powder	DCC 238
4.	Benzyl Penicillin 10 Lac IU + Procaine Penicillin 30 Lac IU Injection	DCC 200
5.	Benzyl Penicillin 2 Lac Unit + Procaine Penicillin 6 Lac Unit/vial Injection	DCC 238
6.	Benzylpenicillin 2 Lac Unit + Procaine Benzylpenicillin 6 Lac Unit/vial Injection	DCC 238
7.	Doxycycline 1 gm + Oxytetracycline 2 gm/100 gm Powder	DCC 238
8.	Doxycycline 10% + Neomycin Sulphate 10% Powder	DCC 238
9.	Doxycycline 10% + Oxytetracycline 20% Powder	DCC 238
10.	Doxycycline 10% + Tylosin 20% Powder	DCC 232
11.	Doxycycline 100 mg + Trimethoprim 100 mg/gm Powder	DCC 238
12.	Doxycycline 100 mg + Tylosin 200 mg Sachet	DCC 243
13.	Doxycycline 150 mg + Neomycin Sulphate 150 mg/gm Powder	DCC 232
14.	Doxycycline 20 gm + Tylosin 23 gm/100 gm Powder	DCC 238
15.	Doxycycline Hydrochloride 10% + Gentamicin 10% Powder	DCC 238
16.	Doxycycline Hydrochloride 25% + Tylosin Tartrate 20% Powder	DCC 232
17.	Gentamicin 2.5% + Neomycin Sulphate 20% Powder	DCC 238
18.	Gentamicin 3 gm + Sulphadimidine 12.5 gm + Trimethoprim 2.5 gm/100 ml Injection	DCC 240
19.	Neomycin Sulphate 5% + Procaine Penicillin 8.3333% Ointment	DCC 238
20.	Oxyclozanide 1.4 gm + Tetracycline Hydrochloride 2 gm Bolus	DCC 131
21.	Procaine Benzylpenicillin 4 Lac IU + Streptomycin 500 mg/vial Injection	DCC 188
22.	Streptomycin 250 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus	DCC 238
23.	Streptomycin 250 mg + Sulphadiazine 1.583 gm + Sulphadimidine 1.583 gm + Sulphapyridine 1.583 gm Bolus	DCC238
24.	Streptomycin 313 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus	DCC238
25.	Sulfaclozine 300 mg + Vitamin K 20 mg/gm Powder	DCC238
26.	Sulfadiazine 1.66 gm + Sulphadimidine 1.66 gm + Sulphapyridine 1.66 gm Powder	DCC131
27.	Sulphachloropyridazine Sodium 100 mg + Trimethoprim 20 mg + Vitamin K .8 mg/gm Powder	DCC238
28.	Sulphachloropyridazone 10 % + Trimethoprim 2 % Powder	DCC238
29.	Sulphadiazine 1.666 gm + Sulphadimidine 1.666 gm + Sulphapyridine 1.666 gm Bolus	DCC188
30.	Sulphadiazine 1.666 gm + Sulphadimidine 1.666 gm + Sulphapyridine 1.666 gm Powder	DCC188
31.	Sulphadiazine 1000 mg + Trimethoprim 200 mg Bolus	DCC238
32.	Sulphadiazine 40 gm + Trimethoprim 8 gm/100 ml Suspension	DCC238
33.	Sulphadiazine 400 mg + Trimethoprim 84.4 mg/ml Injection	DCC238
34.	Sulphamethoxazole 10 gm + Trimethoprim 2 gm/100 ml Suspension	DCC238
35.	Sulphamethoxazole 1000 mg + Trimethoprim 200 mg Bolus	DCC238

Veterinary Antibiotic Combination Preparation (Watch Group)

SL No	Generic Name	DCC No
1	Ciprofloxacin 20 gm + Trimethoprim 50 gm Sachet	DCC238
2	Erythromycin 18 gm + Sulphadiazine 15 gm + Trimethoprim 3 gm/100 gm Powder	DCC234
3	Erythromycin 180 mg + Sulphadiazine 150 mg + Trimethoprim 30 mg Powder	DCC238
4	Erythromycin 50 mg + Sulphadimethoxine Sodium 125 mg + Trimethoprim 25 mg/ml Injection	DCC243
5	Erythromycin 550 mg/gm Powder	DCC238
6	Erythromycin Thiocyanate 18 gm + Sulphadiazine 15 gm + Trimethoprim 3 gm/100 gm Powder	DCC230
7	Guaiphenesin 1.8% + Roxithromycin 1% + Tylosin 1% Powder	DCC240
8	Kanamycin 10000 IU/gm + Rofaxanide 2% Powder	DCC238
9	Lincomycin Base 22.2 gm + Spectinomycin 44.4 gm/100 gm Water Soluble Powder	DCC238
10	Loperamide 1 gm + Norfloxacine 25 gm + Trimethoprim 25 gm + Zinc Oxide 20 gm/KG Oral Powder	DCC238

অধ্যাপক মোঃ ইসমাইল খান, ফার্মকোলজি বিভাগ ও উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয় বলেন যে, Rational Use of Drug এবং এন্টিবায়োটিক রেজিটেন্সের হাত থেকে দেশের জনগণকে রক্ষা করার লক্ষ্যে ঔষধ প্রশাসন অধিদপ্তর বিশ্ব স্বাস্থ্য সংস্থার সুপারিশ মোতাবেক এন্টিবায়োটিক সমূহের মধ্যে Reserve Antibiotic-সমূহ সংরক্ষণের জন্য একটি ভাল উদ্যোগ গ্রহণ করেছে। এজন্য তিনি ঔষধ প্রশাসনকে ধন্যবাদ জ্ঞাপন করেন। তিনি ভেটেরিনারি ঔষধের অনুমোদনের সুপারিশের ক্ষেত্রে Synergistic effects আছে এমন কম্বিনেশন ছাড়া এন্টিবায়োটিক কম্বিনেশন রেজিস্টেশন নিরুৎসাহিত করার পরামর্শ দেন। এছাড়া তিনি অপ্রয়োজনীয় কম্বিনেশনের এ্যান্টিবায়োটিকগুলোর রেজিস্ট্রেশন বাতিলের সুপারিশ করেন।

প্রাণিসম্পদ অধিদপ্তরের সহকারী পরিচালক ডাঃ মোঃ আবু সুফিয়ান বলেন যে, প্রাণিসম্পদ অধিদপ্তর ও বিশ্ব স্বাস্থ্য সংস্থার সুপারিশ মোতাবেক এ্যান্টিবায়োটিক সমূহের অপব্যবহার রোধের ব্যবস্থা গ্রহন করেছে।

জনাব আবদুল মোক্তাদির, বিশেষজ্ঞ প্রতিনিধি, ব্যবস্থাপনা পরিচালক, ইনসেপ্টা ফার্মা লিঃ বলেন যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) কর্তৃক হিউম্যানের জন্য নির্দেশিত Reserve Antibiotic-এর মধ্যে Colistin-এর সাথে ভেটেরিনারি ঔষধের কম্বিনেশন সমূহ বাতিল করা যেতে পারে এবং Colistin-এর একক প্রিপারেশনের রেজিস্ট্রেশন বহাল রাখার বিষয়ে প্রাণি সম্পদ অধিদপ্তরের মতামত গ্রহণ করা যেতে পারে। এছাড়া তিনি একটি ভেটেরিনারি ফর্মূলারী প্রণয়নের মত প্রকাশ করেন।
সভার সভাপতি বলেন যে, Colistin-এর সাথে কম্বিনেশনসমূহ বাতিল করার বিষয়ে সভায় উপস্থিত সদস্যগণ মত প্রকাশ করেছেন এবং Colistin-এর একক প্রিপারেশন এবং Access এবং Watch Group Antibiotic-এর কম্বিনেশনের প্রয়োজনীয়তা পূণঃমূল্যায়নের জন্য মতামত গ্রহণের জন্য প্রাণীসম্পদ অধিদপ্তরে প্রেরণ করা হবে। প্রাণীসম্পদ অধিদপ্তরের মতামতসহ ঔষধগুলোর রেজিস্ট্রেশনের বিষয়ে ঔষধ নিয়ন্ত্রণ কমিটির পরবর্তী সভায় উপস্থাপন করা হবে।

১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সভার সভার সিদ্ধান্তঃ সভায় সর্বসম্মতিক্রমে নিম্নলিখিত সিদ্ধান্ত গৃহীত হয় ঃ

ক) Colistin-এর সাথে ভেটেরিনারি ঔষধের কম্বিনেশন সমূহ বাতিল করার সুপারিশ করেন, তবে এ বিষয়ে প্রাণীসম্পদ অধিদপ্তরের মতামত গ্রহণ করা যেতে পারে ।

খ) Colistin-এর Single Preparation এবং Access এবং Watch Group Antibiotic-এর কম্বিনেশনের প্রয়োজনীয়তা পূণঃমূল্যায়নের জন্য মতামত প্রদানের জন্য প্রাণীসম্পদ অধিদপ্তরে প্রেরণ করা হবে।

গ) ভেটেরিনারী ঔষধের Rational Use of Drug নিশ্চিত করার লক্ষ্যে একটি ভেটেরিনারি ফর্মূলারী প্রণয়ন করতে হবে।

১৭ অক্টোবর, ২০১৮ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সভার আলোচনাঃ

১০ জুলাই, ২০১৮ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সিদ্ধান্ত মোতাবেক ইতঃপূর্বে রেজিস্ট্রেশনকৃত প্রাণী চিকিৎসায় ব্যবহৃত Colistin-এর Single Preparation এবং Colistin-এর সাথে অনান্য এন্টিবায়োটিক এবং অন্যান্য মলিকুলের কম্বিনেশন পদের প্রয়োজনীয়তা পুণঃমূল্যায়ণের জন্য প্রাণিসম্পদ অধিদপ্তরের মতামত গ্রহণের জন্য প্রেরণ করা হয়।

প্রাণীসম্পদ অধিদপ্তর নিম্নোক্ত সুপারিশ প্রেরণ করেছেনঃ

১) Colistin-এর সাথে ভেটেরিনারি ঔষধের কম্বিনেশনসমূহ বাতিল করার সুপারিশ করেছেন।
২) Colistin-এর Single Preparation বহাল রাখার সুপারিশ করেছেন।
৩) Access Group-এর ০৭ টি কম্বিনেশনের বাতিল করার সুপারিশ করেছেন।
৪) Watch Group-এর ০৩টি কম্বিনেশনের বাতিল করার সুপারিশ করেছেন।

বিগত ১৫ অক্টোবর, ২০১৮ তারিখে প্রাণিসম্পদ অধিদপ্তর, বাংলাদেশ ভেটেরিনারি উৎপাদন এসোসিয়েশন, ফুড এন্ড এগ্রিকালচার অরগানাইজেশন ও বিশ্বস্বাস্থ্য সংস্থা প্রতিনিধিদের সহ বিভিন্ন স্ট্যাকহোল্ডারদের সাথে ইতঃপূর্বে রেজিস্ট্রেশনভুক্ত প্রাণী চিকিৎসায় ব্যবহৃত Colistin এবং অন্যান্য এন্টিবায়োটিক কম্বিনেশনের প্রয়োজনীয়তা সম্পর্কে ঔষধ প্রশাসন অধিদপ্তরের সভাকক্ষে মতবিনিময় সভা অনুষ্ঠিত হয়।

উক্ত সভায় উপস্থিত বিশেষজ্ঞগণ সর্বসম্মতিক্রমে নিম্নলিখিত সুপারিশ করেনঃ

১. Colistin-এর Oral Solution form এবং Injectable dosage form ব্যতীত বাকী সব dosage form ও pack size বাতিলের সুপারিশ করা হয়। Oral Solution form এর সর্বনিম্ন প্যাক সাইজ হবে ০১ লিটার।
২. প্রাণি চিকিৎসায় ব্যবহৃত Colistin এর Oral Solution ব্যতিত নিবন্ধিত Colistin এর single এবং Conbination ঔষধ আগামী ০৬ মাসের মধ্যে বাজার থেকে প্রত্যাহারপূর্বক ধ্বংস করতে হবে।
৩. অন্যান্য এন্টিবায়োটি রেজিস্টেন্স এবং Colistin সংবেদনশীল প্রমাণিত হলে **"রেজিস্টার্ড ভেটেরিনারিয়ানের Prescription মোতাবেক Colistin বিক্রয় করতে হবে"** নির্দেশনাটি Colistin দ্বারা উৎপাদিত ঔষধের মোড়কের গায়ে উল্লেখ করতে হবে।
৪. Colistin ঔষধ বিক্রয়ের জন্য জেলা পর্যায়ে ফার্মসী নির্দিষ্ট করে দিতে হবে। ঔষধ উৎপাদনকারী ও আমদানীকারক প্রতিষ্ঠানগুলো উক্ত নির্দিষ্ট ফার্মেসী ব্যতীত অন্য কোন ফার্মেসীতে Colistin সংবলিত ঔষধ বিক্রয় করতে পারবে না। ফার্মেসীতে Colistin সংবলিত ঔষধ বিক্রয়ের রেকর্ড রেজিষ্টারে সংরক্ষণ করতে হবে।
৫. স্থানীয়ভাবে উৎপাদনের জন্য Fosfomycin এর রেজিস্ট্রেশন প্রদান করা হয়নি। তবে আমদানীর জন্য রেজিস্ট্রেশন প্রদান করা হয়েছে। Reserve group এর এন্টিবায়োটিক হিসেবে Fosfomycin এর সকল Dosage form বাতিলের সুপারিশ করা হয়।
৬. প্রাণি চিকিৎসায় ব্যবহৃত Ciprofloxacin এর সাথে সকল Combination রেজিস্ট্রেশন এর বাতিলের সুপারিশ করা হয়।
৭. ক. Azithromycin,
খ. Amoxicillin Trihydrate + Bromhexine Hydrochloride + Vitamin A,
গ. Amoxicillin Trihydrate + Cyproheptadine Hydrochloride + Guaiphenes + Lysozyme Hydrochloride + Vitamin A এর রেজিষ্ট্রেশন বাতিলের সুপারিশ করা হয়।

১৭ অক্টোবর, ২০১৮ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সভার টেকনিক্যাল সাব-কমিটির সভার সিদ্ধান্তঃ

প্রাণিসম্পদ অধিদপ্তরের সুপারিশ এবং ভেটেরিনারি স্ট্যাকহোল্ডারদের মতামতের ভিত্তিতে নিম্নলিখিত সুপারিশ গৃহীত হয়।

১. Colistin-এর সকল কম্বিনেশন বাতিল করা যেতে পারে।

২. বিশ্বস্বাস্থ্য সংস্থা কর্তৃক হিউমেনের জন্য নির্দেশিত Access Group-এর এন্টিবায়োটিকের মধ্যে প্রাণি চিকিৎসায় ব্যবহৃত ইতঃপূর্বে রেজিস্ট্রেশনভুক্ত ২৩টি কম্বিনেশন বাতিল এবং অবশিষ্ট ১২টি কম্বিনেশন বহাল রাখা যেতে পারে (Annex-F)।

৩. বিশ্বস্বাস্থ্য সংস্থা কর্তৃক হিউমেনের জন্য নির্দেশিত Watch Group-এর এন্টিবায়োটিকের মধ্যে প্রাণি চিকিৎসায় ব্যবহৃত ইতঃপূর্বে রেজিস্ট্রেশনভুক্ত ০৫টি কম্বিনেশন বাতিল এবং অবশিষ্ট ০৫ টি কম্বিনেশন বহাল রাখা যেতে পারে (Annex-G)।

৪. প্রাণি চিকিৎসায় ব্যবহৃত Colistin-এর Oral Solution form এবং Injectable dosage form ব্যতীত বাকী সব dosage form ও pack size বাতিল করা যেতে পারে। Oral Solution form সর্বনিম্ন প্যাক সাইজ হবে ০১ লিটার।

৫. প্রাণি চিকিৎসায় ব্যবহৃত Colistin এর Oral Solution ব্যতিত নিবন্ধিত Colistin এর single এবং Conbination ঔষধ আগামী ০৬ মাসের মধ্যে বাজার থেকে প্রত্যাহারপূর্বক ধ্বংস করতে হবে।

৬. অন্যান্য এন্টিবায়োটি রেজিস্টেন্স এবং Colistin সংবেদনশীল প্রমাণিত হলে **"রেজিস্টার্ড ভেটেরিনারিয়ানের** Prescription **মোতাবেক** Colistin **বিক্রয় করতে হবে"** নির্দেশনাটি Colistin দ্বারা উৎপাদিত ঔষধের মোড়কের গায়ে উল্লেখ করতে হবে।

৭. Colistin ঔষধ বিক্রয়ের জন্য জেলা পর্যায়ে ফার্মেসী নির্দিষ্ট করে দিতে হবে। ঔষধ উৎপাদনকারী ও আমদানীকারক প্রতিষ্ঠানগুলো উক্ত নির্দিষ্ট ফার্মেসী ব্যতীত অন্য কোন ফার্মেসীতে Colistin সংবলিত ঔষধ বিক্রয় করতে পারবে না। ফার্মেসীতে Colistin সংবলিত ঔষধ বিক্রয়ের রেকর্ড রেজিষ্টারে সংরক্ষণ করতে হবে।

৮. স্থানীয়ভাবে উৎপাদনের জন্য Fosfomycin এর রেজিষ্ট্রেশন প্রদান করা হয়নি। তবে আমদানীর জন্য রেজিষ্ট্রেশন প্রদান করা হয়েছে। Reserve group এর এন্টিবায়োটিক হিসেবে Fosfomycin এর সকল Dosage form বাতিল করা যেতে পারে।

৯. Ciprofloxacin এর সাথে সকল Combination রেজিস্ট্রেশন বাতিল করা যেতে পারে।

১০. প্রাণি চিকিৎসায় ব্যবহৃত নিম্নবর্ণিত ঔষধসমূহের রেজিস্ট্রেশন বাতিলের বাতিল করা যেতে পারে।
ক. Azithromycin,
খ. Amoxicillin Trihydrate+Bromhexine Hydrochloride+Vitamin A,
গ. Amoxicillin Trihydrate + Cyproheptadine Hydrochloride + Guaiphenes + Lysozyme Hydrochloride + Vitamin A

ঔষধ নিয়ন্ত্রণ কমিটির আলোচনা ও সিদ্ধান্তঃ

সভাপতি মহোদয় উপরোক্ত সিদ্ধান্তকে স্বাগত জানান এবং সভাকে অবহিত করেন যে, মাননীয় প্রধানমন্ত্রী কেবিনেটের মিটিং-এ পোল্ট্রি ফিডে এন্টিবায়োটিকের ব্যবহার বন্ধে প্রাণিসম্পদ অধিদপ্তর এবং ঔষধ প্রশাসন অধিদপ্তরকে সমন্বিতভাবে কাজ করার নির্দেশনা প্রদান করেছেন।

টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

১. **Colistin-এর সকল কম্বিনেশন বাতিল করা হল।**

২. **বিশ্বস্বাস্থ্য সংস্থা কর্তৃক হিউমেনের জন্য নির্দেশিত Access Group-এর এন্টিবায়োটিকের মধ্যে প্রাণি চিকিৎসায় ব্যবহৃত ইতঃপূর্বে রেজিস্ট্রেশনভুক্ত ২৩টি কম্বিনেশন বাতিল এবং অবশিষ্ট ১২টি কম্বিনেশন বহাল রাখা হল (Annex-F)।**

৩. **বিশ্বস্বাস্থ্য সংস্থা কর্তৃক হিউমেনের জন্য নির্দেশিত Watch Group-এর এন্টিবায়োটিকের মধ্যে প্রাণি চিকিৎসায় ব্যবহৃত ইতঃপূর্বে রেজিস্ট্রেশনভুক্ত ০৫টি কম্বিনেশন বাতিল এবং অবশিষ্ট ০৫ টি কম্বিনেশন বহাল রাখা হল (Annex-G)।**

৪. **প্রাণি চিকিৎসায় ব্যবহৃত Colistin-এর Oral Solution form এবং Injectable dosage form ব্যতীত বাকী সব dosage form ও pack size বাতিল করা হল। Oral Solution form সর্বনিম্ন প্যাক সাইজ হবে ০১ লিটার।**

৫. **প্রাণি চিকিৎসায় ব্যবহৃত Colistin এর Oral Solution ব্যতিত নিবন্ধিত Colistin এর single এবং Conbination ঔষধ আগামী ০৬ মাসের মধ্যে বাজার থেকে প্রত্যাহারপূর্বক ধ্বংস করতে হবে।**

৬. **অন্যান্য এন্টিবায়োটি রেজিস্টেন্স এবং Colistin সংবেদনশীল প্রমাণিত হলে "রেজিস্টার্ড ভেটেরিনারিয়ানের Prescription মোতাবেক Colistin বিক্রয় করতে হবে" নির্দেশনাটি Colistin দ্বারা উৎপাদিত ঔষধের মোড়কের গায়ে উল্লেখ করতে হবে।**

৭. **Colistin ঔষধ বিক্রয়ের জন্য জেলা পর্যায়ে ফার্মেসী নির্দিষ্ট করে দিতে হবে। ঔষধ উৎপাদনকারী ও আমদানীকারক প্রতিষ্ঠানগুলো**

উক্ত নির্দিষ্ট ফার্মেসী ব্যতীত অন্য কোন ফার্মেসীতে Colistin সংবলিত ঔষধ বিক্রয় করতে পারবে না। ফার্মেসীতে Colistin সংবলিত ঔষধ বিক্রয়ের রেকর্ড রেজিষ্টারে সংরক্ষণ করতে হবে।

৮. **স্থানীয়ভাবে উৎপাদনের জন্য Fosfomycin এর রেজিষ্ট্রেশন প্রদান করা হয়নি। তবে আমদানীর জন্য রেজিষ্ট্রেশন প্রদান করা হয়েছে। Reserve group এর এন্টিবায়োটিক হিসেবে Fosfomycin এর সকল Dosage form বাতিল করা হল।**

৯. **Ciprofloxacin এর সাথে সকল Combination রেজিস্ট্রেশন বাতিল করা হল।**

১০. **প্রাণি চিকিৎসায় ব্যবহৃত নিম্নবর্ণিত ঔষধসমূহের রেজিস্ট্রেশন বাতিলের বাতিল করা হল।**
ক. Azithromycin,
খ. Amoxicillin Trihydrate+Bromhexine Hydrochloride+Vitamin A,
গ. Amoxicillin Trihydrate + Cyproheptadine Hydrochloride + Guaiphenes + Lysozyme Hydrochloride + Vitamin A

ঝ) মানবদেহেরে জন্য ক্ষতিকর Olaquindox Powder (Vet) Growth Promoter-এর রেজিস্ট্রেশন বাতিলকরণ প্রসঙ্গেঃ
বিগত ১৭ অক্টোবর, ২০১৮ তারিখে অনুষ্ঠিত টেকনিক্যাল সাব কমিটির সভায় উল্লেখ করা হয় যে, ঔষধ নিয়ন্ত্রণ কমিটির বিগত ২৪৪ তম সভায় কোমিফার্ম ইন্টারন্যাশনাল লিঃ, কোরিয়া-এর বাংলাদেশ প্রতিনিধি মেসার্স রফিক মেডিসিন-কে Olaquindox আমদানির নিমিত্তে রেজিস্ট্রেশন প্রদান করা হয়। সদস্যগণ অভিমত ব্যক্ত করেন যে, Olaquindox প্রাণিস্বাস্থ্য ও মানব স্বাস্থ্যের জন্য অত্যন্ত ক্ষতিকর। এ বিষয়ে প্রাণীসম্পদ অধিদপ্তরের মতামত গ্রহণ করা হয়। প্রাণীসম্পদ অধিদপ্তর পদটির রেজিস্ট্রেশন বাতিলের সুপারিশ করেন।

টেকনিক্যাল সাব-কমিটির সভার সিদ্ধান্তঃ
প্রাণীসম্পদ অধিদপ্তরের মতামতের ভিত্তিতে Olaquindox Powder (Vet) Growth Promoter পদটির রেজিস্ট্রেশন বাতিলের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ টেকনিক্যাল সাব কমিটির সুপারিশ মোতাবেক সভায় সর্বসম্মতিক্রমে নিম্নোক্ত সিদ্ধান্ত গৃহীত হয়:

মানবদেহেরে জন্য ক্ষতিকর Olaquindox Powder (Vet) Growth Promoter পদটির রেজিস্ট্রেশন বাতিল করা হল।

ঞ) স্থানীয়ভাবে উৎপাদনের জন্য আবেদিত ৩৩৮টি হিউম্যান ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

স্থানীয় উৎপাদনের জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৩৩৮টি নতুন ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের ভিত্তিতে নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয়ঃ

ক) অনুমোদিত = ১৪৭ টি;
খ) নামঞ্জুরকৃত = ১৯১ টি; (**Annex-H**)

ট) আমদানীর জন্য আবেদিত ৩৪টি হিউম্যান ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

আমদানীর জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৩৪টি নতুন ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের ভিত্তিতে নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয়ঃ

ক) অনুমোদিত = ২৯ টি;
খ) নামঞ্জুরকৃত = ০৫ টি; (**Annex-I**)

ঠ) স্থানীয়ভাবে উৎপাদনের জন্য আবেদিত ০৩টি ভেটেরিনারী ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

স্থানীয় উৎপাদনের জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ০৩টি নতুন ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের ভিত্তিতে নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয়ঃ

ক) অনুমোদিত = ০৩টি; (**Annex-J**)

ড) আমদানীর জন্য আবেদিত ৩৯টি ভেটেরিনারী ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

আমদানীর জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ১৪টি নতুন ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের ভিত্তিতে নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয়ঃ

ক) অনুমোদিত = ১৫ টি
খ) মৎস্য অধিদপ্তরের মতামত গ্রহন করতে হবে = ০১টি এবং
গ) নামঞ্জুরকৃত = ২৩ টি; (**Annex-K**)

ঢ) ঔষধ নিয়ন্ত্রণ কমিটির মেডিকেল ডিভাইসের টেকনিক্যাল সাব কমিটির গত ১৭ অক্টোবর ২০১৮ তারিখে অনুষ্ঠিত সভার সুপারিশসমূহঃ

আমদানীর জন্য আবেদিত ১৫ টি মেডিকেল ডিভাইসের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

আমদানির জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ১৫টি নতুন মেডিক্যাল ডিভাইসের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের ভিত্তিতে নিম্নবর্ণিত সিদ্ধান্ত গৃহীত হয়ঃ

ক) অনুমোদিত = ১৫ টি (**Annex-L**)

ণ। বিবিধঃ মেসার্স নোভারটির বাংলাদেশ লিঃ কর্তৃক আবেদনের পরিপ্রেক্ষিতে উক্ত প্রতিষ্ঠানের লাইসেন্সভুক্ত ১৬টি ভেটেরিনারি ঔষধের রেজিস্ট্রেশন বাতিলকরণ প্রসঙ্গে।

মেসার্স নোভারটির বাংলাদেশ লিঃ নিম্ন বর্ণিত ১৬টি ভেটেরিনারি ঔষধের রেজিস্ট্রেশন বাতিল করার জন্য আবেদন দাখিল করেছেঃ

Sl. No.	Brand Name	Generic Name	DAR No.
01.	Denagard 45% powder (vet)	Tiamulin Hydrogen fumarate INN 45gm	276-108-077
02.	Captor powder	Chlortetracycline hydrochloride BP (vet) 45gm	276-232-077
03.	Fasinex 900 Bolus	Triclabendazole INN 900mg	276-33-077
04.	ESB3 30% powder	Sulfaclozine Sodium INN 30gm	276-34-077
05.	Cosumix plus powder	Sodium Sulphachloropyridazine INN 10gm + Trimethoprim BP 2gm	276-35-077
06.	Endex Bolus	Triclabendazole INN 900mg + Livamisole Hydrochloride BP 708mg (eq. to Levamsole 600mg)	276-73-077
07.	Cinoflox 10% powder	Enrofloxacin Hydrochloride INN 10mg	276-174-077
08.	Oxysentin 20% powder	Oxytetracycline Hydrochloride BP (vet) 20gm	276-180-077
09.	Digitop powder	Ammonium Bicarbonate BP (vet) 1985 25gm + Nuxvomica BP 1985 7gm + Sodium Bicarbonate BP (vet) 1988 65gm + Gentain powder BP 1988 1.50gm + Ginger powder BP 1988 1.50gm	276-38-077

Sl. No.	Brand Name	Generic Name	DAR No.
10.	Trisulfa Bolus	Sulfadiazine BP (vet) 1985 1.666gm + sulfadimidine BP (vet) 1985 1.666gm + Sulfapyridine BP 1988 1.666gm	276-39-077
11.	Streptosulfa Bolus	Sulfadiazine BP (vet) 1.583gm + sulfadimidine BP (vet) 1985 1.583gm + Sulfapyridine BP 1988 1.583gm + Streptomycine sulphate BP (vet) 1985 0.3132gm	276-40-077
12.	Ralnex 600 Bolus	Livamisole Hydrochloride BP 708mg (eqv. to Levamisole 600mg)	276-45-077
13.	Anaron DS Tablet	Cobalt Sulphate BP 100mg +Dried Ferrous Sulphate BP 200mg + Thamine Mononitrate USP 50mg + Vitamine B12 USP 0.04mg + Choline Bitartartrate BP 18.20mg	276-256-83
14.	Poulnex Powder	Livamisole Hydrochloride BP 300mg	276-57-077
15.	Denagard 15% Powder	Tiamulin Hydrogen fumarate INN 18.75gm (eqv. to Tiamulin 15gm)	276-194-077
16.	Oxysentin 500 Tablet	Oxytetracycline Hydrochloride BP (vet) 500mg	276-247-083

উপরোক্ত ভেটেরিনারি ঔষধগুলির রেজিস্ট্রেশন বাতিল করার জন্য ঔষধ নিয়ন্ত্রণ কমিটির সুপারিশ প্রয়োজন।

সভার আলোচনা ও সিদ্ধান্তঃ

মেসার্স নোভারটির বাংলাদেশ লিঃ কর্তৃক আবেদনের পরিপ্রেক্ষিতে উক্ত প্রতিষ্ঠানের লাইসেন্সভুক্ত ১৬টি ভেটেরিনারি ঔষধের রেজিস্ট্রেশন বাতিল করার সুপারিশ করা হল।

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

মেজর জেনারেল মোঃ মোস্তাফিজুর রহমান
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ও
সদস্য-সচিব
ঔষধ নিয়ন্ত্রণ কমিটি।

মোঃ আসাদুল ইসলাম
সচিব
স্বাস্থ্য সেবা বিভাগ
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
ও
সভাপতি
ঔষধ নিয়ন্ত্রণ কমিটি।

Annex-A: List of Human Combination Products

রেফারেন্সবিহীন এন্টিবায়োটিক কম্বিনেশনের তালিকা

Sl No	Strength	DCC No	Reference	Type of Antibiotic
1.	Amoxicillin 250 mg + Clavulanic Acid 125 mg Tablet	DCC-206	No Ref.	Access
2.	Amoxicillin 250 mg + Clavulanic Acid 62.5 mg Tablet	DCC-238	No Ref.	Access
3.	Amoxicillin 250 mg + Clavulanic Acid 31.25 mg/5 ml Powder For Suspension	DCC-238	No Ref.	Access
4.	Amoxicillin 500 mg + Clavulanic Acid 125 mg/5 ml Powder For Suspension	DCC-238	No Ref.	Access
5.	Cefuroxime 250 mg + Clavulanic Acid 62.5 mg Tablet	DCC-241	No Ref.	Access
6.	Cefuroxime 500 mg + Clavulanic Acid 125 mg Tablet	DCC-241	No Ref.	Access
7.	Cefuroxime 125 mg + Clavulanic Acid 31.25 mg/5 ml Powder For Suspension	DCC-241	No Ref.	Access
8.	Cefuroxime 125 mg + Clavulanic Acid 31.25 mg Tablet	DCC241	No Ref.	Access
9.	Cefpodoxime 200 mg + Clavulanic Acid 125 mg Tablet	DCC241	No Ref.	Watch
10.	Cefpodoxime 100 mg + Clavulanic Acid 62.5 mg Tablet	DCC241	No Ref.	Watch
11.	Cilastatin 750 mg + Imipenem 750 mg/vial Injection	DCC241	No Ref.	Watch
12.	Meropenem 500 mg + Vaborbactam 500 mg / Vial Powder for Injection	DCC249	No Ref.	Watch
13.	Meropenem 2.0 gm + Vaborbactam 2.0 gm/Vial Injection	DCC249	No Ref.	Watch
14.	Benzyl Penicillin 1 Lac IU + Procaine Penicillin 3 Lac IU Injection	DCC162	No Ref.	Access
15.	Benzyl Penicillin 2 Lac IU + Procaine Penicillin 6 Lac IU Injection	DCC177	No Ref.	Access

রেফারেন্সভুক্ত এন্টিবায়োটিক কম্বিনেশনের তালিকা

Sl No	Name of the Product	DCC No	Reference	Type of Antibiotic
1.	Amoxicillin 1 gm + Clavulanic Acid 200 mg InjectionÔ	DCC213	WHO EML	Access
2.	Amoxicillin 125 mg + Clavulanic Acid 31.25 mg/5 ml Powder For Suspension	DCC207	WHO EML	Access
3.	Amoxicillin 400 mg + Clavulanic Acid 57.5 mg/5 ml Powder For Suspension	DCC221	USFDA	Access
4.	Amoxicillin 500 mg + Clavulanic Acid 100 mg Injection	DCC213	WHO EML	Access
5.	Amoxicillin 500 mg + Clavulanic Acid 125 mg Tablet	DCC216	USFDA WHO EML	Access
6.	Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet	DCC231	USFDA	Access
7.	Cilastatin 250 mg + Imipenem 250 mg/Vial Injection	DCC241	USFDA	Watch
8.	Cilastatin 500 mg + Imipenem 500 mg IV/IM Injection	DCC233	USFDA	Watch
9.	Meropenem 1.0 gm + Vaborbactam 1.0 gm/Vial Injection	DCC249	USFDA	Watch
10.	Nitrofurantoin 37.5 mg + Nitrofurantoin Microcrystals 12.5 mg Capsule	DCC238	USFDA	Access
11.	Nitrofurantoin 75 mg + Nitrofurantoin Microcrystals 25 mg Capsule	DCC238	USFDA WHO EML (Tablet)	Access

List of Human Combination Products other than Antibiotic Preparation

Sl.	Generic Name with Strength	DCC	Therapeutic Code	Therapeutic Class
1	Amino Acids (Essential) 7 % + Glucose & Electrolytes 10 % IV Infusion	DCC195	3	**Amino acids**
2	Amino Acids (Essential) 8.14% + D-Sorbitol & Electrolytes 5% IV Infusion	DCC242	3	
3	Bupivacaine 5 mg + Dextrose 320 mg/ml Injection	DCC160	4	**Anesthetic**
4	Adrenaline 18 mcg + Lidocaine Hydrochloride 20 mg/ml Injection	DCC160	5	**Anesthetic**
5	Adrenaline 20 mcg + Lidocaine Hydrochloride 20 mg/ml Injection	DCC160	5	
6	Adrenaline 5 mcg + Lidocaine Hydrochloride 10 mg Injection	DCC160	5	
7	Adrenaline 5 mcg + Lidocaine Hydrochloride 20 mg/ml Injection	DCC160	5	
8	Articaine Hydrochloride 4 gm + Epinephrine 1 mg/100 ml Injection	DCC238	5	
9	Bupivacaine 20 mg + Dextrose 320 mg/4 ml Injection	DCC210	5	
10	Bupivacaine 20 mg + Dextrose 320 mg/ml Injection	DCC001	5	
11	Dextrose 75 mg + Lidocaine Hydrochloride 50 mg/ml Injection	DCC211	5	
12	Caffeine 65 mg + Paracetamol 500 mg Tablet	DCC231	6	**Analgesic & Antipyretic**
13	Paracetamol 325 mg + Tramadol Hydrochloride 37.5 mg Tablet	DCC240	6	
14	Aluminium Hydroxide 200 mg + Magnesium Hydroxide 200 mg + Simethicone 30 mg Tablet	DCC189	7	**Antacid**
15	Aluminium Hydroxide 250 mg + Magnesium Hydroxide 400 mg Tablet	DCC160	7	
16	Aluminium Hydroxide 250 mg + Magnesium Trisilicate 500 mg Tablet	DCC150	7	
17	Aluminium Hydroxide 35 gm + Magnesium Trisilicate 15 gm Suspension	DCC146	7	
18	Aluminium Hydroxide 400 mg + Magnesium Hydroxide 400 mg + Simethicone 30 mg Tablet	DCC150	7	
19	Aluminium Oxide 175 mg + Magnesium Hydroxide 225 mg/5 ml Suspension	DCC149	7	
20	Aluminium Oxide 200 mg + Magnesium Hydroxide 125 mg/5 ml Suspension	DCC149	7	
21	Aluminium Oxide 200 mg + Magnesium Hydroxide 225 mg/5 ml Suspension	DCC149	7	
22	Aluminium Oxide 200 mg + Magnesium Hydroxide 400 mg + Simethicone 30 mg/5 ml Suspension	DCC181	7	
23	Aluminium Oxide 200 mg + Magnesium Trisilicate 250 mg/5 ml Suspension	DCC149	7	
24	Magaldrate 480 mg + Simethicone 20 mg Chewable Tablet	DCC239	7	
25	Magaldrate 480 mg + Simethicone 20 mg/5 ml Suspension	DCC234	7	**Antacid**
26	Potassium Bicarbonate 100 mg + Sodium Alginate 500 mg Tablet	DCC240	7	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
27	Potassium Bicarbonate 100 mg + Sodium Alginate 500 mg/5 ml Suspension	DCC240	7	
28	Amitriptyline 12.5 mg + Chlordiazepoxide 5 mg Tablet	DCC243	14	**Anxiolytic & Antidepressant**
29	Glimepiride 1 mg + Metformin Hydrochloride 500 mg Tablet	DCC244	15	**Antidiabetic**
30	Glipizide 2.5 mg + Metformin Hydrochloride 250 mg Tablet	DCC230	15	
31	Glipizide 2.5 mg + Metformin Hydrochloride 500 mg Tablet	DCC230	15	
32	Glipizide 5 mg + Metformin Hydrochloride 500 mg Tablet	DCC230	15	
33	Linagliptin 2.5 mg + Metformin Hydrochloride 1000 mg Tablet	DCC245	15	
34	Linagliptin 2.5 mg + Metformin Hydrochloride 500 mg Tablet	DCC245	15	
35	Linagliptin 2.5 mg + Metformin Hydrochloride 850 mg Tablet	DCC245	15	
36	Linagliptin 5 mg + Metformin Hydrochloride 1000 mg Er Tablet	DCC249	15	
37	Metformin Hydrochloride 1000 mg + Sitagliptin 100 mg Er Tablet	DCC242	15	
38	Metformin Hydrochloride 1000 mg + Sitagliptin 50 mg Er Tablet	DCC240	15	
39	Metformin Hydrochloride 1000 mg + Sitagliptin 50 mg Tablet	DCC240	15	
40	Metformin Hydrochloride 500 mg + Pioglitazone 15 mg Tablet	DCC233	15	
41	Metformin Hydrochloride 500 mg + Rosiglitazone 1 mg Tablet	DCC231	15	
42	Metformin Hydrochloride 500 mg + Sitagliptin 50 mg Er Tablet	DCC240	15	
43	Metformin Hydrochloride 500 mg + Sitagliptin 50 mg Tablet	DCC240	15	
44	Metformin Hydrochloride 500 mg + Vildagliptin 50 mg Tablet	DCC240	15	
45	Metformin Hydrochloride 850 mg + Pioglitazone 15 mg Tablet	DCC233	15	
46	Metformin Hydrochloride 850 mg + Vildagliptin 50 mg Tablet	DCC240	15	
47	Doxylamine Succinate 10 mg + Pyridoxine Hydrochloride 10 mg Dr Tablet	DCC245	18	**Antiemetic**
48	Doxylamine Succinate 20 mg + Pyridoxine Hydrochloride 20 mg Er Tablet	DCC247	18	
49	Meclizine Hydrochloride 25 mg + Pyridoxine Hydrochloride 50 mg Tablet	DCC234	18	
50	Diphenhydramine Hydrochloride 280 mg + L-Menthol 40 mg/100 ml Syrup	DCC245	21	**Antihistamine**
51	Cinnarizine 20 mg + Dimenhydrinate 40 mg Tablet	DCC238	21	
52	Aliskiren 150 mg + Hydrochlorothiazide 12.5 mg Tablet	DCC238	22	**Antihypertensive**
53	Amlodipine 10 mg + Benazepril Hydrochloride 20 mg Capsule	DCC231	22	
54	Amlodipine 10 mg + Hydrochlorothiazide 12.5 mg + Valsartan 160 mg Tablet	Export	22	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
55	Amlodipine 10 mg + Hydrochlorothiazide 25 mg + Valsartan 160 mg Tablet	Export	22	
56	Amlodipine 10 mg + Valsartan 160 mg Tablet	DCC237	22	
57	Amlodipine 10 mg + Valsartan 320 mg Tablet	DCC238	22	
58	Amlodipine 2.5 mg + Benazepril Hydrochloride 10 mg Capsule	DCC231	22	
59	Amlodipine 5 mg + Atenolol 25 mg Tablet	DCC228	22	
60	Amlodipine 5 mg + Atenolol 50 mg Tablet	DCC228	22	
61	Amlodipine 5 mg + Atorvastatin 10 mg Tablet	DCC238	22	
62	Amlodipine 5 mg + Benazepril Hydrochloride 10 mg Capsule	DCC231	22	
63	Amlodipine 5 mg + Benazepril Hydrochloride 20 mg Capsule	DCC231	22	
64	Amlodipine 5 mg + Bisoprolol Hemifumarate 2.5 mg Tablet	DCC248	22	
65	Amlodipine 5 mg + Olmesartan Medoxomil 20 mg Tablet	DCC238	22	
66	Amlodipine 5 mg + Olmesartan Medoxomil 40 mg Tablet	DCC239	22	
67	Amlodipine 5 mg + Telmisartan 40 mg Tablet	DCC239	22	
68	Amlodipine 5 mg + Telmisartan 80 mg Tablet	DCC245	22	
69	Amlodipine 5 mg + Valsartan 160 mg Tablet	DCC237	22	
70	Amlodipine 5 mg + Valsartan 320 mg Tablet	DCC238	22	
71	Amlodipine 5 mg + Valsartan 80 mg Tablet	DCC237	22	
72	Atenolol 100 mg + Chlorthalidone 25 mg Tablet	DCC232	22	
73	Atenolol 50 mg + Chlorthalidone 25 mg Tablet	DCC232	22	
74	Atenolol 50 mg + Nifedipine 20 mg Capsule	DCC234	22	
75	Bisoprolol Hemifumarate 10 mg + Hydrochlorothiazide 6.25 mg Tablet	DCC240	22	
76	Bisoprolol Hemifumarate 2.5 mg + Hydrochlorothiazide 6.25 mg Tablet	DCC240	22	
77	Bisoprolol Hemifumarate 2.5 mg Tablet	DCC232	22	
78	Bisoprolol Hemifumarate 5 mg + Hydrochlorothiazide 6.25 mg Tablet	DCC240	22	
79	Candesartan Cilexetil 16 mg + Hydrochlorothiazide 12.5 mg Tablet	DCC230	22	
80	Candesartan Cilexetil 8 mg + Hydrochlorothiazide 12.5 mg Tablet	DCC230	22	
81	Hydrochlorothiazide 12.5 mg + Irbesartan 150 mg Tablet	DCC229	22	
82	Hydrochlorothiazide 12.5 mg + Irbesartan 300 mg Tablet	DCC229	22	
83	Hydrochlorothiazide 12.5 mg + Irbesartan 75 mg Tablet	DCC231	22	
84	Hydrochlorothiazide 12.5 mg + Losartan Potassium 100 mg Tablet	DCC234	22	
85	Hydrochlorothiazide 12.5 mg + Losartan Potassium 25 mg Tablet	DCC228	22	
86	Hydrochlorothiazide 12.5 mg + Losartan Potassium 50 mg Tablet	DCC228	22	
87	Hydrochlorothiazide 12.5 mg + Olmesartan Medoxomil 20 mg	DCC238	22	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
	Tablet			
88	Hydrochlorothiazide 12.5 mg + Olmesartan Medoxomil 40 mg Tablet	DCC239	22	
89	Hydrochlorothiazide 12.5 mg + Ramipril 2.5 mg Tablet	DCC234	22	
90	Hydrochlorothiazide 12.5 mg + Telmisartan 40 mg Tablet	DCC233	22	
91	Hydrochlorothiazide 12.5 mg + Telmisartan 80 mg Tablet	DCC233	22	
92	Hydrochlorothiazide 12.5 mg + Valsartan 160 mg Tablet	DCC230	22	
93	Hydrochlorothiazide 12.5 mg + Valsartan 80 mg Tablet	DCC230	22	
94	Hydrochlorothiazide 25 mg + Losartan Potassium 100 mg Tablet	DCC231	22	
95	Hydrochlorothiazide 25 mg + Ramipril 5 mg Tablet	DCC234	22	
96	Hydrochlorothiazide 25 mg + Triamterene 50 mg Tablet	DCC146	22	
97	Hydrochlorothiazide 25 mg + Valsartan 160 mg Tablet	DCC230	22	
98	Sacubitril 24 mg + Valsartan 26 mg Tablet	DCC245	22	
99	Sacubitril 49 mg + Valsartan 51 mg Tablet	DCC245	22	
100	Sacubitril 97 mg + Valsartan 103 mg Tablet	DCC245	22	
101	Artemether 20 mg + Lumefantrine 120 mg Tablet	DCC216	24	**Antimalarial**
102	Pyrimethamine 25 mg + Sulfadoxine 500 mg Tablet	DCC121	24	
103	Pyrimethamine 25 mg + Sulfadoxine 500 mg/5 ml Injection	DCC238	24	
104	Carbidopa 10 mg + Levodopa 100 mg Tablet	DCC160	25	**Antiparkinsonism**
105	Carbidopa 12.5 mg + Entacapone 200 mg + Levodopa 50 mg Tablet	DCC240	25	
106	Carbidopa 25 mg + Entacapone 200 mg + Levodopa 100 mg Tablet	DCC240	25	
107	Carbidopa 25 mg + Levodopa 100 mg Cr Tablet	DCC242	25	
108	Carbidopa 25 mg + Levodopa 250 mg Tablet	DCC110	25	
109	Carbidopa 37.5 mg + Entacapone 200 mg + Levodopa 150 mg Tablet	DCC240	25	
110	Carbidopa 50 mg + Entacapone 200 mg + Levodopa 200 mg Tablet	DCC238	25	
111	Carbidopa 50 mg + Levodopa 200 mg Cr Tablet	DCC240	25	
112	Aspirin 75 mg + Clopidogrel 75 mg Capsule	DCC228	26	**Antiplatelet**
113	Aspirin 75 mg + Clopidogrel 75 mg Tablet	DCC228	26	
114	Aspirin Immediate Release Tablet 25 mg + Dipyridamole Extended Release Pellets 200 mg Capsule	DCC244	26	
115	Metronidazole 100 mg + Miconazole Nitrate 100 mg Vaginal Tablet	DCC191	27	**Antiprotozoal**
116	Flupenthixol 500 mcg + Melitracen 10 mg Tablet	DCC238	28	**Antipsychotic**

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
117	Fluphenazine Hydrochloride 1.5 mg + Nortriptyline 30 mg Tablet	DCC238	28	
118	Fluphenazine Hydrochloride 500 mcg + Nortriptyline 10 mg Tablet	DCC238	28	
119	Isopropamide 5 mg + Trifluoperazine 1 mg Tablet	DCC238	28	
120	Isopropamide 5 mg + Trifluoperazine 2 mg Tablet	DCC238	28	
121	Isopropamide 7.5 mg + Trifluoperazine 2 mg Tablet	DCC238	28	
122	Ethambutol 275 mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Rifampicin 150 mg Tablet	DCC216	30	**Antituberculosis (Anti-TB)**
123	Isoniazid 100 mg + Pyrazinamide 500 mg + Rifampicin 150 mg Tablet	DCC134	30	
124	Isoniazid 100 mg + Rifampicin 150 mg Capsule	DCC137	30	
125	Isoniazid 100 mg + Rifampicin 150 mg Tablet	DCC136	30	
126	Isoniazid 100 mg + Thiacetazone 50 mg Tablet	DCC193	30	
127	Isoniazid 150 mg + Pyrazinamide 500 mg + Rifampicin 300 mg Tablet	DCC134	30	
128	Isoniazid 150 mg + Rifampicin 150 mg Tablet	DCC216	30	
129	Isoniazid 150 mg + Rifampicin 300 mg Capsule	DCC140	30	
130	Isoniazid 150 mg + Rifampicin 300 mg Tablet	DCC160	30	
131	Isoniazid 300 mg + Pyrazinamide 500 mg + Rifampicin 450 mg Tablet	DCC209	30	
132	Isoniazid 300 mg + Rifampicin 450 mg Tablet	DCC191	30	
133	Isoniazid 300 mg + Thiacetazone 150 mg Tablet	DCC162	30	
134	Isoniazid 50 mg + Rifampicin 100 mg Tablet	DCC209	30	
135	Isoniazid 75 mg + Pyrazinamide 400 mg + Rifampicin 150 mg Tablet	DCC216	30	
136	Isoniazid 75 mg + Rifampicin 150 mg Tablet	DCC216	30	
137	Chlorpheniramine Maleate 40 mg + Hydrocodon Bitartrate 50 mg + Phenylephrine Hydrochloride 100 mg/100 ml Syrup	DCC226	31	**Antitussives, Expectorants & Mucolytic**
138	Dextromethorphan Hydrobromide 130 mg + Diphenhydramine Hydrochloride 280 mg + Levomenthol 40 mg/100 ml Syrup	DCC249	31	
139	Dextromethorphan Hydrobromide 300 mg + Guaiphenesin 4 gm + Menthol 300 mg/100 ml Syrup	DCC248	31	
140	Dextromethorphan Hydrobromide 400 mg + Phenylephrine Hydrochloride 200 mg + Triprolidine Hydrochloride 50 mg/100 ml Syrup	DCC248	31	
141	Diphenhydramine Hydrochloride 280 mg + Guaiphenesin 2000 mg + Levomenthol 22 mg/100 ml Syrup	DCC249	31	
142	Abacavir 300 mg + Lamivudine 150 mg + Zidovudine 300 mg Tablet	DCC233	32	**Antiviral**

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
143	Acyclovir 5% + Hydrocortisone 1% Cream	DCC243	32	
144	Daclatasvir 60 mg + Sofosbuvir 400 mg Tablet	Export	32	
145	Emtricitabine 200 mg + Tenofovir Alafenamide 25 mg Tablet	Export	32	
146	Emtricitabine 200 mg + Tenofovir Disoproxil Fumarate 300 mg Tablet	DCC242	32	
147	Lamivudine 150 mg + Nevirapine 200 mg + Zidovudine 300 mg Tablet	DCC226	32	
148	Lamivudine 150 mg + Zidovudine 300 mg Tablet	DCC224	32	
149	Ledipasvir 90 mg + Sofosbuvir 400 mg Tablet	DCC244	32	
150	Lopinavir 133.3 mg + Ritonavir 33.3 mg Capsule	DCC226	32	
151	Lopinavir 8% + Ritonavir 2% Oral Solution	DCC226	32	
152	Sofosbuvir 400 mg + Velpatasvir 100 mg Tablet	DCC246	32	
153	Almitrine Bismesylate 30 mg + Raubasine 10 mg Tablet	DCC238	36	**Cerebral Vasodilator**
154	Desogestrel 150 mcg + Ethinylestradiol 20 mcg Tablet	DCC227	39	**Contraceptives**
155	Desogestrel 150 mcg + Ethinylestradiol 30 mcg Tablet	DCC238	39	
156	Drospirenone 3 mg + Ethinylestradiol .03 mg Tablet	DCC240	39	
157	Drospirenone 3 mg + Ethinylestradiol 20 mcg Tablet	DCC242	39	
158	Drospirenone 3 mg + Ethinylestradiol 30 mcg + L-Methylfolte Calcium 451 mcg Tablet	DCC248	39	
159	Ethinylestradiol .03 mg + Ferrous Fumarate 75 mg + Norgestrel .3 mg Tablet	DCC207	39	
160	Ethinylestradiol 2.7 mg + Etonogestrel 11.7 mg Vaginal Ring	DCC226	39	
161	Ethinylestradiol 30 mcg + Gestodene 75 mcg Tablet	DCC240	39	
162	Ethinylestradiol 30 mcg + Levo Norgestrel 150 mcg Tablet	DCC162	39	
163	Ethinylestradiol 37.5 mcg + Lynestrenol 750 mcg Tablet	DCC238	39	
164	Ethinylestradiol 50 mcg + Lynestrenol 2.5 mg Tablet	DCC162	39	
165	Amiloride Hydrochloride 5 mg + Frusemide 20 mg Tablet	DCC189	42	**Diuretics**
166	Amiloride Hydrochloride 5 mg + Hydrochlorothiazide 50 mg Tablet	DCC155	42	
167	Frusemide 20 mg + Spironolactone 50 mg Tablet	DCC189	42	
168	Indapamide 1.25 mg + Perindopril Erbumine 4 mg Tablet	DCC230	42	
169	Indapamide 625 mcg + Perindopril Erbumine 2 mg Tablet	DCC230	42	
170	Beclomethasone Dipropionate 100 mcg + Formoterol Fumarate Dihydrate 6 mcg Inhalation Aerosol	DCC248	44	**Antiasthmatic**
171	Beclomethasone Dipropionate 200 mcg + Formoterol Fumarate Dihydrate 6 mcg Inhalation Aerosol	DCC248	44	
172	Budesonide 100 mcg + Formoterol Fumarate 6 mcg Cozycap	DCC238	44	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
173	Budesonide 160 mcg + Formoterol Fumarate 4.5 mcg/Puff Inhalation Aerosol	DCC238	44	
174	Budesonide 200 mcg + Formoterol Fumarate 6 mcg Cozycap	DCC238	44	
175	Budesonide 400 mcg + Formoterol Fumarate 12 mcg Cozycap	DCC238	44	
176	Budesonide 80 mcg + Formoterol Fumarate 4.5 mcg/Puff Inhalation Aerosol	DCC238	44	
177	Fluticasone Propionate 100 mcg + Salmeterol 50 mcg Capsule	DCC224	44	
178	Fluticasone Propionate 100 mcg + Salmeterol 50 mcg Inhalation Capsule	DCC216	44	
179	Fluticasone Propionate 125 mcg + Formoterol Fumarate Dihydrate 5 mcg/Puff Inhalation Aerosol	DCC245	44	
180	Fluticasone Propionate 125 mcg + Salmeterol 25 mcg/Metered Inhalation Aerosol Inhalation	DCC221	44	
181	Fluticasone Propionate 250 mcg + Formoterol Fumarate Dihydrate 10 mcg/Puff Inhalation Aerosol	DCC245	44	
182	Fluticasone Propionate 250 mcg + Salmeterol 25 mcg/Metered Inhalation Aerosol Inhalation	DCC221	44	
183	Fluticasone Propionate 250 mcg + Salmeterol 50 mcg Inhalation Capsule	DCC215	44	
184	Fluticasone Propionate 50 mcg + Formoterol Fumarate Dihydrate 5 mcg/Puff Inhalation Aerosol	DCC245	44	
185	Fluticasone Propionate 50 mcg + Salmeterol 25 mcg/Metered Inhalation Aerosol Inhalation	DCC221	44	
186	Fluticasone Propionate 500 mcg + Salmeterol 50 mcg Inhalation Capsule	DCC216	44	
187	Glycopyrronium 50 mcg + Indacaterol 110 mcg Inhalation Capsule	DCC243	44	
188	Ipratropium Bromide 0.0333% + Salbutamol 0.1% Nebuliser Solution	DCC243	44	
189	Ipratropium Bromide 0.04% + Salbutamol 0.12% Nebuliser Solution	DCC237	44	
190	Ipratropium Bromide 20 mcg + Salbutamol 100 mcg/Metered Inhalation Aerosol Inhalation	DCC230	44	
191	Carbonyl Iron 50 mg + Folic Acid 500 mcg + Zinc 22.5 mg Capsule	DCC226	45	**Drug used in Anemia and other Blood disorder**
192	Carbonyl Iron 50 mg + Folic Acid 500 mcg Capsule	DCC226	45	
193	Cyanocobalamin 2 mg + Folic Acid 2.5 mg + Pyridoxine Hydrochloride 25 mg Tablet	DCC230	45	
194	Cyanocobalamin 25 mg + Elemental Iron 100 mg + Folic Acid 1 mg Capsule	DCC230	45	
195	Cyanocobalamin 25 mg + Elemental Iron 100 mg + Folic Acid 1 mg/5 ml Syrup	DCC230	45	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
196	Elemental Iron (As Ferrous sulphate) 47 mg + Folic Acid .5 mg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Vitamin C 50 mg + Zinc 22.5 mg Capsule	DCC228	45	
197	Elemental Iron (As Iron (III) Hydroxide Polymaltose Complex) 47 mg + Folic Acid 500 mcg + Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc (As Zinc Sulphate) 22.5 mg Capsule	DCC230	45	
198	Elemental Iron 100 mg + Folic Acid 350 mcg + Vitamin C 50 mg + Zinc 22.5 mg Tablet	DCC238	45	
199	Elemental Iron 47 mg + Folic Acid 500 mcg + Zinc 22.5 mg Tablet	DCC226	45	
200	Elemental Iron 48 mg + Folic Acid 500 mcg + Zinc Sulphate Monohydrate 61.8 mg Tablet	DCC210	45	
201	Elemental Iron 50 mg + Folic Acid 500 mcg + Nicotinamide 1 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Vitamin C 50 mg Capsule	DCC228	45	
202	Elemental Iron 50 mg + Folic Acid 500 mcg + Zinc 22.5 mg Capsule	DCC226	45	
203	Elemental Iron 60 mg + Folic Acid 400 mcg Tablet	DCC237	45	
204	Ferrous Fumarate 200 mg + Folic Acid 200 mcg Capsule	DCC124	45	
205	Ferrous Fumarate 200 mg + Folic Acid 200 mcg Tablet	DCC124	45	
206	Ferrous Fumarate 200 mg + Folic Acid 200 mg Tablet	DCC124	45	
207	Ferrous Fumarate 200 mg + Folic Acid 350 mcg Capsule	DCC146	45	
208	Ferrous Fumarate 200 mg + Folic Acid 400 mcg Tablet	DCC238	45	
209	Ferrous Fumarate 200 mg + Folic Acid 500 mcg Capsule	DCC128	45	
210	Ferrous Fumarate 308 mg + Folic Acid 350 mcg Tablet	DCC146	45	
211	Ferrous Sulphate 150 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Vitamin C 50 mg Capsule	DCC224	45	
212	Ferrous Sulphate 150 mg + Folic Acid 500 mcg + Zinc 22.5 mg Capsule	DCC210	45	
213	Ferrous Sulphate 150 mg + Folic Acid 500 mcg + Zinc 22.5 mg Tablet	DCC210	45	
214	Ferrous Sulphate 150 mg + Folic Acid 500 mcg Capsule	DCC238	45	
215	Folic Acid 5 mg + Zinc 20 mg Tablet	DCC233	45	
216	Folic Acid 500 mg + Zinc 22.5 mg Capsule	DCC215	45	
217	Caffeine 100 mg + Ergotamine Tartrate 2 mg Suppository	DCC211	47	**Drug used in Migraine**
218	Eletriptan 40 mg Tablet	DCC237	47	
219	Alendronic Acid 10 mg + Vitamin D3 400 IU Tablet	DCC238	48	**Drug used in Osteoporosis**

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
220	Dutasteride 500 mcg + Tamsulosin Hydrochloride 400 mcg Capsule	DCC242	49	**Drug used in urine Retention**
221	Metronidazole 200 mg + Neomycin Sulphate 35000 IU + Nystatin 1 Lac IU + Polymixin B Sulphate 35000 IU Soft Gelatin Capsule	DCC207	49	
222	Metronidazole 200 mg + Neomycin Sulphate 35000 IU + Nystatin 1 Lac IU + Polymixin B Sulphate 35000 IU Suppository	DCC207	49	
223	Azelastine 0% + Fluticasone Propionate 0% Nasal Spray	DCC00242	50	**Eye & Ear Preparations**
224	Benzocaine 0.25% + Oxytetracycline 0.025% + Polymixin B Sulphate 500 IU/ml Ear Drop	DCC238	50	
225	Betamethasone Sodium Phosphate 0.1% + Neomycin Sulphate 0.35% Eye, Ear & Nasal Drops	DCC238	50	
226	Betamethasone Sodium Phosphate 0.1% + Neomycin Sulphate 0.5% Eye, Ear & Nasal Drops	DCC238	50	
227	Chloramphenicol 0.5% + Lidocaine Hydrochloride 0.1% Ear Drop	DCC238	50	
228	Clioquinol 1% + Flumetasone Pivalate 0.02% Ear Drop	DCC238	50	
229	Neomycin Sulphate 0.35% + Phenylephrine Hydrochloride 0% Nasal Drops	DCC206	50	
230	Sodium Cromoglycate 0.003% + Xylometazoline Hydrochloride 0.033% Nasal Spray	DCC228	50	
231	Sodium Cromoglycate 2% + Xylometazoline Hydrochloride 0.025% Nasal Drops	DCC228	50	
232	Adenosine 0.2% + Cytochrome C 0.05% + Nicotinamide 1% + Sodium Succinate 0.06% Eye Drops	DCC208	52	
233	Adenosine 0.2% + Cytochrome C 0.05% + Nicotinamide 1% + Sodium Succinate 0.1% Eye Drops	DCC208	52	
234	Adenosine 0.2% + Cytochrome C 0.05% + Nicotinamide 2% + Sodium Succinate 0.1% Eye Drops	DCC208	52	
235	Antazoline Hydrochloride 0.05% + Tetryzoline Hydrochloride 0.04% Eye Drops	DCC211	52	**Eye & Ear Preparations**
236	Bacitracin Zinc 400 IU + Neomycin Sulphate 3.5 mg + Polymixin B Sulphate 5000 IU/gm Eye Ointment	DCC162	52	
237	Bacitracin Zinc 500 IU + Polymixin B Sulphate 10000 IU/gm Eye Ointment	DCC238	52	
238	Betamethasone Sodium Phosphate 0.1% + Neomycin Sulphate 0.35% Eye Drops	DCC238	52	
239	Betamethasone Sodium Phosphate 0.1% + Neomycin Sulphate 0.5% Eye Ointment	DCC169	52	
240	Bimatoprost 0% + Timolol 0.5% Eye Drops	DCC247	52	
241	Brimonidine Tartrate 0.2% + Brinzolamide 1% Eye Drops	DCC243	52	
242	Brimonidine Tartrate 0.2% + Timolol Maleate 0.5% Eye Drops	DCC235	52	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
243	Calcium Chloride 48 mg + Magnessium Chloride 30 mg + Potassium Chloride 75 mg + Sodium Acetate 390 mg + Sodium Chloride 490 mg + Sodium Citrate 170 mg/100 ml Irrigation Solution	DCC207	52	
244	Carboxymethylcellulose Sodium 0.25% + Hypromellose 0.3% Eye Drops	DCC241	52	
245	Carboxymethylcellulose Sodium 0.5% + Glycerine 0.9% Eye Drops	DCC238	52	
246	Chloramphenicol 0.5% + Dexamethasone 0.1% Eye Drops	DCC214	52	
247	Chlorpheniramine Maleate 0.5% + Dexamethasone 0.1% Eye Drops	DCC238	52	
248	Chondroitin Sulfate Sodium 40 mg + Sodium Hyaluronate 30 mg/ml Viscoelastic Solution	DCC238	52	
249	Ciprofloxacin 0.3% + Dexamethasone 0.1% Eye and Ear Drops	DCC226	52	
250	Ciprofloxacin 0.3% + Dexamethasone 0.1% Eye Drops	DCC226	52	
251	Ciprofloxacin 0.3% + Hydrocortisone Acetate 1% Ear Drop	DCC238	52	
252	Clioquinol 1% + Flumetasone Pivalate 0% Eye Drops	DCC238	52	
253	Clioquinol 1% + Flumetasone Pivalate 0.02% Eye Drops	DCC238	52	
254	Dexamethasone 0.05% + Tobramycin 0.3% Eye Drops	DCC242	52	
255	Dexamethasone 0.1% + Gatifloxacin 0.3% Eye Drops	DCC235	52	
256	Dexamethasone 0.1% + Moxifloxacin 0.5% Eye Drops	DCC248	52	
257	Dexamethasone 0.1% + Neomycin 0.35% + Polymixin 60 IU/gm Eye Ointment	DCC162	52	
258	Dexamethasone 0.1% + Neomycin 0.35% + Polymixin B Sulphate 60 IU/ml Eye Drops	DCC160	52	
259	Dexamethasone 0.1% + Tobramycin 0.3% Eye Drops	DCC206	52	
260	Dexamethasone 0.1% + Tobramycin 0.3% Eye Ointment	DCC210	52	
261	Dextran 70 0.1% + Disodium Edetate 0.1% + Potassium Chloride 0.1% + Sodium Chloride 0.8% Eye Drops	DCC204	52	
262	Dextran 70 0.1% + Hypromellose 0.3% Eye Drops	DCC234	52	
263	Fluormetholone 0.1% + Neomycin Sulphate 0.5% Eye Drops	DCC195	52	
264	Fluorometholone 0.1% + Gentamicin 0.3% Eye Drops	DCC206	52	
265	Fluorometholone 0.1% + Gentamicin 0.3% Eye Ointment	DCC206	52	
266	Fluorometholone 0.1% + Tetrahydrozoline Hydrochloride 0.025% Eye Drops	DCC211	52	
267	Fluorometholone 0.1% + Tetryzoline Hydrochloride 0.025% Eye Drops	DCC211	52	
268	Gatifloxacin 0.3% + Loteprednol Etabonate 0.5% Eye Drops	DCC244	52	
269	Gentamicin 0.3% + Hydrocortisone Acetate 1% Eye and Ear Drops	DCC238	52	
270	Glycerol 0.2% + Hypromellose 0.36% + Polyethylene Glycol 400 1% Eye Drops	DCC241	52	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
271	Gramacidin 2500 IU + Neomycin 1.7 Lac IU + Polymixin 5 Lac IU/100 ml Eye Drops	DCC238	52	
272	Hydrocortisone 1% + Neomycin Sulphate 3400 IU/ml + Polymixin B Sulphate 10000 IU/ml Eye and Ear Drops	DCC238	52	
273	Latanoprost 0% + Timolol 0.5% Eye Drops	DCC235	52	
274	Liquid Paraffin 42.5% + White Soft Paraffin 57.3% + Wool Alcohol 0.2% Eye Ointment	DCC242	52	
275	Loteprednol Etabonate 0.5% + Tobramycin 0.3% Eye Drops	DCC238	52	
276	Naphazoline Hydrochloride 0% + Pheniramine Maleate 0.3% Eye Drops	DCC212	52	
277	Naphazoline Nitrate 0.005% + Zinc Sulphate 0.02% Eye Drops	DCC238	52	
278	Neomycin Sulphate 0.35% + Polymixin B Sulphate 0.127% + Prednisolone 0.5% Eye Drops	DCC234	52	
279	Neomycin Sulphate 0.5% + Prednisolone 0.5% Eye and Ear Drops	DCC221	52	
280	Oxytetracycline 0.5% + Polymixin B Sulphate .01 Lac IU/gm Eye and Ear Ointment	DCC137	52	
281	Oxytetracycline 0.5% + Polymixin B Sulphate .01 Lac IU/gm Eye Ointment	DCC137	52	
282	Phenylephrine 0.12% + Tetryzoline Hydrochloride 0.04% + Zinc Sulphate 0.1% Eye Drops	DCC238	52	
283	Phenylephrine Hydrochloride 0.12% + Zinc Sulphate 0.25% Eye Drops	DCC206	52	
284	Phenylephrine Hydrochloride 5% + Tropicamide 0.8% Eye Drops	DCC226	52	
285	Polyethylene Glycol 400 0.4% + Propylene Glycol 0.3% Eye Drops	DCC229	52	
286	Polymixin B Sulphate 0.14% + Trimethoprim 0.1% Eye Drops	DCC216	52	
287	Polymixin B Sulphate 0.14% + Trimethoprim 0.5% Eye Ointment	DCC216	52	
288	Timolol Maleate 0.5% + Travoprost 0% Eye Drops	DCC237	52	
289	Neomycin 0.35% + Polymixin B Sulphate 1% + Prednisolone 0.5% Eye Drops	DCC234	52	
290	Conjugated Oestrogens 625 mcg + Norgestrel 150 mcg Tablet	DCC206	56	**Hormone**
291	Drospirenone 500 mcg + Estradiol 1 mg Tablet	DCC245	56	
292	Testosterone Decanoate 100 mg + Testosterone Isocaproate 60 mg + Testosterone Phenyl propionate 60 mg + Testosterone Propionate 30 mg/ml Injection	DCC238	56	
293	Calcium Chloride 0.549% + Glacial Acetic Acid 0.856% + Magnessium Chloride 0.374% + Potassium Chloride 0.549% + Sodium Chloride 16.143% Dialysis Solution	DCC012	59	**Kidney Dialysis Fluid**

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
294	Calcium Chloride 0.973% + Glacial Acetic Acid 0.88% + Magnessium Chloride 0.374% + Potassium Chloride 0.55% + Sodium Chloride 16.143% Dialysis Solution	DCC230	59	
295	Acetic Acid .469 % + Calcium Chloride 1.008 % + Magnessium Chloride .754 % + Potassium Chloride .554 % + Sodium Chloride 21.968 % Dialysis Solution	DCC193	59	
296	Calcium Chloride % + Dextrose Anhydrous 7 % + Magnessium Chloride % + Sodium Chloride .561 % + Sodium Lactate % Dialysis Solution	DCC238	59	
297	Calcium Chloride .0257 % + Dextrose Anhydrous 1.5 % + Magnessium Chloride .0152 % + Sodium Acetate .369 % + Sodium Chloride .561 % Dialysis Solution	DCC171	59	
298	Calcium Chloride .257 % + Dextrose Anhydrous 7 % + Magnessium Chloride .0152 % + Sodium Acetate 3.69 % + Sodium Chloride .561 % Dialysis Solution	DCC171	59	
299	Calcium Chloride .514 % + Magnessium Chloride .356 % + Potassium Chloride .521 % + Sodium Acetate 18.088 % + Sodium Chloride 19.84 % Dialysis Solution	DCC193	59	
300	Calcium Chloride 0.257% + Dextrose Anhydrous 3.86% + Magnessium Chloride 0.015% + Sodium Acetate 0.369% + Sodium Chloride 0.561% Dialysis Solution	DCC171	59	
301	Calcium Chloride 0.5% + Magnessium Chloride 0.4% + Potassium Chloride 0.5% + Sodium Acetate gm/Litres + Sodium Chloride 19.8% Dialysis Solution	DCC227	59	
302	Calcium Chloride 0.974% + Glacial Acetic Acid 0.884% + Magnessium Chloride 0.374% + Potassium Chloride 0.55% + Sodium Chloride 16.143% Dialysis Solution	DCC230	59	
303	Calcium Chloride 1% + Glacial Acetic Acid 0.9% + Magnessium Chloride 0.4% + Potassium Chloride 0.5% + Sodium Chloride 16.1% Dialysis Solution	DCC227	59	
304	Calcium Chloride 22 mg + Dextrose Anhydrous 1.5 gm + Magnessium Chloride 15 mg + Potassium Chloride 22 mg + Sodium Acetate 476 mg + Sodium Chloride 556 mg/100 ml Dialysis Solution	DCC238	59	
305	Calcium Chloride 9 mg + Dextrose Anhydrous 70 mg + Magnessium Chloride 1.189 mg + Potassium Chloride 594.57 mg + Sodium Acetate .03 mg + Sodium Chloride 5.94 mg/100 ml Dialysis Solution	DCC238	59	
306	Sodium Bicarbonate 6.6% + Sodium Chloride 3.1% Dialysis Solution	DCC227	59	
307	Citric Acid Anhydrous 12 gm + Magnesium Hydroxide 3.5 gm + Sodium Picosulfate 10 mg Powder For Oral Solution	DCC249	60	**Laxatives**
308	Ispaghula Husk 3.5 gm + Mebeverine Hydrochloride 135 mg Sachet	DCC243	60	
309	Light Liquid Paraffin 1.25 ml + Magnesium Hydroxide 300 mg/5 ml Suspension	DCC238	60	
310	Liquid Paraffin 1.25 ml + Magnesium Hydroxide 300 mg/5 ml	DCC238	60	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
	Suspension			
311	Liquid Paraffin 30 ml + Magnesium Hydroxide Dried Gel, 96% 5 gm + Magnesium Hydroxide Paste, 34% 7.06 gm/120 ml Suspension	DCC238	60	
312	Macrogol 3350 13.125 gm + Potassium Chloride 46.6 mg + Sodium Bicarbonate 178.5 mg + Sodium Chloride 350.7 mg Sachet	DCC242	60	
313	Macrogol 3350 52.5% + Potassium Chloride 0.187% + Sodium Bicarbonate 0.714% + Sodium Chloride 1.4% Oral Solution	DCC244	60	
314	Disodium Hydrogen Phosphate Dodecahydrate 24% + Sodium Dihydrogen Phosphate Dihydrate 54.22% Oral Solution	DCC240	60	
315	Niacin 500 mg + Simvastatin 20 mg Er Tablet	DCC238	61	**Lipid lowering**
316	Ascorbic Acid 500 mg + Calcium Carbonate 327 mg + Calcium Gluconate 578 mg + Calcium Lactate 422 mg Tablet	DCC216	62	**Minerals & Calcium Preparation**
317	Ascorbic Acid 60 mg + Boron (As Sodium Borate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Gluconate) 1 mg + Magnesium (As Magnesium Oxide) 20 mg + Manganese (As Manganese Sulphate) 1 mg + Vitamin D3 (As Cholecalciferol) 200 IU + Vitamin E 15 IU + Zinc (As Zinc Oxide) 7.5 mg Tablet	DCC233	62	
318	Boron (As Boron Citrate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Sulphate) 1 mg + Magnesium (As Magnesium Hydroxide) 40 mg + Manganese (As Manganese Sulphate) 1.8 mg + Viamin D 200 IU + Zinc (As Zinc Sulphate) 7 mg Tablet	DCC230	62	
319	Boron (As Boron Citrate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Sulphate) 1 mg + Magnesium (As Magnesium Hydroxide) 40 mg + Manganese (As Manganese Sulphate) 1.8 mg + Vitamin D3 5 mcg + Zinc (As Zinc Sulphate) 7.5 mg Tablet	DCC230	62	**Minerals & Calcium Preparation**
320	Boron 250 mcg + Calcium 600 mg + Copper 1 mg + Magnesium 40 mg + Manganese 1.8 mg + Vitamin D 200 IU + Zinc 7 mg Tablet	DCC230	62	
321	Calcium (Coral Calcium) 225 mg + Vitamin D3 800 IU Tablet	DCC244	62	
322	Calcium (Coral Calcium) 600 mg + Vitamin D3 400 IU Tablet	DCC241	62	
323	Calcium 500 mg + Vitamin D3 200 IU Tablet	DCC230	62	
324	Calcium 500 mg + Vitamin D3 400 IU Tablet	DCC239	62	
325	Calcium 600 mg + Cholecalciferol (Vit. D3) 400 IU Tablet	DCC241	62	
326	Calcium Carbonate 327 mg + Calcium Lactate Gluconate 1 gm + Vitamin C 500 mg + Vitamin D 400 IU Tablet	DCC228	62	
327	Calcium Carbonate 327 mg + Calcium Lactate Gluconate 1 gm + Vitamin C 500 mg Tablet	DCC216	62	
328	Calcium Pantothenate 5 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 4 mg + Vitamin B1 50 mg/2 ml Injection	DCC238	62	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
329	Citric Acid Monohydrate 5% + Potassium Citrate 30% Oral Solution	DCC238	62	
330	Potassium Bicarbonate 200 mg + Potassium Chloride 448 mg Tablet	DCC238	62	
331	Chondroitin 200 mg + Glucosamine 250 mg Tablet	DCC226	64	**Drug Used in Arthitris**
332	Chondroitin 600 mg + Glucosamine 750 mg Tablet	DCC248	64	
333	Diclofenac 75 mg + Lidocaine Hydrochloride 20 mg/2 ml IM Injection	DCC207	64	**NSAID**
334	Diclofenac Sodium 50 mg + Misoprostol 200 mcg Tablet	DCC228	64	
335	Diclofenac Sodium 50 mg Suppository	DCC238	64	
336	Diclofenac Sodium 75 mg + Misoprostol 200 mcg Tablet	DCC228	64	
337	Esomeprazole 20 mg + Naproxen 375 mg Dr Tablet	DCC240	64	
338	Esomeprazole 20 mg + Naproxen 375 mg Tablet	DCC240	64	
339	Esomeprazole 20 mg + Naproxen 500 mg Dr Tablet	DCC240	64	
340	Esomeprazole 20 mg + Naproxen 500 mg Tablet	DCC240	64	
341	Lidocaine Hydrochloride 2.5 mg + Tolperisone Hydrochloride 100 mg Injection	DCC238	70	**Skeleton Muscle Relaxant**
342	Adapalene 0.1% + Benzoyl Peroxide 2.5% Gel	DCC238	71	**Skin & Mucous Membrane Preparations**
343	Anhydrous Benzoyl Peroxide 5% + Clindamycin 1% Gel	DCC241	71	
344	Arachis Oil 30.5% + Cetostearyl Alcohol 2% + Virgin Castor Oil 0.05% + White Beeswax 10% + Zinc Oxide 7.5% Ointment	DCC226	71	**Skin & Mucous Membrane Preparations**
345	Avobenzone 2% + Oxybenzone 3% + Padimate O 8% + Titanium Dioxide 2% Lotion	DCC239	71	
346	Bacitracin Zinc 500 IU/gm + Neomycin Sulphate 0.5% Ointment	DCC155	71	
347	Bacitracin Zinc 250 IU + Neomycin Sulphate 5 mg/gm Powder	DCC106	71	
348	Benzocaine 0.065% + Camphor 0.25% + Methanol 0.25% + Phenol 0.45% Solution	DCC234	71	
349	Benzocaine 0.2% + Camphor 0.25% + Methanol 0.25% + Phenol 0.45% Solution	DCC234	71	
350	Benzocaine 18 gm + Tetracaine 2 gm/100 ml Spray	DCC244	71	
351	Benzoyl Peroxide 5% + Clindamycin 1% Gel	DCC241	71	
352	Benzoyl Peroxide 5% + Erythromycin 3% Cream	DCC215	71	
353	Betamethasone 0.05% + Calcipotriol 0.005% Ointment	DCC240	71	
354	Betamethasone 0.05% + Clotrimazole 1% + Gentamicin 0.1% Cream	DCC244	71	
355	Betamethasone 0.05% + Clotrimazole 1% Cream	DCC189	71	
356	Betamethasone 0.05% + Gentamicin 0.1% Cream	DCC235	71	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
357	Betamethasone 0.05% + Lidocaine Hydrochloride 2.5% + Phenylephrine Hydrochloride 0.1% Rectal Ointment	DCC179	71	
358	Betamethasone 0.05% + Salicylic Acid 2% Lotion	DCC237	71	
359	Betamethasone 0.05% + Salicylic Acid 3% Ointment	DCC245	71	
360	Betamethasone 0.1% + Clotrimazole 1% Cream	DCC189	71	
361	Betamethasone 0.1% + Clotrimazole 1% Ointment	DCC181	71	
362	Betamethasone 0.1% + Fusidic Acid 2% Cream	DCC235	71	
363	Betamethasone 0.1% + Neomycin Sulphate 0.5% Cream	DCC181	71	
364	Betamethasone 0.1% + Neomycin Sulphate 0.5% Ointment	DCC109	71	
365	Betamethasone 50 mg + Calcipotriol 5 mg/100 gm Topical Suspension	DCC241	71	
366	Boric Acid 2% + Dithranol 0.1% + Salicylic Acid 1% Ointment	DCC238	71	
367	Calamine 15% + Zinc Oxide 5% Lotion	DCC162	71	
368	Calcium Dobesilate 4% + Dexamethasone Acetate 0.025% + Lidocaine Hydrochloride 2% Ointment	DCC243	71	
369	Camphor 2.5% + Menthol 2% + Oil Clove 2.5% + Oil Eucalyptus 1.25% + Oil Turpentine 1% Ointment	DCC109	71	
370	Camphor 3% + Menthol 2.82% + Oil Eucalyptus 0.35% + Oil Turpentine 4.77% + Thymol 0.1% Ointment	DCC109	71	
371	Camphor 4% + Menthol 10% + Methyl Salicylate 30% Cream	DCC241	71	
372	Cetrimide 0.5% + Chlorhexidine Hydrochloride 0.1% Cream	DCC238	71	**Skin & Mucous Membrane Preparations**
373	Cetrimide 15% + Chlorhexidine Gluconate 1.5% Solution	DCC160	71	
374	Cetrimide 3% + Chlorhexidine Gluconate 0.3% Solution	DCC153	71	
375	Chlorhexidine Gluconate 0.25% + Lidocaine Hydrochloride 2% Gel	DCC220	71	
376	Chloroxylenol 0.3% + Triclosan 0.3% Cream	DCC122	71	
377	Cinchocaine Hydrochloride 0.5% + Esculin 1% + Hydrocortisone 0.5% + Neomycin Sulphate 1% Ointment	DCC238	71	
378	Clobetasol Propionate 0.05% + Neomycin Sulphate 0.5% + Nystatin 1 Lac IU/gm Cream	DCC230	71	
379	Clobetasol Propionate 0.05% + Neomycin Sulphate 0.5% + Nystatin 1 Lac IU/gm Ointment	DCC230	71	
380	Clobetasol Propionate 0.05% + Salicylic Acid 3% Ointment	DCC237	71	
381	Clotrimazole 1% + Hydrocortisone 1% Cream	DCC218	71	
382	Coal Tar Solution 12 gm + Precipitated Sulpher 4 gm + Salicylic Acid 2 gm/100 gm Scalp Ointment	DCC240	71	
383	Condroitin Sulphate Sodium 3% + Glucosamine Sulphate 2% Cream	DCC241	71	
384	Crotamiton 10% + Permethrin .05 gm/ml Lotion	DCC230	71	
385	Dioxybenzone 0.3% + Hydroquinone 0.4% + Octyldimethyl p-aminobenzoate 0.8% + Oxybenzone 0.2% Cream	DCC220	71	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
386	Diphenhydramine Hydrochloride 2 gm + Zinc Acetate 100 mg/100 gm Spray	DCC242	71	
387	Diphenhydramine Hydrochloride 2% + Zinc Acetate 0.1% Cream	DCC234	71	
388	Econazole Nitrate 1% + Triamcinolone Acetonide 0.1% Cream	DCC118	71	
389	Econazole Nitrate 1% + Triamcinolone Acetonide 0.1% Ointment	DCC118	71	
390	Ethyl Alcohol 0% + Isopropyl Alcohol 0% Gel	DCC240	71	
391	Fluocinolone 0.01% + Hydroquinone 4% + Tretinoin 0.05% Cream	DCC239	71	
392	Fluocinolone 0.025% + Neomycin Sulphate 0.5% Cream	DCC238	71	
393	Fluocinolone 0.025% + Neomycin Sulphate 0.5% Ointment	DCC238	71	
394	Fusidic Acid 2% + Hydrocortisone Acetate 1% Cream	DCC214	71	
395	Fusidic Acid 2% + Hydrocortisone Acetate 1% Ointment	DCC238	71	
396	Gentamicin 0.3% + Hydrocortisone Acetate 1% Cream	DCC134	71	
397	Gramicidin 0.025% + Neomycin Sulphate 0.25% + Nystatin 1 Lac IU/gm + Triamcinolone Acetonide 0.1% Cream	DCC001	71	
398	Hydrocortisone 1% + Miconazole Nitrate 2% Cream	DCC189	71	
399	Hydrocortisone 1% + Miconazole Nitrate 2% Ointment	DCC189	71	
400	Hydrocortisone Acetate 0.5% + Lidocaine Hydrochloride 3% Cream	DCC243	71	
401	Hydrocortisone Acetate 0.5% + Neomycin Sulphate 0.5% Cream	DCC150	71	**Skin & Mucous Membrane Preparations**
402	Hydrocortisone Acetate 0.5% + Neomycin Sulphate 0.5% Ointment	DCC162	71	
403	Hydrocortisone Acetate 2.5% + Pramoxine 1% Cream	DCC233	71	
404	Hydrocortisone Acetate 2.5% + Pramoxine 1% Ointment	DCC233	71	
405	Lidocaine 2.5 gm + Prilocaine 2.5 gm/100 gm Cream	DCC235	71	
406	Lidocaine 7% + Tetracaine 7% Cream	DCC242	71	
407	Light Liquid Paraffin 3% + White Soft Paraffin 8% Lotion	DCC239	71	
408	Light Liquid Paraffin 6% + White Soft Paraffin 15% Cream	DCC239	71	
409	Menthol 1% + Pramoxine Hydrochloride 1% Cream	DCC241	71	
410	Menthol 10% + Methyl Salicylate 15% Cream	DCC231	71	
411	Menthol 10% + Methyl Salicylate 30% Cream	DCC231	71	
412	Neomycin Sulphate 0.4% + Polymixin B Sulphate 10000 IU/gm + Pramoxine 1% Cream	DCC234	71	
413	Nicotinamide 4% Gel	DCC242	71	
414	Oxytetracycline 3% + Polymixin B Sulphate 845 IU/gm Ointment	DCC149	71	
415	Precipitated Sulpher 3% + Salicylic Acid 2% Ointment	DCC157	71	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
416	Neomycin Sulphate 0.6% + Polymixin B Sulphate 10000 IU/gm + Pramoxine 1% Cream	DCC234	71	
417	Cetalkonium Chloride 0.01% + Choline Salicylate 8.714% Oral Gel	DCC238	73	**Throat Preparations, Mouth Washes & Gargles**
418	Glycerine .75 ml + Liquid Sugar 1.93 ml/5 ml Syrup	DCC231	73	
419	Eucalypytol gm/ml + Menthol 0.042% + Thymol gm/ml Mouth Wash	DCC241	73	
420	Eucalypytol 0.091% + Menthol 0.042% + Thymol 0.063% Mouth Wash	DCC241	73	
421	Eucalypytol 0.092% + Menthol 0.042% + Methyl Salicylate 0.06% + Sodium Fluoride 0.02% + Thymol 0.064% Mouth Wash	DCC241	73	
422	Eucalypytol 0.092% + Menthol 0.042% + Methyl Salicylate 0.06% + Thymol 0.064% Mouth Wash	DCC235	73	
423	Eucalypytol 92 mg + Menthol 42 mg + Methyl Salicylate 60 mg + Thymol 64 mg/100 ml Mouth Wash Antiseptic	DCC235	73	
424	Cinchocaine Hydrochloride 5 mg + Esculin 10 mg + Hydrocortisone 5 mg + Neomycin Sulphate 10 mg Suppository	DCC238	75	**Antihaemorrhoidal**
425	Cinchocaine Hydrochloride 5 mg + Hydrocortisone 5 mg Suppository	DCC214	75	**Antihaemorrhoidal**
426	Diosmin 450 mg + Hesperidin 50 mg Tablet	DCC238	75	**Antihaemorrhoidal**
427	Diosmin 900 mg + Hesperidin 100 mg Tablet	DCC248	75	**Antihaemorrhoidal**
428	L-Ornithine L-Aspartate 150 mg + Pancreatin 100 mg Tablet	DCC243	75	**Antihyperammonia**
429	Ascorbic Acid (As Ascorbic Acid) 25 mg + Ascorbic Acid (As Sodium Ascorbate) 25 mg + Dexpanthanol 1.25 mg + Nicotinamide 5 mg + Pyridoxine Hydrochloride .35 mg + Riboflavin .4 mg + Viamin D 140 IU + Vitamin A 666.67 IU + Vitamin B1 .3 mg + Vitamin E 2 IU/5 ml Syrup	DCC233	78	**Vitamins & Minerals**
430	Ascorbic Acid 100 mg + Biotin .06 mg + Cyanocobalamin .005 mg + Folic Acid .4 mg + Nicotinamide 40 mg + Pantothenic acid 15 mg + Pyridoxine 4 mg + Riboflavin 3.6 mg + Thiamine 2.5 mg/vial Injection	DCC240	78	
431	Ascorbic Acid 100 mg + Biotin 60 mcg + Cyanocobalamin 5 mcg + Dexpanthanol 15 mg + Folic Acid 400 mcg + Nicotinamide 40 mg + Pyridoxine Hydrochloride 4 mg + Riboflavine Sodium Phosphate 3.6 mg + Thiamine Nitrate 2.5 mg/vial Injection	DCC240	78	
432	Ascorbic Acid 100 mg + Nicotinamide 1 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2.85 mg + Vitamin A 5000 IU + Vitamin B1 1.67 mg + Vitamin D 666 IU/ml Paediatric Drops	DCC238	78	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
433	Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Soft Gelatin Capsule	DCC227	78	
434	Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Capsule	DCC227	78	
435	Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Tablet	DCC227	78	**Vitamins & Minerals**
436	Ascorbic Acid 125 mg + Biotin 69 mcg + Cholecalciferol (Vit. D3) 220 IU + Cyanocobalamin 6 mcg + Dl-Alpha Tocoferol (Vitamin E) 11.2 IU + Folic Acid 414 mcg + Nicotinamide 46 mg + Pantothenic acid 17.25 mg + Pyridoxine Hydrochloride 5.5 mg + Retinol Palmitate 3500 IU + Riboflavin 4.14 mg + Thiamine Mononitrate (B1) 3.51 mg/vial Injection	DCC240	78	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
437	Ascorbic Acid 1350 mg + Biotin 650 mcg + Calcium (As Calcium Lactate) 550 mg + Choline Bitartrate 200 mg + Chromium (As Chromium Ploynicotinate) 70 mcg + Cyanocobalamin 60 mcg + Inositol 200 mg + Iodine (As Potassium Iodide) 500 mcg + Magnesium (As Magnesium Lactate) 150 mg + Manganese (As Manganese Gluconate) 15 mg + Pantothenic acid 70 mg + Para-Amino-Benzoic Acid 10 mg + Pottassium (As Potassium Citrate) 140 mg + Riboflavin 20 mg + Selenium (As Selenomethionine) 350 mcg + Vitamin A (As Beta Carotene) 17000 IU + Vitamin A (As Ratinol Palmitate) 17000 IU + Vitamin B1 (As Thiamine Hydrochloride) 20 mg + Vitamin D3 2750 IU + Vitamin E (As dl-Alpha Tocopheryl Acetate) 200 IU + Zinc (As Zinc Gluconate) 50 mg Syrup	DCC233	78	
438	Ascorbic Acid 150 mg + Calcium d-Pantothenate 12.5 mg + Cyanocobalamin 5 mcg + Folic Acid 1 mg + Nicotinamide 50 mg + Pyridoxine Hydrochloride 3 mg + Riboflavin 10 mg + Vitamin B1 10 mg Capsule	DCC230	78	
439	Ascorbic Acid 17.5 mg + Cod Liver Oil 100 mg + Nicotinamide 9 mg + Pyridoxine Hydrochloride .35 mg + Riboflavin .85 mg + Vitamin A 2000 IU + Vitamin B1 .7 mg + Vitamin D3 200 IU + Vitamin E 1.5 mg/5 ml Syrup	DCC233	78	
440	Ascorbic Acid 175 mg + Calcium d-Pantothenate 25 mg + Cynocobalamin 5 mcg + Folic Acid 500 mcg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 25 mg + Vitamin B1 50 mg Capsule	DCC231	78	
441	Ascorbic Acid 200 mg + Copper (As Cupric Oxide) 1 mg + Manganese (As Manganese Sulphate) 3 mg + Selenium (As Sodium Selenate) 70 mcg + Vitamin A (As Beta Carotene) 2000 IU + Vitamin E 50 IU + Vitamin K 75 mcg + Zinc (As Zinc Oxide) 15 mg Capsule	DCC226	78	
442	Ascorbic Acid 200 mg + Copper (As Cupric Oxide) 1 mg + Manganese (As Manganese Sulphate) 3 mg + Selenium (As Sodium Selenate) 70 mcg + Vitamin A (As Beta Carotene) 2000 IU + Vitamin E 50 IU + Vitamin K 75 mcg + Zinc (As Zinc Oxide) 15 mg Tablet	DCC226	78	**Vitamins & Minerals**
443	Ascorbic Acid 250 mg + Dexpanthanol 24.906 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 7 mg + Riboflavin 8 mg + Sodium Acetate 280 mg + Thiamine Hydrochloride 6 mg + Vitamin A 13332 IU + Vitamin D 2800 IU + Vitamin E 40 IU/100 ml Syrup	DCC233	78	
444	Ascorbic Acid 250 mg + Dexpanthanol 24.906 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 7 mg + Riboflavin 8 mg + Sodium Acetate 280 mg + Thiamine Hydrochloride 6 mg + Vitamin A 13332 IU + Vitamin D 2800 IU + Vitamin E 40 IU/100 ml Syrup	DCC233	78	
445	Ascorbic Acid 30 mg + Folic Acid .16 mg + Iron 12.5 mg + Vitamin A .3 mg + Zinc (As Gluconate) 5 mg Sachet	DCC232	78	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
446	Ascorbic Acid 50 mg + Elemental Iron (As Carbonyl Iron) 50 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2.2 mg + Vitamin B1 2.2 mg + Zinc (As Zinc Sulphate) 22.5 mg Capsule	DCC229	78	
447	Ascorbic Acid 50 mg + Elemental Iron (As Ferrous sulphate) 47 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Zinc (As Zinc Sulphate) 22.5 mg Capsule	DCC228	78	
448	Ascorbic Acid 50 mg + Elemental Iron (As Ferrous sulphate) 47 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg Capsule	DCC228	78	
449	Ascorbic Acid 50 mg + Elemental Iron 50 mg + Folic Acid .5 mg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg Capsule	DCC224	78	
450	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 162 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6 mcg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 109 mg + Pottassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B1 1.5 mg + Vitamin D3 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Soft Gelatin Capsule	DCC228	78	**Vitamins & Minerals**

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
451	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 162 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6 mcg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 109 mg + Pottassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B1 1.5 mg + Vitamin D3 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Tablet	DCC228	78	
452	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 200 mg + Chromium (As Chromium Chloride) 150 mcg + Copper (As Copper Lysinate) 2 mg + Cyanocobalamin 25 mcg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Glycinate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 48 mg + Pottassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 3 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 45 IU + Vitamin K 10 mcg + Zinc (As Zinc Oxide) 15 mg Soft Gelatin Capsule	DCC228	78	**Vitamins & Minerals**

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
453	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium Carbonate (As Calcium 20.975) 52.49 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6 mcg + Diabasic Calcium Phosphate (As Calcium 141.025 mg) 478.695 mg + Diabasic Calcium Phosphate (As Phosphorous 109 mg) 478.695 mg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Potassium Chloride (As Chloride 72 mg) 152.52 mg + Potassium Chloride (As Potassium 80 mg) 152.52 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Sodium Metasilicate) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Tablet	DCC233	78	
454	Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Tablet	DCC193	78	
455	Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Capsule	DCC193	78	**Vitamins & Minerals**
456	Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Soft Gelatin Capsule	DCC228	78	
457	Ascorbic Acid 60 mg + Copper 2 mg + Lutein 6 mg + Vitamin E 30 mg + Zinc 15 mg Capsule	DCC226	78	
458	Ascorbic Acid 60 mg + Copper 2 mg + Lutein 6 mg + Vitamin E 30 mg + Zinc 15 mg Soft Gelatin Capsule	DCC226	78	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
459	Ascorbic Acid 75 mg + Calcium Pantothenate 5 mg + Cyanocobalamin 2 mcg + Nicotinamide 13 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 10 mg + Vitamin A 5000 IU + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 5 IU Capsule	DCC193	78	
460	Ascorbic Acid 75 mg + Calcium Pantothenate 5 mg + Cyanocobalamin 2 mcg + Nicotinamide 13 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 10 mg + Vitamin A 5000 IU + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 5 IU Tablet	DCC193	78	
461	Beta Carotene 3 mg + Calcium 59 mg + Cholecalciferol (Vit. D3) 250 IU + Cyanocobalamin 1.5 mcg + Folic Acid 250 mcg + Iodine 125 mcg + Iron 5 mg + Magnesium 15 mg + Nicotinamide 7.5 mg + Phosphorous 45.6 mg + Pyridoxine Hydrochloride 750 mcg + Riboflavin 750 mcg + Thiamine Nitrate 500 mcg + Vitamin C 15 mg + Vitamin E 5.2 IU + Zinc 8 mg Tablet	DCC238	78	
462	Beta Carotene 6 mg + Copper 1 mg + Manganese 3 mg + Selenium 70 mcg + Vitamin C 200 mg + Vitamin E 50 mg + Vitamin K 75 mcg + Zinc 15 mg Capsule	DCC226	78	
463	Beta Carotene 6 mg + Copper 1 mg + Manganese 3 mg + Selenium 70 mcg + Vitamin C 200 mg + Vitamin E 50 mg + Vitamin K 75 mcg + Zinc 15 mg Tablet	DCC226	78	
464	Betacarotene 6 mg + Vitamin C 200 mg + Vitamin E 50 mg Soft Gelatin Capsule	DCC210	78	
465	Betacarotene 6 mg + Vitamin C 200 mg + Vitamin E 50 mg Tablet	DCC209	78	
466	Biotin 300 mcg + Calcium 200 mg + Chromium 120 mcg + Copper 2 mg + Folic Acid 400 mcg + Iron 9 mg + Magnesium 100 mg + Manganese 2 mg + Niacin 30 mg + Pantothenic acid 10 mg + Riboflavin 4.2 mg + Selenium 20 mcg + Thiamine 3.75 mg + Vitamin A 2500 IU + Vitamin B12 15 mcg + Vitamin B6 5 mg + Vitamin C 120 mg + Vitamin D 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc 15 mg Tablet	DCC241	78	**Vitamins & Minerals**
467	Biotin 300 mcg + Calcium 300 mg + Chromium 120 mcg + Copper 2 mg + Folic Acid 400 mcg + Iron 18 mg + Magnesium 50 mg + Manganese 2 mg + Niacin 30 mg + Pantothenic acid 10 mg + Riboflavin 2.6 mg + Selenium 20 mcg + Thiamine 2.3 mg + Vitamin A 2500 IU + Vitamin B12 9 mcg + Vitamin B6 3 mg + Vitamin C 120 mg + Vitamin D 800 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc 15 mg Tablet	DCC241	78	
468	Biotin 45 mcg + Calcium 43.31 mg + Cholecalciferol (Vit. D3) 400 IU + Chromium 20 mcg + Copper 2 mg + Cyanocobalamin 6 mcg + Diabasic Calcium Phosphate 220 mg + Folic Acid 400 mcg + Iodine 150 mcg + Iron 18 mg + Magnesium 40 mg + Manganese 1 mg + Molybdenum 20 mcg + Niacin 20 mg + Pantothenic acid 10 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Thiamine Nitrate 1.5 mg + Vitamin A 1015 IU + Vitamin A Acetate 2485 IU + Vitamin C 60 mg + Vitamin E 60 mg + Vitamin K 10 mcg +	DCC238	78	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
	Zinc 15 mg Chewable Tablet			
469	Calcitriol .25 mcg + Calcium 252 mg Tablet	DCC241	78	
470	Calcium (Coral Calcium) 500 mg + Vitamin D3 200 IU Tablet	DCC230	78	
471	Calcium 250 mg + Vitamin D3 250 IU Gummy Tablet	DCC244	78	
472	Calcium 500 mg + Vitamin D3 500 IU Gummy Tablet	DCC244	78	
473	Cod Liver Oil 50 mg + Pantothenic acid 5 mg + Vitamin B1 1.6 mg + Vitamin B2 1 mg + Vitamin B3 10 mg + Vitamin B6 1 mg + Vitamin C 50 mg/ml Paediatric Drops	DCC238	78	
474	Copper mg + Folic Acid .15 mg + Iodine .09 mg + Iron 10 mg + Niacin 6 mg + Pyridoxine .5 mg + Riboflavin .5 mg + Selenium .017 mg + Vitamin A .4 mg + Vitamin B1 .5 mg + Vitamin B12 .0002 mg + Vitamin C 30 mg + Vitamin D .005 mg + Vitamin E 5 mg + Zinc mg Sachet	DCC240	78	
475	Copper .56 mg + Folic Acid .15 mg + Iodine .09 mg + Iron 10 mg + Niacin 6 mg + Pyridoxine .5 mg + Riboflavin .5 mg + Selenium .017 mg + Vitamin A .4 mg + Vitamin B1 .5 mg + Vitamin B12 .0009 mg + Vitamin C 30 mg + Vitamin D .005 mg + Vitamin E 5 mg + Zinc 4.1 mg Sachet	DCC238	78	
476	Cyanocobalamin 1 mg + Pyridoxine Hydrochloride 100 mg + Vitamin B1 100 mg/3 ml Injection	DCC230	78	
477	Cyanocobalamin 1 mg/ml Injection	DCC162	78	
478	Cyanocobalamin 200 mcg + Pyridoxine Hydrochloride 200 mg + Vitamin B1 100 mg Tablet	DCC230	78	
479	Dexpanthanol 25 mg + Nicotinamide 500 mg + Pyridoxine Hydrochloride 50 mg + Riboflavin 20 mg + Vitamin B1 250 mg/10 ml Injection	DCC125	78	**Vitamins & Minerals**
480	D-Panthenol 5 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 4 mg + Vitamin B1 50 mg/2 ml Injection	DCC114	78	
481	Elemental Iron 50 mg + Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc 10 mg/5 ml Syrup	DCC230	78	
482	Folic Acid 250 mcg + L-Lysine 50 mg + Nicotinamide 2.5 mg + Vitamin A 1500 IU + Vitamin B1 250 mcg + Vitamin B12 2 mcg + Vitamin B2 250 mcg + Vitamin B6 250 mcg + Vitamin C 50 mg + Vitamin D3 100 IU + Vitamin E 10 IU Tablet	DCC241	78	
483	Iron 50 mg + Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc 10 mg/5 ml Syrup	DCC230	78	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
484	Niacinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc 10 mg/5 ml Syrup	DCC231	78	
485	Niacinamide 400 mg + Pyridoxine Hydrochloride 40 mg + Riboflavin 40 mg + Thiamine Hydrochloride 100 mg + Zinc 200 mg/100 ml Syrup	DCC231	78	
486	Nicotinamide 10 mg + Pantothenic acid 5 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 1 mg + Vitamin A 5000 IU + Vitamin B1 1.6 mg + Vitamin C 50 mg + Vitamin D 1000 IU/ml Paediatric Drops	DCC238	78	
487	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg Capsule	DCC140	78	
488	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg Tablet	DCC172	78	
489	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg/5 ml Syrup	DCC202	78	
490	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2.75 mg + Vitamin B1 5 mg + Zinc 10 mg Tablet	DCC233	78	
491	Nicotinamide 400 mg + Pyridoxine Hydrochloride 40 mg + Riboflavin 50 mg + Vitamin B1 100 mg + Zinc 200 mg/100 ml Syrup	DCC231	78	
492	Pantothenic acid 500 mg + Pyridoxine Hydrochloride 100 mg + Riboflavin 100 mg + Vitamin A 5 Lac IU + Vitamin B1 160 mg + Vitamin C 5 gm + Vitamin D 1 gm/100 ml Paediatric Drops	DCC238	78	
493	Pyridoxine Hydrochloride 100 mg + Riboflavin 5 mg + Vitamin B1 100 mg Injection	DCC238	78	
494	Pyrimethamine 1 gm + Sodium Salicylate 5 gm + Sulphaquinoxaline 5 gm + Vitamin A 1 gm + Vitamin K 20 mg/100 ml Liquid	DCC238	78	
495	Vitamin C 200 mg + Vitamin E 200 mg Tablet	DCC216	78	
496	Vitamin C 200 mg + Vitamin E 50 mg Tablet	DCC238	78	
497	Vitamin C 250 mg + Vitamin E 200 mg Capsule	DCC230	78	
498	Vitamin C 250 mg + Vitamin E 200 mg Tablet	DCC238	78	
499	Anhydros Citricacid 384 mg + Anhydrous Glucose 1.62 gm + Potassium Chloride 186 mg + Sodium Bicarbonate 336 mg + Sodium Chloride 117 mg Tablet	DCC223	79	**Electrolytes**
500	Anhydrous Glucose 1.62 gm + Citric Acid 384 mg + Potassium Chloride 186 mg + Sodium Bicarbonate 336 mg + Sodium Chloride 117 mg Ors Tablet	DCC234	79	
501	Anhydrous Glucose 10 gm + Potassium Chloride 750 mg + Sodium Bicarbonate 1.25 gm + Sodium Chloride 1.75 gm Oral Saline	DCC161	79	
502	Anhydrous Glucose 6.75 gm + Potassium Chloride 750 mg + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm Oral Saline	DCC226	79	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
503	Calcium Chloride .48 mg + Magnessium Chloride .3 mg + Potassium Chloride .75 mg + Sodium Acetate 3.9 mg + Sodium Chloride 6.4 mg + Sodium Citrate 1.7 mg/ml Salt Solution	DCC235	79	
504	Calcium Chloride 0.033% + Potassium Chloride 0.03% + Sodium Chloride 0.86% IV Infusion	DCC238	79	
505	Calcium Chloride 0.048% + Magnesium Hydroxide 0.03% + Potassium Chloride 0.075% + Sodium Acetate 0.39% + Sodium Chloride 0.64% + Sodium Citrate 0.17% IV Infusion	DCC231	79	
506	Calcium Chloride 20 mg + Dextrose Anhydrous 5 gm + Potassium Chloride 30 mg + Sodium Chloride 600 mg + Sodium Lactate 310 mg/100 ml IV Infusion	DCC235	79	
507	Calcium Chloride 27 mg + Potassium Chloride 40 mg + Sodium Chloride 600 mg + Sodium Lactate 320 mg/100 ml IV Infusion	DCC162	79	
508	Dextran 40 10% + Dextrose 5% IV Infusion	DCC171	79	
509	Dextran 40 10% + Sodium Chloride 0.9% IV Infusion	DCC171	79	
510	Dextran 40 40 mg + Sodium Chloride 9 mg Injection	DCC171	79	
511	Dextran 40 70 mg + Sodium Chloride 9 mg Injection	DCC171	79	
512	Dextran 70 6 gm + Sodium Chloride 900 mg IV Infusion	DCC171	79	
513	Dextran 70 6% + Dextrose 5% IV Infusion	DCC171	79	
514	Dextran 70 6% + Sodium Chloride 0.9% IV Infusion	DCC171	79	
515	Dextran 70 60 gm + Sodium Chloride 75 gm/Litres Solution For Infusion	DCC227	79	
516	Dextrose 10% + Sodium Chloride %/ IV Infusion	DCC171	79	
517	Dextrose 10% + Sodium Chloride 0.225% IV Infusion	DCC166	79	
518	Dextrose 10% IV Infusion	DCC166	79	
519	Dextrose 4.3% + Sodium Chloride 0.18% IV Infusion	DCC212	79	
520	Dextrose 5% + Sodium Chloride %/ IV Infusion	DCC166	79	**Electrolytes**
521	Dextrose 5% + Sodium Chloride %/ IV Infusion	DCC166	79	
522	Dextrose 5% + Sodium Chloride %/ IV Infusion	DCC216	79	
523	Dextrose 5% + Sodium Chloride 0.18% IV Infusion	DCC171	79	
524	Dextrose 5% + Sodium Chloride 0.225% IV Infusion	DCC166	79	
525	Dextrose 5% + Sodium Chloride 0.25% IV Infusion	DCC171	79	
526	Dextrose 5% + Sodium Chloride 0.45% IV Infusion	DCC166	79	
527	Dextrose 5% + Sodium Chloride 0.9% IV Infusion	DCC123	79	
528	Dextrose Anhydrous 10 gm + Potassium Chloride 750 gm + Sodium Chloride 1.75 gm + Trisodium Citrate 1.45 gm/500 ml Oral Saline	DCC171	79	
529	Dextrose Anhydrous 10 gm + Potassium Chloride 750 mg + Sodium Chloride 1.75 gm + Trisodium Citrate 1.45 gm/500 ml Oral Saline	DCC171	79	

List of Human Combination Products other than Antibiotic Preparation				
Sl.	**Generic Name with Strength**	**DCC**	**Therapeutic Code**	**Therapeutic Class**
530	Dextrose Anhydrous 13.5 gm + Potassium Chloride 1.5 gm + Sodium Chloride 2.6 gm + Trisodium Citrate 2.9 gm/Litres Oral Saline	DCC226	79	
531	Dextrose Anhydrous 20 gm + Potassium Chloride 1.5 gm + Sodium Chloride 3.5 gm + Trisodium Citrate 2.9 gm/Litres Oral Saline	DCC171	79	
532	Dextrose Anhydrous 4.09 gm + Fructose 70 mg + Potassium Chloride 380 mg + Sodium Bicarbonate 420 mg + Sodium Chloride 440 mg + Sucrose 8.07 gm/250 ml Oral Saline	DCC223	79	
533	Dextrose Anhydrous 6.75 gm + Potassium Chloride 750 mg + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm/500 ml Oral Saline	DCC226	79	
534	Poly (0-2 Hydroxyethyl Starch (Hydroxyethyl 130/0.4) 60 gm + Sodium Chloride 9 gm/1000 ml Solution For Infusion	DCC220	79	
535	Potassium Chloride .75 gm + Rice Powder (Pregelatineized) 25 gm + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm Oral Saline	DCC233	79	
536	Potassium Chloride .75 gm + Rice Powder (Pregelatineized) 25 gm + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm/500 ml Oral Saline	DCC233	79	
537	Potassium Chloride .75 mg + Rice Powder (Pregelatineized) 25 gm + Sodium Chloride 1.3 mg + Sodium Citrate 1.45 gm Oral Saline	DCC233	79	
538	Potassium Chloride 0.003% + Sodium Chloride 0.004% + Sodium Lactate 0.007% IV Infusion	DCC238	79	
539	Potassium Chloride 0.1% + Sodium Acetate 0.65% + Sodium Chloride 0.5% IV Infusion	DCC171	79	

Annex-B: ইতঃপূর্বে অনুমোদিত ভিটামিন ও মিনারেলস জাতীয় কম্বিনেশন ঔষধের তালিকা

(List of Human Vitamins & Minerals Combination Products)

Sl.		Generic Name with Strength	DCC
1.	191	Carbonyl Iron 50 mg + Folic Acid 500 mcg + Zinc 22.5 mg Capsule	DCC226
2.	192	Carbonyl Iron 50 mg + Folic Acid 500 mcg Capsule	DCC226
3.	193	Cyanocobalamin 2 mg + Folic Acid 2.5 mg + Pyridoxine Hydrochloride 25 mg Tablet	DCC230
4.	194	Cyanocobalamin 25 mg + Elemental Iron 100 mg + Folic Acid 1 mg Capsule	DCC230
5.	195	Cyanocobalamin 25 mg + Elemental Iron 100 mg + Folic Acid 1 mg/5 ml Syrup	DCC230
6.	196	Elemental Iron (As Ferrous sulphate) 47 mg + Folic Acid .5 mg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Vitamin C 50 mg + Zinc 22.5 mg Capsule	DCC228
7.	197	Elemental Iron (As Iron (III) Hydroxide Polymaltose Complex) 47 mg + Folic Acid 500 mcg + Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc (As Zinc Sulphate) 22.5 mg Capsule	DCC230
8.	198	Elemental Iron 100 mg + Folic Acid 350 mcg + Vitamin C 50 mg + Zinc 22.5 mg Tablet	DCC238
9.	199	Elemental Iron 47 mg + Folic Acid 500 mcg + Zinc 22.5 mg Tablet	DCC226
10.	200	Elemental Iron 48 mg + Folic Acid 500 mcg + Zinc Sulphate Monohydrate 61.8 mg Tablet	DCC210
11.	201	Elemental Iron 50 mg + Folic Acid 500 mcg + Nicotinamide 1 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Vitamin C 50 mg Capsule	DCC228
12.	202	Elemental Iron 50 mg + Folic Acid 500 mcg + Zinc 22.5 mg Capsule	DCC226
13.	203	Elemental Iron 60 mg + Folic Acid 400 mcg Tablet	DCC237
14.	204	Ferrous Fumarate 200 mg + Folic Acid 200 mcg Capsule	DCC124
15.	205	Ferrous Fumarate 200 mg + Folic Acid 200 mcg Tablet	DCC124
16.	206	Ferrous Fumarate 200 mg + Folic Acid 200 mg Tablet	DCC124
17.	207	Ferrous Fumarate 200 mg + Folic Acid 350 mcg Capsule	DCC146
18.	208	Ferrous Fumarate 200 mg + Folic Acid 400 mcg Tablet	DCC238
19.	209	Ferrous Fumarate 200 mg + Folic Acid 500 mcg Capsule	DCC128
20.	210	Ferrous Fumarate 308 mg + Folic Acid 350 mcg Tablet	DCC146
21.	211	Ferrous Sulphate 150 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Vitamin C 50 mg Capsule	DCC224
22.	212	Ferrous Sulphate 150 mg + Folic Acid 500 mcg + Zinc 22.5 mg Capsule	DCC210
23.	219	Alendronic Acid 10 mg + Vitamin D3 400 IU Tablet	DCC238
24.	316	Ascorbic Acid 500 mg + Calcium Carbonate 327 mg + Calcium Gluconate 578 mg + Calcium Lactate 422 mg Tablet	DCC216
25.	317	Ascorbic Acid 60 mg + Boron (As Sodium Borate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Gluconate) 1 mg + Magnesium (As Magnesium Oxide) 20 mg + Manganese (As Manganese Sulphate) 1 mg + Vitamin D3 (As Cholecalciferol) 200 IU + Vitamin E 15 IU	DCC233

Sl.		Generic Name with Strength	DCC
		+ Zinc (As Zinc Oxide) 7.5 mg Tablet	
26.	318	Boron (As Boron Citrate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Sulphate) 1 mg + Magnesium (As Magnesium Hydroxide) 40 mg + Manganese (As Manganese Sulphate) 1.8 mg + Viamin D 200 IU + Zinc (As Zinc Sulphate) 7 mg Tablet	DCC230
27.	319	Boron (As Boron Citrate) 250 mcg + Calcium (As Calcium Carbonate) 600 mg + Copper (As Copper Sulphate) 1 mg + Magnesium (As Magnesium Hydroxide) 40 mg + Manganese (As Manganese Sulphate) 1.8 mg + Vitamin D3 5 mcg + Zinc (As Zinc Sulphate) 7.5 mg Tablet	DCC230
28.	320	Boron 250 mcg + Calcium 600 mg + Copper 1 mg + Magnesium 40 mg + Manganese 1.8 mg + Vitamin D 200 IU + Zinc 7 mg Tablet	DCC230
29.	321	Calcium (Coral Calcium) 225 mg + Vitamin D3 800 IU Tablet	DCC244
30.	322	Calcium (Coral Calcium) 600 mg + Vitamin D3 400 IU Tablet	DCC241
31.	323	Calcium 500 mg + Vitamin D3 200 IU Tablet	DCC230
32.	324	Calcium 500 mg + Vitamin D3 400 IU Tablet	DCC239
33.	325	Calcium 600 mg + Cholecalciferol (Vit. D3) 400 IU Tablet	DCC241
34.	326	Calcium Carbonate 327 mg + Calcium Lactate Gluconate 1 gm + Vitamin C 500 mg + Vitamin D 400 IU Tablet	DCC228
35.	327	Calcium Carbonate 327 mg + Calcium Lactate Gluconate 1 gm + Vitamin C 500 mg Tablet	DCC216
36.	328	Calcium Pantothenate 5 mg + Pyridoxine Hydrochloride 10mg + Riboflavin 4 mg + Vitamin B1 50 mg/2 ml Injection	DCC238
37.	329	Citric Acid Monohydrate 5% + Potassium Citrate 30% Oral Solution	DCC238
38.	330	Potassium Bicarbonate 200 mg + Potassium Chloride 448 mg Tablet	DCC238
39.	429	Ascorbic Acid (As Ascorbic Acid) 25 mg + Ascorbic Acid (As Sodium Ascorbate) 25 mg + Dexpanthanol 1.25 mg + Nicotinamide 5 mg + Pyridoxine Hydrochloride .35 mg + Riboflavin .4 mg + Viamin D 140 IU + Vitamin A 666.67 IU + Vitamin B1 .3 mg + Vitamin E 2 IU/5 ml Syrup	DCC233
40.	430	Ascorbic Acid 100 mg + Biotin .06 mg + Cyanocobalamin .005 mg + Folic Acid .4 mg + Nicotinamide 40 mg + Pantothenic acid 15 mg + Pyridoxine 4 mg + Riboflavin 3.6 mg + Thiamine 2.5 mg/vial Injection	DCC240
41.	431	Ascorbic Acid 100 mg + Biotin 60 mcg + Cyanocobalamin 5 mcg + Dexpanthanol 15 mg + Folic Acid 400 mcg + Nicotinamide 40 mg + Pyridoxine Hydrochloride 4 mg + Riboflavine Sodium Phosphate 3.6 mg + Thiamine Nitrate 2.5 mg/vial Injection	DCC240
42.	432	Ascorbic Acid 100 mg + Nicotinamide 1 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2.85 mg + Vitamin A 5000 IU + Vitamin B1 1.67 mg + Vitamin D 666 IU/ml Paediatric Drops	DCC238
43.	433	Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU +	DCC227

Sl.		Generic Name with Strength	DCC
		Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Soft Gelatin Capsule	
44.	434	Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Capsule	DCC227
45.	435	Ascorbic Acid 120 mg + Chromium 25 mg + Copper (As Cupric Oxide) 2 mg + Elemental Iron (As Ferrous sulphate) 30 mg + Folic Acid 800 mcg + Inositol 50 mg + Iodine (As Potassium Iodide) 175 mcg + Manganese 1.2 mcg + Molybdenum (As Sodium Molybdate) 25 mcg + Niacin 40 mg + Pantothenic acid (As Calcium Pantothenate) 20 mg + Pyridoxine Hydrochloride 10 mg + Quercetin 54 mcg + Riboflavin 3.4 mg + Selenium (As Sodium Selenate) 12.5 mcg + Vitamin A (As Beta Carotene) 2700 IU + Vitamin A (As Vitamin A Palmitate) 2700 IU + Vitamin B1 3.4 mg + Vitamin E 30 IU + Vitamin K 65 mcg + Zinc (As Zinc Oxide) 25 mg Tablet	DCC227
46.	436	Ascorbic Acid 125 mg + Biotin 69 mcg + Cholecalciferol (Vit. D3) 220 IU + Cyanocobalamin 6 mcg + Dl-Alpha Tocoferol (Vitamin E) 11.2 IU + Folic Acid 414 mcg + Nicotinamide 46 mg + Pantothenic acid 17.25 mg + Pyridoxine Hydrochloride 5.5 mg + Retinol Palmitate 3500 IU + Riboflavin 4.14 mg + Thiamine Mononitrate (B1) 3.51 mg/vial Injection	DCC240
47.	437	Ascorbic Acid 1350 mg + Biotin 650 mcg + Calcium (As Calcium Lactate) 550 mg + Choline Bitartrate 200 mg + Chromium (As Chromium Ploynicotinate) 70 mcg + Cyanocobalamin 60 mcg + Inositol 200 mg + Iodine (As Potassium Iodide) 500 mcg + Magnesium (As Magnesium Lactate) 150 mg + Manganese (As Manganese Gluconate) 15 mg + Pantothenic acid 70 mg + Para-Amino-Benzoic Acid 10 mg + Pottassium (As Potassium Citrate) 140 mg + Riboflavin 20 mg + Selenium (As Selenomethionine) 350 mcg + Vitamin A (As Beta Carotene) 17000 IU + Vitamin A (As Ratinol Palmitate) 17000 IU + Vitamin B1 (As Thiamine Hydrochloride) 20 mg + Vitamin D3 2750 IU + Vitamin E (As dl-Alpha Tocopheryl Acetate) 200 IU + Zinc (As Zinc Gluconate) 50 mg Syrup	DCC233
48.	438	Ascorbic Acid 150 mg + Calcium d-Pantothenate 12.5 mg + Cyanocobalamin 5 mcg + Folic Acid 1 mg + Nicotinamide 50 mg + Pyridoxine Hydrochloride 3 mg + Riboflavin 10 mg + Vitamin B1 10 mg Capsule	DCC230
49.	439	Ascorbic Acid 17.5 mg + Cod Liver Oil 100 mg + Nicotinamide 9 mg + Pyridoxine Hydrochloride .35 mg + Riboflavin .85 mg + Vitamin A 2000 IU + Vitamin B1 .7 mg + Vitamin D3 200 IU + Vitamin E 1.5 mg/5 ml Syrup	DCC233
50.	440	Ascorbic Acid 175 mg + Calcium d-Pantothenate 25 mg + Cynocobalamin 5 mcg + Folic Acid 500 mcg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 25 mg + Vitamin B1 50 mg Capsule	DCC231
51.	441	Ascorbic Acid 200 mg + Copper (As Cupric Oxide) 1 mg + Manganese (As Manganese Sulphate) 3 mg + Selenium (As Sodium Selenate) 70 mcg +	DCC226

Sl.		Generic Name with Strength	DCC
		Vitamin A (As Beta Carotene) 2000 IU + Vitamin E 50 IU + Vitamin K 75 mcg + Zinc (As Zinc Oxide) 15 mg Capsule	
52.	442	Ascorbic Acid 200 mg + Copper (As Cupric Oxide) 1 mg + Manganese (As Manganese Sulphate) 3 mg + Selenium (As Sodium Selenate) 70 mcg + Vitamin A (As Beta Carotene) 2000 IU + Vitamin E 50 IU + Vitamin K 75 mcg + Zinc (As Zinc Oxide) 15 mg Tablet	DCC226
53.	443	Ascorbic Acid 250 mg + Dexpanthanol 24.906 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 7 mg + Riboflavin 8 mg + Sodium Acetate 280 mg + Thiamine Hydrochloride 6 mg + Vitamin A 13332 IU + Vitamin D 2800 IU + Vitamin E 40 IU/100 ml Syrup	DCC233
54.	444	Ascorbic Acid 250 mg + Dexpanthanol 24.906 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 7 mg + Riboflavin 8 mg + Sodium Acetate 280 mg + Thiamine Hydrochloride 6 mg + Vitamin A 13332 IU + Vitamin D 2800 IU + Vitamin E 40 IU/100 ml Syrup	DCC233
55.	445	Ascorbic Acid 30 mg + Folic Acid .16 mg + Iron 12.5 mg + Vitamin A .3 mg + Zinc (As Gluconate) 5 mg Sachet	DCC232
56.	446	Ascorbic Acid 50 mg + Elemental Iron (As Carbonyl Iron) 50 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2.2 mg + Vitamin B1 2.2 mg + Zinc (As Zinc Sulphate) 22.5 mg Capsule	DCC229
57.	447	Ascorbic Acid 50 mg + Elemental Iron (As Ferrous sulphate) 47 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg + Zinc (As Zinc Sulphate) 22.5 mg Capsule	DCC228
58.	448	Ascorbic Acid 50 mg + Elemental Iron (As Ferrous sulphate) 47 mg + Folic Acid 500 mcg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg Capsule	DCC228
59.	449	Ascorbic Acid 50 mg + Elemental Iron 50 mg + Folic Acid .5 mg + Nicotinamide 10 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 2 mg + Vitamin B1 2 mg Capsule	DCC224
60.	450	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 162 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6 mcg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 109 mg + Pottassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B1 1.5 mg + Vitamin D3 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Soft Gelatin Capsule	DCC228
61.	451	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 162 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6	DCC228

Sl.		Generic Name with Strength	DCC
		mcg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 109 mg + Pottassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B1 1.5 mg + Vitamin D3 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Tablet	
62.	452	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium (As Calcium Carbonate) 200 mg + Chromium (As Chromium Chloride) 150 mcg + Copper (As Copper Lysinate) 2 mg + Cyanocobalamin 25 mcg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein (As Marigold Extract) 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Glycinate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Phosphorous (As Calcium Phosphate) 48 mg + Pottassium (As Potassium Chloride) 80 mg + Pyridoxine Hydrochloride 3 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Silicon Dioxide) 2 mg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin A (As Beta Carotene) 5000 IU + Vitamin A (As Vitamin A Palmitate) 5000 IU + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 45 IU + Vitamin K 10 mcg + Zinc (As Zinc Oxide) 15 mg Soft Gelatin Capsule	DCC228
63.	453	Ascorbic Acid 60 mg + Biotin 30 mcg + Boron (As Boron Citrate) 150 mcg + Calcium Carbonate (As Calcium 20.975) 52.49 mg + Chromium (As Chromium Chloride) 120 mcg + Copper (As Cupric Oxide) 2 mg + Cyanocobalamin 6 mcg + Diabasic Calcium Phosphate (As Calcium 141.025 mg) 478.695 mg + Diabasic Calcium Phosphate (As Phosphorous 109 mg) 478.695 mg + Elemental Iron (As Ferrous sulphate) 18 mg + Folic Acid 400 mcg + Iodine (As Potassium Iodide) 150 mcg + Lutein 250 mcg + Magnesium (As Magnesium Oxide) 100 mg + Manganese (As Manganese Sulphate) 2 mg + Molybdenum (As Sodium Molybdate) 75 mcg + Niacin 20 mg + Nickel (As Nickel Sulphate) 5 mcg + Pantothenic acid (As Calcium Pantothenate) 10 mg + Potassium Chloride (As Chloride 72 mg) 152.52 mg + Potassium Chloride (As Potassium 80 mg) 152.52 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Selenium (As Sodium Selenate) 20 mcg + Silicon (As Sodium Metasilicate) 2 mg + Tin (As Stanous Chloride) 10 mcg + Vanadium (As Sodium Metavandate) 10 mcg + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc (As Zinc Oxide) 15 mg Tablet	DCC233
64.	454	Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B1 1.5 mg + Vitamin D 10	DCC193

Sl.		Generic Name with Strength	DCC
		mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Tablet	
65.	455	Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Capsule	DCC193
66.	456	Ascorbic Acid 60 mg + Calcium Pantothenate 10.92 mg + Cupric Sulphate 2 mg + Cyanocobalamin 6 mcg + Ferrous Sulphate 50 mg + Folic Acid 400 mcg + Manganese Sulphate 1 mg + Nicotinamide 20 mg + Potassium Iodide 196 mcg + Potassium Sulphate 11.141 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Vitamin A 1.5 mg + Vitamin B1 1.5 mg + Vitamin D 10 mcg + Vitamin E 15 IU + Zinc Sulphate 41.16 mg Soft Gelatin Capsule	DCC228
67.	457	Ascorbic Acid 60 mg + Copper 2 mg + Lutein 6 mg + Vitamin E 30 mg + Zinc 15 mg Capsule	DCC226
68.	458	Ascorbic Acid 60 mg + Copper 2 mg + Lutein 6 mg + Vitamin E 30 mg + Zinc 15 mg Soft Gelatin Capsule	DCC226
69.	459	Ascorbic Acid 75 mg + Calcium Pantothenate 5 mg + Cyanocobalamin 2 mcg + Nicotinamide 13 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 10 mg + Vitamin A 5000 IU + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 5 IU Capsule	DCC193
70.	460	Ascorbic Acid 75 mg + Calcium Pantothenate 5 mg + Cyanocobalamin 2 mcg + Nicotinamide 13 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 10 mg + Vitamin A 5000 IU + Vitamin B1 1.5 mg + Vitamin D 400 IU + Vitamin E 5 IU Tablet	DCC193
71.	461	Beta Carotene 3 mg + Calcium 59 mg + Cholecalciferol (Vit. D3) 250 IU + Cyanocobalamin 1.5 mcg + Folic Acid 250 mcg + Iodine 125 mcg + Iron 5 mg + Magnesium 15 mg + Nicotinamide 7.5 mg + Phosphorous 45.6 mg + Pyridoxine Hydrochloride 750 mcg + Riboflavin 750 mcg + Thiamine Nitrate 500 mcg + Vitamin C 15 mg + Vitamin E 5.2 IU + Zinc 8 mg Tablet	DCC238
72.	462	Beta Carotene 6 mg + Copper 1 mg + Manganese 3 mg + Selenium 70 mcg + Vitamin C 200 mg + Vitamin E 50 mg + Vitamin K 75 mcg + Zinc 15 mg Capsule	DCC226
73.	463	Beta Carotene 6 mg + Copper 1 mg + Manganese 3 mg + Selenium 70 mcg + Vitamin C 200 mg + Vitamin E 50 mg + Vitamin K 75 mcg + Zinc 15 mg Tablet	DCC226
74.	464	Betacarotene 6 mg + Vitamin C 200 mg + Vitamin E 50 mg Soft Gelatin Capsule	DCC210
75.	465	Betacarotene 6 mg + Vitamin C 200 mg + Vitamin E 50 mg Tablet	DCC209
76.	466	Biotin 300 mcg + Calcium 200 mg + Chromium 120 mcg + Copper 2 mg + Folic Acid 400 mcg + Iron 9 mg + Magnesium 100 mg + Manganese 2 mg + Niacin 30 mg + Pantothenic acid 10 mg + Riboflavin 4.2 mg + Selenium 20 mcg + Thiamine 3.75 mg + Vitamin A 2500 IU + Vitamin B12 15 mcg + Vitamin B6 5 mg + Vitamin C 120 mg + Vitamin D 400 IU + Vitamin E 30 IU + Vitamin K 25 mcg + Zinc 15 mg Tablet	DCC241
77.	467	Biotin 300 mcg + Calcium 300 mg + Chromium 120 mcg + Copper 2 mg + Folic Acid 400 mcg + Iron 18 mg + Magnesium 50 mg + Manganese 2 mg + Niacin 30 mg + Pantothenic acid 10 mg + Riboflavin 2.6 mg + Selenium 20 mcg + Thiamine 2.3 mg + Vitamin A 2500 IU + Vitamin B12 9 mcg + Vitamin B6 3 mg + Vitamin C 120 mg + Vitamin D 800 IU + Vitamin E 30 IU +	DCC241

Sl.		Generic Name with Strength	DCC
		Vitamin K 25 mcg + Zinc 15 mg Tablet	
78.	468	Biotin 45 mcg + Calcium 43.31 mg + Cholecalciferol (Vit. D3) 400 IU + Chromium 20 mcg + Copper 2 mg + Cyanocobalamin 6 mcg + Diabasic Calcium Phosphate 220 mg + Folic Acid 400 mcg + Iodine 150 mcg + Iron 18 mg + Magnesium 40 mg + Manganese 1 mg + Molybdenum 20 mcg + Niacin 20 mg + Pantothenic acid 10 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 1.7 mg + Thiamine Nitrate 1.5 mg + Vitamin A 1015 IU + Vitamin A Acetate 2485 IU + Vitamin C 60 mg + Vitamin E 60 mg + Vitamin K 10 mcg + Zinc 15 mg Chewable Tablet	DCC238
79.	469	Calcitriol 0.25 mcg + Calcium 252 mg Tablet	DCC241
80.	470	Calcium (Coral Calcium) 500 mg + Vitamin D3 200 IU Tablet	DCC230
81.	471	Calcium 250 mg + Vitamin D3 250 IU Gummy Tablet	DCC244
82.	472	Calcium 500 mg + Vitamin D3 500 IU Gummy Tablet	DCC244
83.	473	Cod Liver Oil 50 mg + Pantothenic acid 5 mg + Vitamin B1 1.6 mg + Vitamin B2 1 mg + Vitamin B3 10 mg + Vitamin B6 1 mg + Vitamin C 50 mg/ml Paediatric Drops	DCC238
84.	474	Copper mg + Folic Acid .15 mg + Iodine .09 mg + Iron 10 mg + Niacin 6 mg + Pyridoxine .5 mg + Riboflavin .5 mg + Selenium .017 mg + Vitamin A .4 mg + Vitamin B1 .5 mg + Vitamin B12 .0002 mg + Vitamin C 30 mg + Vitamin D .005 mg + Vitamin E 5 mg + Zinc mg Sachet	DCC240
85.	475	Copper .56 mg + Folic Acid .15 mg + Iodine .09 mg + Iron 10 mg + Niacin 6 mg + Pyridoxine .5 mg + Riboflavin .5 mg + Selenium .017 mg + Vitamin A .4 mg + Vitamin B1 .5 mg + Vitamin B12 .0009 mg + Vitamin C 30 mg + Vitamin D .005 mg + Vitamin E 5 mg + Zinc 4.1 mg Sachet	DCC238
86.	476	Cyanocobalamin 1 mg + Pyridoxine Hydrochloride 100 mg + Vitamin B1 100 mg/3 ml Injection	DCC230
87.	478	Cyanocobalamin 200 mcg + Pyridoxine Hydrochloride 200 mg + Vitamin B1 100 mg Tablet	DCC230
88.	479	Dexpanthanol 25 mg + Nicotinamide 500 mg + Pyridoxine Hydrochloride 50 mg + Riboflavin 20 mg + Vitamin B1 250 mg/10 ml Injection	DCC125
89.	480	D-Panthenol 5 mg + Nicotinamide 100 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 4 mg + Vitamin B1 50 mg/2 ml Injection	DCC114
90.	481	Elemental Iron 50 mg + Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc 10 mg/5 ml Syrup	DCC230
91.	482	Folic Acid 250 mcg + L-Lysine 50 mg + Nicotinamide 2.5 mg + Vitamin A 1500 IU + Vitamin B1 250 mcg + Vitamin B12 2 mcg + Vitamin B2 250 mcg + Vitamin B6 250 mcg + Vitamin C 50 mg + Vitamin D3 100 IU + Vitamin E 10 IU Tablet	DCC241
92.	483	Iron 50 mg + Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc 10 mg/5 ml Syrup	DCC230
93.	484	Niacinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg + Zinc 10 mg/5 ml Syrup	DCC231
94.	485	Niacinamide 400 mg + Pyridoxine Hydrochloride 40 mg + Riboflavin 40 mg + Thiamine Hydrochloride 100 mg + Zinc 200 mg/100 ml Syrup	DCC231
95.	486	Nicotinamide 10 mg + Pantothenic acid 5 mg + Pyridoxine Hydrochloride 1 mg + Riboflavin 1 mg + Vitamin A 5000 IU + Vitamin B1 1.6 mg + Vitamin C 50 mg + Vitamin D 1000 IU/ml Paediatric Drops	DCC238

Sl.		Generic Name with Strength	DCC
96.	487	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg Capsule	DCC140
97.	488	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg Tablet	DCC172
98.	489	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2 mg + Vitamin B1 5 mg/5 ml Syrup	DCC202
99.	490	Nicotinamide 20 mg + Pyridoxine Hydrochloride 2 mg + Riboflavin 2.75 mg + Vitamin B1 5 mg + Zinc 10 mg Tablet	DCC233
100.	491	Nicotinamide 400 mg + Pyridoxine Hydrochloride 40 mg + Riboflavin 50 mg + Vitamin B1 100 mg + Zinc 200 mg/100 ml Syrup	DCC231
101.	492	Pantothenic acid 500 mg + Pyridoxine Hydrochloride 100 mg + Riboflavin 100 mg + Vitamin A 5 Lac IU + Vitamin B1 160 mg + Vitamin C 5 gm + Vitamin D 1 gm/100 ml Paediatric Drops	DCC238
102.	493	Pyridoxine Hydrochloride 100 mg + Riboflavin 5 mg + Vitamin B1 100 mg Injection	DCC238
103.	494	Pyrimethamine 1 gm + Sodium Salicylate 5 gm + Sulphaquinoxaline 5 gm + Vitamin A 1 gm + Vitamin K 20 mg/100 ml Liquid	DCC238
104.	495	Vitamin C 200 mg + Vitamin E 200 mg Tablet	DCC216
105.	496	Vitamin C 200 mg + Vitamin E 50 mg Tablet	DCC238
106.	497	Vitamin C 250 mg + Vitamin E 200 mg Capsule	DCC230
107.	498	Vitamin C 250 mg + Vitamin E 200 mg Tablet	DCC238

Annex-E: List of amino acids & Electrolytes Combinations

(রেজিস্ট্রেশন বহালকৃত ঔষধের তালিকা)

List of Human Combination Products (Amino acids)

Sl.	Generic Name with Strength	DCC	বিশেষজ্ঞ কমিটির সুপারিশ	টেকনিক্যাল সাব-কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1	Amino Acids (Essential) 7 % + Glucose & Electrolytes 10 % IV Infusion	DCC195	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
2	Amino Acids (Essential) 8.14% + D-Sorbitol & Electrolytes 5% IV Infusion	DCC242	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।

List of Human Combination Products (Electrolytes)

	Generic Name with Strength	DCC	বিশেষজ্ঞ কমিটির সুপারিশ	টেকনিক্যাল সাব-কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Anhydrous Glucose 6.75 gm + Potassium Chloride 750 mg + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm Oral Saline	DCC226	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
2.	Calcium Chloride 0.033% + Potassium Chloride 0.03% + Sodium Chloride 0.86% IV Infusion	DCC238	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
3.	Calcium Chloride 0.048% + Magnesium Hydroxide 0.03% + Potassium Chloride 0.075% + Sodium Acetate 0.39% + Sodium Chloride 0.64% + Sodium Citrate 0.17% IV Infusion	DCC231	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
4.	Calcium Chloride 20 mg + Dextrose Anhydrous 5.0gm + Potassium Chloride 30mg + Sodium Chloride 600mg + Sodium Lactate 310mg/100 ml IV Infusion	DCC235	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
5.	Calcium Chloride 27mg + Potassium Chloride 40.0mg + Sodium Chloride 600 mg + Sodium Lactate 320 mg/100 ml IV Infusion	DCC162	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
6.	Dextran 40 10% + Dextrose 5% IV Infusion	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
7.	Dextran 40 10% + Sodium Chloride 0.9% IV Infusion	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
8.	Dextran 70 6% + Dextrose 5% IV Infusion	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
9.	Dextran 70 6% + Sodium Chloride 0.9% IV Infusion	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
10.	Dextrose 10% + Sodium Chloride 0.225% IV Infusion	DCC166	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
11.	Dextrose 5% + Sodium Chloride 0.18 %/ IV Infusion	DCC166	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
12.	Dextrose 5% + Sodium Chloride 0.225 %/ IV Infusion	DCC166	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
13.	Dextrose 5% + Sodium Chloride 0.25% IV Infusion	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
14.	Dextrose 5% + Sodium Chloride 0.45 %/ IV Infusion	DCC166	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
15.	Dextrose 5% + Sodium Chloride 0.9 %/ IV Infusion	DCC216	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
16.	Dextrose Anhydrous 10 gm + Potassium Chloride 750 gm + Sodium Chloride 1.75 gm + Trisodium Citrate 1.45 gm/500 ml Oral Saline	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
17.	Dextrose Anhydrous 20 gm + Potassium Chloride 1.5 gm + Sodium Chloride 3.5 gm + Trisodium Citrate 2.9 gm/Liters Oral Saline	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।

	Generic Name with Strength	DCC	বিশেষজ্ঞ কমিটির সুপারিশ	টেকনিক্যাল সাব-কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
18.	Dextrose Anhydrous 4.09 gm + Fructose 70 mg + Potassium Chloride 380 mg + Sodium Bicarbonate 420 mg + Sodium Chloride 440 mg + Sucrose 8.07 gm/250ml Oral Saline	DCC223	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
19.	Dextrose Anhydrous 6.75gm + Potassium Chloride 750 mg + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm/500ml Oral Saline	DCC226	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
20.	Poly (0-2 Hydroxyethyl Starch (Hydroxyethyl 130/0.4) 60 gm + Sodium Chloride 9 gm/1000 ml Solution For Infusion	DCC220	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
21.	Potassium Chloride 0.75 gm + Rice Powder (Pregelatineized) 25gm + Sodium Chloride 1.3 gm + Trisodium Citrate 1.45 gm/500ml Oral Saline	DCC233	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
22.	Potassium Chloride 0.1% + Sodium Acetate 0.65% + Sodium Chloride 0.5% IV Infusion	DCC171	বহাল রাখা যেতে পারে।	বহাল রাখা যেতে পারে।	বহাল রাখা হল।

(রেজিস্ট্রেশন বাতিলকৃত ঔষধের তালিকা)

List of Human Combination Products (Electrolytes)

	Generic Name with Strength	DCC	বিশেষজ্ঞ কমিটির সুপারিশ	টেকনিক্যাল সাব-কমিটির সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Anhydrous Glucose 1.62 gm + Anhydrous Citric Acid 384 mg + Potassium Chloride 186 mg + Sodium Bicarbonate 336 mg + Sodium Chloride 117 mg Tablet	DCC223	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
2.	Anhydrous Glucose 1.62 gm + Citric Acid 384 mg + Potassium Chloride 186 mg + Sodium Bicarbonate 336 mg + Sodium Chloride 117 mg Ors Tablet	DCC234	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
3.	Anhydrous Glucose 10 gm + Potassium Chloride 750 mg + Sodium Bicarbonate 1.25 gm + Sodium Chloride 1.75 gm Oral Saline	DCC161	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
4.	Calcium Chloride 0.48 mg + Magnesium Chloride 0.3 mg + Potassium Chloride 0.75 mg + Sodium Acetate 3.9mg + Sodium Chloride 6.4 mg + Sodium Citrate 1.7 mg/ml Salt Solution	DCC 235	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
5.	Dextran 70 60 gm + Sodium Chloride 75 gm/Liters Solution For Infusion	DCC227	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
6.	Dextrose 10% + Sodium Chloride 0.18 %/ IV Infusion	DCC171	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
7.	Dextrose 4.3% + Sodium Chloride 0.18% IV Infusion	DCC212	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
8.	Dextrose Anhydrous 13.5 gm + Potassium Chloride 1.5 gm + Sodium Chloride 2.6 gm + Trisodium Citrate 2.9 gm/Litres Oral Saline	DCC226	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।
9.	Potassium Chloride 0.003% + Sodium Chloride 0.004% + Sodium Lactate 0.007% IV Infusion	DCC238	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা যেতে পারে।	প্রয়োজন নেই বিধায় কম্বিনেশনটি বাতিল করা হল।

Annex-F: Veterinary Antibiotic Combination Preparation (Access Group)

(রেজিস্ট্রেশন বাতিলকৃত ঔষধের তালিকা)

SL No	Generic Name	DCC No	রেফারেন্স	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Amoxicillin 1.25 gm + Cloxacillin 1.25 gm/vial Injection	DCC 237	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল।
2.	Amoxicillin Trihydrate 10% + Bromhexine Hydrochloride 2% + Vitamin A 500000 IU/KG Powder	DCC 209	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
3.	Doxycycline 1 gm + Oxytetracycline 2 gm Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
4.	Doxycycline 1 gm + Oxytetracycline 2 gm/100 gm Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
5.	Doxycycline 10% + Neomycin Sulphate 10% Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
6.	Doxycycline 10% + Oxytetracycline 20% Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
7.	Doxycycline 10% + Tylosin 20% Powder	DCC 232	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
8.	Doxycycline 100 mg + Trimethoprim 100 mg/gm Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
9.	Doxycycline 100 mg + Tylosin 200 mg Sachet	DCC 243	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
10	Doxycycline 150 mg + Neomycin Sulphate 150 mg/gm Powder	DCC 232	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
11	Doxycycline 20 gm + Tylosin 23 gm/100 gm Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
12	Doxycycline Hydrochloride 10% + Gentamicin 10% Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
13	Gentamicin 2.5% + Neomycin Sulphate 20% Powder	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
14	Gentamicin 3 gm + Sulphadimidine 12.5 gm + Trimethoprim 2.5 gm/100 ml Injection	DCC 240	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
15	Neomycin Sulphate 5% + Procaine Penicillin 8.3333% Ointment	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
16	Oxyclozanide 1.4 gm + Tetracycline Hydrochloride 2 gm Bolus	DCC 131	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
17	Procaine Benzylpenicillin 4 Lac IU + Streptomycin 500 mg/vial Injection	DCC 188	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
18	Streptomycin 250 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus	DCC 238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
19	Streptomycin 250 mg + Sulphadiazine 1.583 gm + Sulphadimidine 1.583 gm + Sulphapyridine 1.583 gm Bolus	DCC238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
20	Streptomycin 313 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus	DCC238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
21	Sulfaclozine 300 mg + Vitamin K 20 mg/gm Powder	DCC238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
22	Sulphachloropyridazine Sodium 100 mg + Trimethoprim 20 mg + Vitamin K .8 mg/gm Powder	DCC238	NO	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল
23	Amoxicillin Trihydrate 5% + Cyproheptadine Hydrochloride 1% + Guaiphenesin 3.5% + Lysozyme Hydrochloride 1% + Vitamin A 2500% Powder	DCC 238	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।।	রেজিস্ট্রেশন বাতিল করা হল

(রেজিস্ট্রেশন বহালকৃত ঔষধের তালিকা)

SL No	Generic Name	DCC No	রেফারেন্স	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Benzyl Penicillin 10 Lac IU + Procaine Penicillin 30 Lac IU Injection	DCC 200	British Veterinary Formulary	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
2.	Benzyl Penicillin 2 Lac Unit + Procaine Penicillin 6 Lac Unit/vial Injection	DCC 238	British Veterinary Formulary	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
3.	Doxycycline Hydrochloride 25% + Tylosin Tartrate 20% Powder	DCC 232	NO	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
4.	Sulfadiazine 1.66 gm + Sulphadimidine 1.66 gm + Sulphapyridine 1.66 gm Powder	DCC131	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
5.	Sulphachloropyridazone 10 % + Trimethoprim 2 % Powder	DCC238	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
6.	Sulphadiazine 1.666 gm + Sulphadimidine 1.666 gm + Sulphapyridine 1.666 gm Bolus	DCC188	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
7.	Sulphadiazine 1.666 gm + Sulphadimidine 1.666 gm + Sulphapyridine 1.666 gm Powder	DCC188	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
8.	Sulphadiazine 1000 mg + Trimethoprim 200 mg Bolus	DCC238	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
9.	Sulphadiazine 40 gm + Trimethoprim 8 gm/100 ml Suspension	DCC238	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
10.	Sulphadiazine 400 mg + Trimethoprim 84.4 mg/ml Injection	DCC238	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
11.	Sulphamethoxazole 10 gm + Trimethoprim 2 gm/100 ml Suspension	DCC238	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
12.	Sulphamethoxazole 1000 mg + Trimethoprim 200 mg Bolus	DCC238	OIE list of antimicrobials	বহাল রাখা যেতে পারে।	বহাল রাখা হল।

OIE=_Officina Internacional de Epizootias (Spanish) (Eng: World Organization for Animal Health)

Annex-G: Veterinary Antibiotic Combination Preparation (Watch Group)

(রেজিস্ট্রেশন বাতিলকৃত ঔষধের তালিকা)

SL No	Generic Name	DCC No	রেফারেন্স	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Ciprofloxacin 20 gm + Trimethoprim 50 gm Sachet	DCC238	No.	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল।
2.	Erythromycin 50 mg + Sulphadimethoxine Sodium 125 mg + Trimethoprim 25 mg/ml Injection	DCC243	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল।
3.	Guaiphenesin 1.8% + Roxithromycin 1% + Tylosin 1% Powder	DCC240	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল।
4.	Kanamycin 10000 IU/gm + Rofaxanide 2% Powder	DCC238	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল।
5.	Loperamide 1 gm + Norfloxacine 25 gm + Trimethoprim 25 gm + Zinc Oxide 20 gm/KG Oral Powder	DCC238	No	রেজিস্ট্রেশন বাতিল করা যেতে পারে।	রেজিস্ট্রেশন বাতিল করা হল।

(রেজিস্ট্রেশন বহালকৃত ঔষধের তালিকা)

SL No	Generic Name	DCC No	রেফারেন্স	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত
1.	Erythromycin 18 gm + Sulphadiazine 15 gm + Trimethoprim 3 gm/100 gm Powder	DCC234	Germany	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
2.	Erythromycin 180 mg + Sulphadiazine 150 mg + Trimethoprim 30 mg Powder	DCC238	Germany	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
3.	Erythromycin 550 mg/gm Powder	DCC238	USFDA, UKMHRA	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
4.	Erythromycin Thiocyanate 18 gm + Sulphadiazine 15 gm + Trimethoprim 3 gm/100 gm Powder	DCC230	Germany	বহাল রাখা যেতে পারে।	বহাল রাখা হল।
5.	Lincomycin Base 22.2 gm + Spectinomycin 44.4 gm/100 gm Water Soluble Powder	DCC238	USFDA, UKMHRA	বহাল রাখা যেতে পারে।	বহাল রাখা হল।

Annex-H: List of Human Products (Local Manufactured)

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
1.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Minoxidil 5gm+ Finasteride 0.1gm/100ml Topical Solution	Minoxidil USP 5gm+ Finasteride USP 0.1gm/100ml	Alopecia Agent	This topical solution is indicated for the treatment of androgenic alopecia (male pattern baldness) in men in the age group of 18 to 60 years.	**Contra-indication:** Hypersensitivity to minoxidil, finasteride or any of the constituents of the solution. Pregnancy. **Side-effect:** • The most common side effects are itching and skin irritation of the treated area of the scalp. • Other adverse effects include hypertrichosis, local erythema, and dry skin/scalp.	Finasteride 1mg, 5mg Tablet & Minoxidil 20 mg/ml, 50 mg/ml Scalp Lotion,		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
2.	Ziska Pharmaceuticals Ltd.	Minoxidil 10% Topical Solution	Minoxidil INN 10gm/100ml	Alopecia Agent	Androgenic alopecia & alopecia areata	**Contraindications:** Hypersensitivity, local irritation, use with caution in patient with severe renal impairment. **Side effects:** Common side effects includes Headache, Unusual hair growth, on the face, arm, and back, Redness, irritation and itching at the site of application.	Minoxidil 2% & 5% topical solution		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
3.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Mesalamine 800.00mg Delayed Release Tablet	Mesalamine USP 800.00mg	Aminosalicylates	It is a locally acting aminosalicylate indicated for the treatment of moderately active ulcerative colitis.	**Contra-indication:** History of hypersensitivity to salicylates or aminosalicylates **Adverse reactions:** The most common adverse reactions (observed in >2% of patients) were headache, nausea, nasopharyngitis, abdominal pain, and worsening of ulcerative colitis.	Mesalazine (Mesalamine) 1000 mg Suppository & 400mg DR Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
4.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Parecoxib sodium 40mg/Vial Poeder for solution for Injection	Parecoxib Sodium INN 42.3600 mg Eq. to 40mg Parecoxib/Vial	Analgesic	For a single peri-operative dose for the management of post-operative pain. The decision to prescribe PARECOXIB should be based on an assessment of the individual patient's overall risks and the potential risk/benefit profile of alternative parenteral therapies. As the cardiovascular risks of the selective COX-2 inhibitors may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used.	**Contraindications:** contraindicated in patients undergoing cardiac or major vascular surgery, patients who have previously had a myocardial infarction or stroke, patients with known hypersensitivity to parecoxib sodium, valdecoxib or to any other ingredient of the product. **Side-effects:** 1. Ulcer and gastrointestinal bleeding, 2. Jaundice and abnormal liver function, 3. Heart failure, heart attack, slow heart rate, high/low blood pressure and abnormal heart rhythm, 4. Swelling, rash, itching and difficulty in breathing. 5. Back pain, low platelet counts, agitation, disturbed sleeping and decreased urination.	New	BNF75 Page: 1268	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
5.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 2.167gm + Dextromethorphan Hydrobromide 0.1gm + Doxylamine Succinate 0.042gm/100ml Syrup	Paracetamol BP 2.167gm + Dextromethorphan Hydrobromide USP 0.1gm + Doxylamine Succinate USP 0.042gm/100ml	Analgesic + Antitussive + Antihistamine	It is indicated for Dry or unproductive cough, Fever, Body aches, Watery eyes, Sneezing.	**Contraindications:** This is contraindicated in patients hypersensitive to any of the ingredients. **Side effects:** Most common side effects include: Constipation; diarrhea; dizziness; drowsiness; excitability; headache; loss of appetite; nausea; nervousness or anxiety; trouble sleeping; upset stomach; vomiting; weakness.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
6.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 3.25gm + Dextromethorphan Hydrobromide 0.1gm + Guaifenesin 2.0gm + Phenylephrine Hydrochloride 0.05gm/100ml Syrup	Paracetamol BP 3.25gm + Dextromethorphan Hydrobromide USP 0.1gm + Guaifenesin USP 2.0gm + Phenylephrine Hydrochloride USP 0.05gm/100ml	Analgesic + Antitussive + Expectorant + Sympathomimetic	It relieving congestion, cough, and throat and airway irritation due to colds, flu, or hay fever.	**Contraindications:** Any known allergies to any of the ingredients. **Side effects:** Constipation; diarrhea; dizziness; drowsiness; dry mouth, nose, or throat; excitability; headache; nervousness; trouble sleeping; upset stomach.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
7.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 2.167gm + Dextromethorphan Hydrobromide 0.067gm + Phenylephrine Hydrochloride 0.033gm/100ml Syrup	Paracetamol BP 2.167gm + Dextromethorphan Hydrobromide USP 0.067gm + Phenylephrine Hydrochloride USP 0.033gm/100ml	Analgesic + Antitussive + Sympathomimetic	It is indicated for Headache, Fever, Body aches, Cough, Stuffy nose & Sinus congestion caused by allergies, the common cold, or the flu.	**Contraindications:** This is contraindicated in patients hypersensitive to any of the ingredients. **Side effects:** General side effects of Brand Name have included pallor, dizziness; excitability; headache; nausea; nervousness or anxiety; trouble sleeping; weakness.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
8.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Sodium Alginate 250mg + Sodium Bicarbonate 133.5mg + Calcium Bicarbonate 80mg/5ml Suspension	Sodium alginate BP 250mg + Sodium bicarbonate BP 133.5mg + Calcium bicarbonate BP 80mg/5ml	Antacid	1. Gastric reflux 2. Heartburn 3. Flatulence associated with gastric reflux 4. Heartburn of pregnancy 5. All cases of epigastric and retrosternal distress where the underlying cause is gastric reflux	Contraindications: This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients including methyl parahydrobenzoate and propyl parahydrobenzoate. Each 10 ml dose has a sodium content of 141 mg (6.2 mmol). This shoul be taken into account when a highly restricted salt diet is recommended. E.g. in some cases of congestive cardiac failure and renal impairment. Side-effects: Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.	New	BNF- 75 Page No: 82	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
9.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Dicycloverine Hydrochloride INN 0.05gm + Simeticone BP 0.4gm + Magnesium Oxide BP 2.0gm + Aluminium Hydroxid BP 4.0gm/100ml suspension	Dicycloverine Hydrochloride INN 0.05gm + Simeticone BP 0.4gm + Magnesium Oxide BP 2.0gm + Aluminium Hydroxid BP 4.0gm/100ml	Antacid	Treatment and prophylaxis of the symptoms of peptic ulcer, functional dyspepsia, irritable bowel syndrome, oesophagitis, hiatus hernia, gastritis and iatrogenic gastritis.	**Contraindications:** Patients who are allergic to any of the ingredients of Dicycloverine Hydrochloride, Simeticone, Magnesium Oxide, and Aluminium Hydroxide Suspension Patients who have difficulty passing urine because of an enlarged prostate or other condition patients who have ulcerative colitis or other conditions affecting movement of food through the gastro-intestinal tract patients who have myasthenia gravis (a very rare muscle disease) patients who have glaucoma (a condition involving increased pressure within the eye resulting in poor vision).		BNF75 Page:84	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						Side-effects: Most medicines can cause some side-effects but not everyone taking the same medicine will get the same side-effects.The following side-effects have been associated with people taking this medicine: atropine-like effects such as dry mouth, blurred vision, urinary retention or constipation phosphorus deficiency - this may happen in people who are on a low phosphorus diet.				
10.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Sodium Alginate 250mg + Sodium Bicarbonate 106.50mg + Calcium Carbonate (Heavy) 187.50mg Tablet	Sodium Alginate USP 250mg + Sodium Bicarbonate BP 106.50mg + Calcium Carbonate (Heavy) BP 187.50mg	Antacid	It is indicated for the treatment of gastro-oesophageal reflux i.e. acid regurgitation, heartburn, indigestion (for example following meals or during pregnancy) and for symptoms of excess stomach acid (hyperacidity) It acts in a dual mechanism mood, quickly neutralizes excess stomach acid and also forms a protective layer over stomach content	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	Potassium Bicarbonate 100 mg + Sodium Alginate 500 mg Tablet	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
11.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Sodium Alginate 5.0 gm + Sodium Bicarbonate 2.13gm + Calcium Carbonate (light) 3.25gm/100ml Oral Suspension	Sodium Alginate BP 5.0gm + Sodium Bicarbonate BP 2.13gm + Calcium Carbonate BP 3.25gm / 100ml	Antacid	It is indicated for the treatment of gastro-oesophageal reflux i.e. acid regurgitation, heartburn, indigestion (for example following meals or during pregnancy) and for symptoms of excess stomach acid (hyperacidity) It acts in a dual mechanism mood, quickly neutralizes excess stomach acid and also forms a protective layer over stomach content	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	Potassium Bicarbonate 100mg + Sodium Alginate 500mg/5ml	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
12.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Salicylic Acid 2gm/100gm lotion	Salicylic acid BP/Ph. EUR 2gm/100gm	Antiacne	It is indicated for the treatment of acne and oil control.	**Contraindications:**It should not be used in any patient known to be sensitive to Salicylic Acid or any other listed ingredients. **Side-effects/Toxicity :**An allergic reaction (shortness of breath, closing of the throat, swelling of the lips, face or tongue or hives) or severe skin irritation.	Salicylic Acid 0.5%, 6%, 12%, 25% Cream		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
13.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur Sadar, Gazipur	Procainamide HCl 500mg Tablet	Procainamide HCl USP 500mg	Antiarrhythmic	It is indicated for the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that in the judgment of the physician are life-threatening	**Contra-indication :** Complete Heart Block, Idiosyncratic Hypersensitivity, Lupus Erythematosus, Torsades De Pointes, Digitalis Intoxication, First Degree Heart Block, Predigitalization for Atrial Flutter or Fibrillation, Congestive Heart Failure, Concurrent Other Antiarrhythmic Agents, Renal Insufficiency, Myasthenia Gravis	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
14.	a) Navana Pharmaceuticals, Narayanganj b) Square Formulations Ltd., Gorai, Tangail	Doxofylline 400mg SR + Montelukast 10mg Tablet	Doxofylline INN 400mg SR + Montelukast Sodium USP 10 mg	Antiasthma & COPD	It is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: • Asthma • Hay fever • Exercise-induced asthma • Chronic asthma • Seasonal allergic rhinitis • Perennial allergic rhinitis	**Contraindication:** Contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients. It should not be used if you have the following conditions: • Allergic reactions • Asthma exacerbations • Hypersensitivity • Lactation • Pregnancy **Side effect:** The following is a list of possible side-effects that may occur from all constituting ingredients of this tablet. This is not a comprehensive list. These side effects are possible, but do not always occur. • Nausea, Vomiting, Epigastric pain, Palpitations,Headache, Insomnia	Doxophylline 400 mg SR Tablet, Montelukast 10mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
15.	Navana Pharmaceuticals, Narayanganj	Doxofylline 100 mg Injection	Doxofylline INN 100mg/10ml	Anti-asthma & COPD	It is indicated in bronchial asthma, Chronic asthmatic bronchitis, other breathing problems caused by spasms.	**Contraindication:** Do not take if patients are allergic to doxofylline or xanthine derivatives and those who have acute myocardial infarction. **Side Effects:** Using xanthine derivatives may cause nausea, vomiting, upper abdominal pain, headache, insomnia, irritability, tachycardia, premature systole, shortness of breath, high blood glucose.	200 mg Tablet, 400 mg Tablet, 400 SR Tablet & 100 mg/5ml syrup.		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
16.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Benralizumab 30 mg/ml solution in a single-dose prefilled syringe	Benralizumab 30mg/ml	Antiasthmatic	• Benralizumab is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. • Benralizumab is not indicated for treatment of other eosinophilic conditions. Benralizumab is not indicated for the relief of acute bronchospasm or status asthmaticus	**Contraindications:** Benralizumab is contraindicated in patients who have known hypersensitivity to benralizumab or any of its excipients. **Side Effects:** Allergic (hypersensitivity) reactions, including anaphylaxis. Serious allergic reactions can happen after getting benralizumab injection. Allergic reactions can sometimes happen hours or days after you get your injection. Tell your healthcare provider or get emergency help right away if someone has any of the following symptoms of an allergic reaction: • swelling of your face, mouth and tongue • breathing problems • fainting, dizziness, feeling lightheaded (low blood pressure) • rash, hives	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
17.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur Sadar, Gazipur	Umeclidinium Bromide, Micronized 62.5mcg + Vilanterol (as Vilanterol Trifenatate), Micronized 25mcg Dry Powder Inhaler Capsule	Umeclidinium Bromide, Micronized INN 0.0625mg + Vilanterol (as Vilanterol	Antiasthmatic	is a combination of umeclidinium, an anticholinergic, and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for the long-term,	**Contra-indication:** Severe hypersensitivity to milk proteins or any ingredients. **Adverse Reactions:** Most common adverse reactions (incidence ≥1% and more common than placebo) include pharyngitis, sinusitis, lower	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

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			Trifenatate), Micronized INN 0.025mg		once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). **Important limitations:** Not indicated for the relief of acute bronchospasm or for the treatment of asthma.	respiratory tract infection, constipation, diarrhea, pain in extremity, muscle spasms, neck pain, and chest pain.				
18.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur Sadar, Gazipur	Fluticasone Furoate, Micronized 100mcg + Vilanterol (as Vilanterol Trifenatate), Micronized 25mcg Dry Powder Inhaler Capsule	Fluticasone Furoate, Micronized INN 0.100mg + Vilanterol (as Vilanterol Trifenatate), Micronized INN 0.025mg	Antiasthmatic	It is a combination of fluticasone furoate, an inhaled corticosteroid (ICS), and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for long-term, once-daily, maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD). **Important limitations:** Not indicated for relief of acute bronchospasm or for treatment of asthma.	**Contraindication:** Severe hypersensitivity to milk proteins or any ingredients. **Adverse Reactions:** Most common adverse reactions (incidence ≥3%) are nasopharyngitis, upper respiratory tract infection, headache, and oral candidiasis.	Fluticasone Furoate 50mcg/100mcg/ 200mcg/250mcg / 500mcg Dry Powder Inhalation Capsule	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
19.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur Sadar, Gazipur	Fluticasone Furoate, Micronized 200mcg + Vilanterol (as Vilanterol Trifenatate), Micronized 25mcg **Dry Powder Inhaler Capsule**	Fluticasone Furoate, Micronized INN 0.200mg + Vilanterol (as Vilanterol Trifenatate), Micronized INN 0.025mg	Antiasthmatic	It is a combination of fluticasone furoate, an inhaled corticosteroid (ICS), and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for long-term, once-daily, maintenance treatment of airflow obstruction and for reducing exacerbations in	**Contraindication:** Severe hypersensitivity to milk proteins or any ingredients. **Adverse Reactions:** Most common adverse reactions (incidence ≥3%) are nasopharyngitis, upper respiratory tract infection, headache, and oral candidiasis.	Fluticasone Furoate 50mcg/100mcg/ 200mcg/250mcg / 500mcg Dry Powder Inhalation Capsule	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					patients with chronic obstructive pulmonary disease (COPD). **Important limitations:** Not indicated for relief of acute bronchospasm or for treatment of asthma.					
20.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur Sadar, Gazipur	Fluticasone Furoate, Micronized 100mcg + Umeclidinium Bromide, Micronized 62.5mcg + Vilanterol (as Vilanterol Trifenatate), Micronized 25mcg Dry Powder Inhaler Capsule	Fluticasone Furoate, Micronized INN 0.100mg + Umeclidinium Bromide, Micronized INN 0.0625mg + Vilanterol (as Vilanterol Trifenatate), Micronized INN 0.025mg	Antiasthmatic	It is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. **Important limitations of use:** Not indicated for relief of acute bronchospasm or the treatment of asthma.	**Contraindication:** Severe hypersensitivity to milk proteins or any ingredients **Adverse Reactions :**Most common adverse reactions (incidence ≥1%) are upper respiratory tract infection, pneumonia, bronchitis, oral candidiasis, headache, back pain, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, dysgeusia, constipation, urinary tract infection, diarrhea, gastroenteritis, oropharyngeal pain, cough, and dysphonia.	Fluticasone Furoate 50mcg/100mcg/ 200mcg/250mcg / 500mcg Dry Powder Inhalation Capsule	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
21.	a) Beximco Pharmaceuticals Ltd. b) Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Fosfomycin 4 gm/vial powder for solution for infusion	Fosfomycin Sodium & Succinic Acid sterile Mixture 5.38gm containing Fosfomycin Sodium BP 5.28 gm eq. to 4.00gm Fosfomycin/Vial	Antibiotic	Fosfomycin is indicated for the treatment of the following infections in adults and children including neonates : - Osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above	**Contraindications:** Hypersensitivity to fosfomycin. **Side effects:**GI disturbances (e.g. nausea, diarrhoea), transient increase in aminotransferase levels, headache, visual disturbances, skin rashes, eosinophilia, angioedema, aplastic anaemia, exacerbation of asthma, cholestatic jaundice, hepatic necrosis, toxic megacolon. Potentially Fatal: Anaphylactic shock, antibiotic-associated colitis and pseudomembranous colitis.	3gm/Vial powder for oral suspension	BNF75 Page: 549 MHRA	WHO Reserve List আছে বিধায় ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা যেতে পারে।	ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা হল।
22.	a) Navana Pharmaceutical, Narayanganj b) Square Pharmaceuticals ltd., Dhaka Unit	Faropenem 200 mg Tablet	Faropenem Sodium INN 215.40mg eq. to 200mg Faropenem	Antibiotic	**Lower respiratory tract infections:** Eg, acute bronchitis, pneumonia, pulmonary suppuration. **Ear, nose and throat (ENT) infections:** Eg, otitis externa, tympanitis, sinusitis. **Genito-urinary infections:** Eg, pyelonephritis, cystitis, prostatitis, seminal gland inflammation. **Upper respiratory tract infections:** Eg, pharyngitis, tonsillitis. **Skin and skin structure infections:** Eg, pustular acne, folliculitis, contagious impetigo, erysipelas, lymphangitis, suppurative nail	**CONTRAINDICATION:** Faropenem is contraindicated in patients with known hypersensitivity to any of the components of this product or to other drugs in the same class, or in patients who have demonstrated anaphylactic reactions to beta-lactams. **ADVERSE EFFECTS:** Faropenem is generally welltolerated. The most frequently reported adverse reactions are diarrhea, abdominal pain, loose bowel movements, nausea and rash. The following adverse reactionshave also been observed: • Shock, pseudoanaphylactic symptoms: Feeling of discomfort, wheezing, breathing trouble, dizziness, feeling a need to evacuate the bowel, ringing in the ear, sweating, flushing of the whole body, vascular edema, low blood pressure. • Acute renal impairment.	New		প্রয়োজনীয় রেফারেন্স নেই এবং পার্শ্বপ্রতিক্রিয়া আনেক বেশী থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই এবং পার্শ্বপ্রতিক্রিয়া আনেক বেশী থাকায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					inflammation, subcutaneous abscess, hidradenitis (sweat gland inflammation), infective sebaceous cyst, chronic pyoderma, secondary infection of external wounds or surgical wound. **Gynecological infections:** Eg, adnexitis, bartholingland inflammation	• Serious colitis accompanied by pseudomembranous colitis: Bloody stool, stomachache, frequent diarrhea. • Mucocutaneous ocular syndrome (Stevens-Johnson syndrome), toxic epidermal necrosis (Lyell syndrome). • Interstitial pneumonia: Pyrexia, cough, breathing trouble, abnormalities in the chest X-ray. If these symptoms appear, appropriate measures should be taken, such as administration of an adrenal cortical hormone. • Liver function disorder, jaundice: An increase in AST (SGOT), ALT (SGPT), ALP, etc. • Agranulocytosis. • Striated muscle softening: Muscular pain, feeling of exhaustion, increase in CK (CPK), increase in myoglobinin the blood and in the urine, and subsequently, acute renal impairment. • Pulmonary infiltration with eosinophilia (PIE) syndrome: Pyrexia, cough, breathing trouble, abnormalities in the chest X-ray and eosinophilia. If these symptoms appear, appropriate measures should be taken, such as administration of an adrenal cortical hormone. • Hypersensitivity reactions: Rash, pyrexia, redness, hives, red spots on the skin, etc. • Abnormal laboratory findings: Eg, increases in liver function tests (ALT, AST, bilirubin, LDH, etc.), eosinophilia, increase in BUN-creatinine, changes in granulocyte and platelets. • Vitamin deficiency: Symptoms of vitamin K deficiency (low prothrombin, tendency of hemorrhage, etc). Symptoms of vitamin B-group deficiency (inflammation of the tongue, stomatitis, lack of appetite, neuritis, etc.) might				

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						occur rarely. • Gastrointestinal disorders: Vomiting, stomachache, diarrhea, lack of appetite, gastritis, constipation, inflammation of the corners of the mouth and lips, stomatitis. • Others: Burning sensation, headache, dizziness, drowsiness, edema, dryness of the mouth and lips, change in nail color, and a washed-out feeling, all of them can occur rarely.				
23.	Acme Laboratories Ltd., Dhamrai, Dhaka	Cefcapene Film Coated Tablet	Cefcapene Pivoxil Hydrochloride Hydrate INN 137.20 mg eq. to 100mg Cefcapene	Antibiotic	It is indicated in superficial skin infection, deep skin infection, lymphangitis, lymphadentitis, chronic pyoderma. -Secondary infections in trauma, burns, surgical wounds etc., mastitis, periproctic abscess. -Pharyngolaryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infections in chronic respiratory diseases -Cystitis, pyelonephritis -Urethritis, cervicitis	**Contraindication:** This drug is contraindicated in patients with known allergy to penicllin or cephalosporin class of antibiotics or any of the components of this formulation. Patients with a history of shock following exposure to any of the ingredients in this product. Patients with a history of hypersensitivity to any of the ingredients in this product or to other cephalosporin antibiotics. **Side Effects:** Clinically significant adverse reactions are given below. • Shock, anaphylactoid reaction, Acute renal failure • Agranulocytosis, thrombocytopenia, hemolytic anemia • Pseudomembranous colitis, hemorrhagic colitis • Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome, erythroderma.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
24.	Beximco Pharmaceuticals Ltd.	Fosfomycin 8 gm/vial powder for solution for infusion	Fosfomycin sodium BP 10.56 gm eq. to 8 gm Fosfomycin/vial	Antibiotic	Fosfomycin is indicated for the treatment of the following infections in adults and children including neonates : - Osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections	**Contraindications:** Hypersensitivity to fosfomycin. **Side effects:** GI disturbances (e.g. nausea, diarrhoea), transient increase in aminotransferase levels, headache, visual disturbances, skin rashes, eosinophilia, angioedema, aplastic anaemia, exacerbation of asthma, cholestatic jaundice, hepatic necrosis, toxic megacolon.	Fosfomycin 3g powder for oral suspension	MHRA	WHO Reserve List আছে বিধায় ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা যেতে পারে।	ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					- Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above	Potentially Fatal: Anaphylactic shock, antibiotic-associated colitis and pseudomembranous colitis.				
25.	Beximco Pharmaceuticals Ltd., Tongi, Gazipur	Fosfomycin 2 gm/vial powder for solution for infusion	Fosfomycin Sodium BP 2.64 gm eq. to 2.0 gm Fosfomycin/Vial	Antibiotic	Fosfomycin is indicated for the treatment of the following infections in adults and children including neonates : - Osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above	**Contraindications:** Hypersensitivity to fosfomycin. **Side effects:** GI disturbances (e.g. nausea, diarrhoea), transient increase in aminotransferase levels, headache, visual disturbances, skin rashes, eosinophilia, angioedema, aplastic anaemia, exacerbation of asthma, cholestatic jaundice, hepatic necrosis, toxic megacolon. Potentially Fatal: Anaphylactic shock, antibiotic-associated colitis and pseudomembranous colitis.	Fosfomycin 3g/Vial powder for oral suspension	BNF75 Page: 549 MHRA	WHO Reserve List আছে বিধায় ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা যেতে পারে।	ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা হল।
26.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Azithromycin 500mg + Ambroxol HCl 75mg Sustained Release Tablet	Azithromycin BP 500mg + Ambroxol HCl BP 75mg	Antibiotic and Expectorant	It is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below. Upper Respiratory Tract Infections Pharyngitis/Tonsillitis Acute Bacterial Sinusitis Otitis Media Lower Respiratory Tract Infections Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease Community-Acquired	**Contraindications:** Azithromycin Plus is contraindicated in patients with known hypersensitivity to ambroxol, azithromycin, erythromycin, or any macrolide antibiotic. **Side effects:** In clinical trials, most of the reported side effects with Azithromycin were mild to moderate in severity and were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain. Rarely but potentially serious side effects were angioedema and cholestatic jaundice. Ambroxol: The side effects on account of ambroxol include gastrointestinal side effects, skin rashes, headache, dizziness and sweating.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					Pneumonia [CAP].					
27.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Azithromycin 250mg + Ambroxol Hydrochloride 75mg Sustained Release Tablet	Azithromycin BP 250mg + Ambroxol Hydrochloride BP 75mg	Antibiotic and Expectorant	It is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below. Upper Respiratory Tract Infections Pharyngitis/Tonsillitis Acute Bacterial Sinusitis Otitis Media Lower Respiratory Tract Infections Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease Community-Acquired Pneumonia [CAP].	**Contraindications:** Azithromycin Plus is contraindicated in patients with known hypersensitivity to ambroxol, azithromycin, erythromycin, or any macrolide antibiotic. **Side effects:** In clinical trials, most of the reported side effects with Azithromycin were mild to moderate in severity and were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain. Rarely but potentially serious side effects were angioedema and cholestatic jaundice. Ambroxol: The side effects on account of ambroxol include gastrointestinal side effects, skin rashes, headache, dizziness and sweating.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
28.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fusidic Acid 480mg/Vial Powder for Injection	Sodium Fusidate BP 500mg eq. to 480mg Fusidic Acid/Vial	Antibiotic	It is indicated in the treatment of all staphylococcal infections due to susceptible organisms such as: osteomyelitis, pneumonia, septicemia, wound infections, endocarditis, superinfected cystic fibrosis, cutaneous infections. It should be administered intravenously whenever oral therapy is inappropriate, which includes cases where absorption from the gastro-intestinal tract is unpredictable.	**Contraindications:** Hypersensitivity, This product should not be infused with amino acid solutions or in whole blood, Due to local tissue injury, this product should not be administered intramuscularly or subcutaneously. **Side effects:** Drowsiness, Dizziness, Hyperbilirubinaemia, Venous intolerance, Thrombophlebitis.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
29.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fusidic Acid BP 5gm/100ml Suspension	Fusidic Acid BP 5gm/100ml	Antibiotic	It is indicated in the treatment of all staphylococcal infections due to susceptible organisms such as: osteomyelitis, pneumonia, septicemia, wound infections, endocarditis, superinfected cystic fibrosis, cutaneous infections.	**Contraindications:** Hypersensitivity, This product should not be infused with amino acid solutions or in whole blood, Due to local tissue injury, this product should not be administered intramuscularly or subcutaneously. **Side effects:** Drowsiness, Dizziness, Hyperbilirubinaemia, Venous intolerance, Thrombophlebitis.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
30.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Ozenoxacin 10mg/1gm Cream	Ozenoxacin INN 10mg/1gm	Antibiotic	Ozenoxacin is a quinolone antimicrobial indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older	**Contra-indication:** None **Side-effect:** Adverse reactions (rosacea and seborrheic dermatitis) were reported in 1 adult patient treated with ozenoxacin.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
31.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Colistimethate Sodium 2 million IU/Vial Powder for Solution for Injection or Infusion	Colistimethate Sodium USP 2 million IU eq. to 68 mg colistin	Antibiotic	Treatment of the following infections where sensitivity testing suggests that they are caused by susceptible bacteria: Treatment by inhalation of Pseudomonas aeruginosa lung infection in patient swith cysticfibrosis (CF). Intravenous administration for the treatment of some serious infections caused by gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of	**Contraindications:** Hypersensitivity to colistimethate sodium (colistin) or to polymyxin B. Patients with myasthenia gravis. **Side-effects:** **Systemic Treatment:** The likehood of adverse events may be related to the age, renal function and condition of the patient. In cystic fibrosis patients, neurological events have been reported in up to 27% of patients. These are generally mild and resolve during or shortly after treatment. Neurotoxicity may be associated with overdose, failure to reduce the dose in patients with renal insufficiency and concomitant use of either neuromuscular-blocking drugs or other drugs with similar neurological effects. Reducing the dose may alleviate symptoms. Effects may include apnoea, transient sensory disturbances (eg, facial paraesthesia and vertigo) and rarely, vasomotor instability, slurred speech, visual disturbances,	Colistimethate Sodium, 1 Million International Units (IU) Powder for Solution for Injection or Infusion	BNF-75 Page: 512	WHO Reserve List আছে বিধায় ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা যেতে পারে।	ঔষধটি বিশেষ ক্ষেত্রে ব্যবহারের শর্ত সাপেক্ষে অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					bacterial resistance.	confusion or psychosis. Adverse effects on renal function have been reported, usually following use of higher than recommended doses in patients with normal renal function, or failure to reduce the dosage in patients with renal impairment or during concomitant use of other nephrotoxic drugs. The effects are usually reversible on discontinuation of therapy. In cystic fibrosis patients treated within the recommended dosage limits, nephrotoxicity appears to be rare (<1%). In seriously ill hospitalised non-CF patients, signs of nephrotoxicity have been reported in approximately 20% of patients. Hypersensitivity reactions including skin rash and drug fever have been reported. If these occur treatment should be withdrawn. Local irritation at the site of injection may occur. **Inhalation Treatment:** Inhalation may induce coughing or bronchospasm. Sore throat or mouth has been reported and may be due to Candida albicans infection or hypersensitivity. Skin rash may also indicate hypersensitivity, if this occurs treatment should be withdrawn				
32.	Navana Pharmaceuticals, Narayanganj	Cefixime Trihydrate 500 mg/5 ml Powder for Suspension	Cefixime Trihydrate BP 500 mg/ 5ml	Antibiotic	It is a cephalosporin antibacterial drug indicated for Uncomplicated Urinary Tract Infections • Otitis Media • Pharyngitis and Tonsillitis • Acute Exacerbations of Chronic Bronchitis • Uncomplicated Gonorrhea (cervical/urethral)	**Side Effects:** Diarrhea or loose stools, nausea, abdominal pain, headache, vomiting, dyspepsia, dry mouth, flatulence, loss of appetite, oral lesions, dizziness, insomnia, confusion, fungal infection, anxiety, cough, urticaria, rash, dry skin, sun burn may occur. Other side effects reported eosinophilia and blood disorder, reversible interstitial nephritis, nervousness. **Contraindication:** Cefixime is contraindicated in patients with a known allergy to Cefixime or to the Cephalosporin group of antibiotic.	200mg, 400mg Tablet/Capsule 100mg/5 ml, 200 mg/5ml	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
33.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Cefixime 50mg + Clavulanic Acid 31.25mg Tablet	Cefixime BP 50mg + Diluted Clavulanate Potassium BP 74.460mg eq. to Clavulanic Acid 31.25mg	Antibiotic	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of – 1) Uncomplicated Urinary Tract Infections. 2) Otitis Media. 3) Pharyngitis and Tonsillitis. 4) Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis. 5) Uncomplicated gonorrhea etc.	**Contraindications:** Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases,e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism have different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. **Side effects:** Cefixime-Clavulanic Acid are diarrhea 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.	Cefixime 100 mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100 ml Paediatric Drop		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
34.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Cefixime 100mg + Clavulanic Acid 62.5mg Tablet	Cefixime BP 100mg + Diluted Clavulanate Potassium BP 148.920mg eq. to Clavulanic Acid 62.5mg	Antibiotic	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of – 1) Uncomplicated Urinary Tract Infections. 2) Otitis Media. 3) Pharyngitis and Tonsillitis. 4) Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis. 5) Uncomplicated	**Contraindications:** Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases,e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism have different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. **Side effects:** Cefixime-Clavulanic Acid are diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur. Thrombocytosis, thrombocytopenia, leucopenia,	Cefixime 100 mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100 ml Paediatric Drop		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					gonorrhea etc.	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.				
35.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Cefixime 200mg + Clavulanic Acid 125mg Tablet	Cefixime BP 200mg + Diluted Clavulanate Potassium BP 297.840mg eq. to Clavulanic Acid 125mg	Antibiotic	Cefixime-Clavulanic Acid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanic Acid is indicated for the treatment of – 1) Uncomplicated Urinary Tract Infections. 2) Otitis Media. 3) Pharyngitis and Tonsillitis. 4) Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis. 5) Uncomplicated gonorrhea etc.	**Contraindications:** Cefixime is contraindicated in patients with known allergy to the Cephalosporin class of antibiotics. Clavulanic Acid does not inactivate all β-Lactamases. Most chromosomally mediated β-Lactamases,e.g. the enzyme produced by pseudomonas aeruginosa, are resistant to its action. Other organism have different mechanisms of acquired resistance to β-Lactam antibiotics, against which clavulanic acid is ineffective. **Side effects:** Cefixime-Clavulanic Acid are diarrhea 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.	Cefixime 100 mg, 200mg & 400mg Capsule Cefixime 200mg/5ml Powder For Suspension Cefixime 2.5gm/100 ml Paediatric Drop		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
36.	Renata Limited Rajendrapur, Gazipur	Cefcapene 100mg Tablet	Cefcapene Pivoxil Hydrochloride Hydrate INN 137.18mg eq. to Cefcapene 100mg	Antibiotic	Cefcapene exerts antibacterial action by inhibiting the synthesis of the bacterial cell-wall, and its action is bactericidal. Cefcapene showed high binding affinity to all of the subtypes 1, 2 and 3 of PBP	**Contraindication:** Cefcapene is contraindicated in the following patients' patients with a history of shock following exposure to any of the ingredients in this product. **Side effects :** Few major adverse events have been observed. The adverse events found during trial are Urticaria, pruritus, redness, erythema, swelling, fever, Proteinuria, hematuria, increased creatinine,	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					(penicillin binding protein), which are known to be target molecules lethal to Staphylococcus aureus. Furthermore, it showed high binding affinity to PBP3, which is an enzyme essential to the synthesis of bacterial cell-wall.	edema.				
37.	Renata Limited Rajendrapur, Gazipur	Ertapenem 500mg/Vial Powder for Infusion	Ertapenem Sodium INN 523mg eq. to 500mg Ertapenem/Vial	Antibiotic	Ertapenem is bactericidal and act by binding to penicillin binding proteins (PBPs). This binding inactivates the PBPs, and prevents the transpeptidation (crosslinking) of peptidoglycan strands, which is essential for the synthesis of intact bacterial peptidoglycan.	Contraindication : Ertapenem is contraindicated in patients with known hypersensitivity to any component of this product or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to betalactams. Due to the use of lidocaine HCl as a diluent, ERTAPENEM administered intramuscularly is contraindicated in patients with a known hypersensitivity to local anesthetics of the amide type.Side effects : The most common drug-related adverse experiences in patients treated with Ertapenem, including those who were switched to therapy with an oral antimicrobial, were diarrhea (5.5%), infused vein complication (3.7%), nausea (3.1%), headache (2.2%), vaginitis in females (2.1%), hlebitis/thrombophlebitis (1.3%), and vomiting (1.1%).	1 gm/vial Injection		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
38.	Ziska Pharmaceuticals Ltd.	Telavancin 250mg/Vial Injection	Telavancin HCl Sterile Lyophilized Powder INN 265.59mg eq. to 250mg Telavancin	Antibiotic	Telavancin is a lipoglycopeptide antibacterial indicated for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria.	**Contraindications:** None **Side effects:** Most common adverse reactions (≥10% of patients treated with Telavancin) include: taste disturbance, nausea, vomiting, and foamy urine	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
39.	Ziska Pharmaceuticals Ltd.	Telavancin 750 mg/Vial Injection	Telavancin HCl Sterile Lyophilized Powder INN 796.78mg eq. to 750mg Telavancin	Antibiotic	Telavancin is a lipoglycopeptide antibacterial indicated for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria.	**Contraindications:** None **Side effects:** Most common adverse reactions (≥10% of patients treated with Telavancin) include: taste disturbance, nausea, vomiting, and foamy urine	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
40.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Rucaparib 200mg Tablet	Rucaparib Camslate INN 344.00mg eq. to 200mg Rucaparib	Anticancer	It is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rucaparib This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.	**Contra-indication : None** **Side-effect:** Most common adverse reactions (≥ 20%) were nausea, fatigue (including asthenia), vomiting, anemia, abdominal pain, dysgeusia, constipation, decreased appetite, diarrhea, thrombocytopenia, and dyspnea. • Most common laboratory abnormalities (≥ 35%) were increase in creatinine, increase in ALT, increase in AST, decrease in hemoglobin, decrease in lymphocytes, increase in cholesterol, decrease in platelets, and decrease in absolute neutrophil count	300mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
41.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Rucaparib 250mg Tablet	Rucaparib Camslate INN 430.000mg eqv. To Rucaparib 250mg	Anticancer	It is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rucaparib This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.	**Contra-indication : None** **Side-effect:** Most common adverse reactions (≥ 20%) were nausea, fatigue (including asthenia), vomiting, anemia, abdominal pain, dysgeusia, constipation, decreased appetite, diarrhea, thrombocytopenia, and dyspnea. • Most common laboratory abnormalities (≥ 35%) were increase in creatinine, increase in ALT, increase in AST, decrease in hemoglobin, decrease in lymphocytes, increase in cholesterol, decrease in platelets, and decrease in absolute neutrophil count	300mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
42.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Olaparib 100mg Tablet	Olaparib INN 100mg	Anticancer	It is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated: • for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. • for the treatment of adult	**Contra-indication : None** **Side-effect:** • Most common adverse reactions (≥20%) in clinical trials were anemia, nausea, fatigue (including asthenia), vomiting,nasopharyngitis/upper respiratory tract infection/influenza, diarrhea,thralgia/myalgia, dysgeusia, headache, dyspepsia, decreased appetite, constipation. and stomatitis. • Most common laboratory abnormalities (≥25%) were decrease in hemoglobin, increase in mean	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.	corpuscular volume, decrease in lymphocytes, decrease in leukocytes, decrease in absolute neutrophil count, increase in serum creatinine and decrease in platelets.				
43.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Olaparib 150mg Tablet	Olaparib INN 150mg	Anticancer	It is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated: • for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. • for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.	**Contra-indication : None** **Side-effect:** • Most common adverse reactions (≥20%) in clinical trials were anemia, nausea, fatigue (including asthenia), vomiting,nasopharyngitis/upper respiratory tract infection/influenza, diarrhea,thralgia/myalgia, dysgeusia, headache, dyspepsia, decreased appetite, constipation. and stomatitis. • Most common laboratory abnormalities (≥25%) were decrease in hemoglobin, increase in mean corpuscular volume, decrease in lymphocytes, decrease in leukocytes, decrease in absolute neutrophil count, increase in serum creatinine and decrease in platelets.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
44.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Enzalutamide 160mg Capsule	Enzalutamide INN 160mg	Anticancer	It is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel	**Contra-indication :** Pregnancy **Side-effect:** The most common adverse reactions (≥ 5%) are asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
45.	Drug International Ltd. UNIT-2 Plot# 13A & 14A, Tongi Industrial Area, Tongi, Gazipur	Apalutamide 60mg Tablet	Apalutamide INN 60 mg	Anticancer	Apalutamide is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.	**Contraindications:** Pregnancy **Adverse Reactions:** The most common adverse reactions (≥10%) are fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
46.	Drug International Ltd. UNIT-2 Plot# 13A & 14A, Tongi Industrial Area, Tongi, Gazipur	Venetoclax 10mg Tablet	Venetoclax INN 10mg	Anticancer	It is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.	**Contraindications:** Concomitant use of VENCLEXTA with strong inhibitors of CYP3A at initiation and during ramp-up phase is contraindicated. **Adverse Reactions:** The most common adverse reactions (≥20%) with Venetoclax in combination with rituximab were neutropenia, diarrhea, upper respiratory tract infection, fatigue, cough, and nausea. (6.1) The most common adverse reactions (≥20%) with VENCLEXTA in the monotherapy studies were neutropenia, diarrhea, nausea, upper respiratory tract infection, anemia, fatigue, thrombocytopenia, musculoskeletal pain, edema, and cough.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
47.	Drug International Ltd. UNIT-2 Plot# 13A & 14A, Tongi Industrial Area, Tongi, Gazipur	Venetoclax 50mg Tablet	Venetoclax INN 50mg	Anticancer	It is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.	**Contraindications:** Concomitant use of Venetoclax with strong inhibitors of CYP3A at initiation and during ramp-up phase is contraindicated. **Adverse Reactions:** The most common adverse reactions (≥20%) with Venetoclax in combination with rituximab were neutropenia, diarrhea, upper respiratory tract infection, fatigue, cough, and nausea. (6.1) The most common adverse reactions (≥20%) with Venetoclax in the monotherapy studies were neutropenia, diarrhea, nausea, upper respiratory tract infection, anemia, fatigue, thrombocytopenia, musculoskeletal pain, edema, and cough.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
48.	Drug International Ltd. UNIT-2 Plot# 13A & 14A, Tongi Industrial Area, Tongi, Gazipur, Bangladesh.	Venetoclax 100mg Tablet	Venetoclax INN 100mg	Anticancer	It is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.	**Contraindications:** Concomitant use of Venetoclax with strong inhibitors of CYP3A at initiation and during ramp-up phase is contraindicated. **Adverse Reactions:** The most common adverse reactions (≥20%) with Venetoclax in combination with rituximab were neutropenia, diarrhea, upper respiratory tract infection, fatigue, cough, and nausea. (6.1) The most common adverse reactions (≥20%) with Venetoclax in the monotherapy studies were neutropenia, diarrhea, nausea, upper respiratory tract infection, anemia, fatigue, thrombocytopenia, musculoskeletal pain, edema, and cough.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
49.	Healthcare Pharmaceutical ltd., Rajendrapur , Gazipur	Dasatinib 140 mg film coated tablet	Dasatinib Monohydrate INN 145.166mg eq. to 140.0mg Dasatinib	Anticancer	treatment of 1.newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The trial is ongoing and further data will be required to determine long-term outcome. 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	**Contraindications:** Known hypersensitivity to Dasatinib INN or any excipients in formulation **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.	20mg, 50mg and 100mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
50.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Abemaciclib 150 mg Tablet	Abemaciclib INN 150 mg	Anticancer	Abemaciclib is a kinase inhibitor indicated: • in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.	**Contraindications:** None. **Side Effects:** Diarrhea: Diarrhea is common with abemaciclib treatment and may sometimes be severe. Diarrhea may cause to develop dehydration or an infection. The most common time to develop diarrhea is during the first month of abemaciclib treatment. If anyone develop diarrhea during treatment with abemaciclib, healthcare provider may tell to temporarily stop taking abemaciclib, stop treatment, or decrease dose. -If have any loose stools, right away tell healthcare provider, start taking an antidiarrheal medicine (such as loperamide), and drink more fluids.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					• as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.	Low white blood cell counts (neutropenia): Low white blood cell counts are common during treatment with abemaciclib and may cause serious infections that can lead to death. Healthcare provider should check white blood cell counts before and during treatment. If develop low white blood cell counts during treatment with abemaciclib, healthcare provider may tell to temporarily stop taking abemacicliob, decrease dose, or wait before starting next month of treatment. Tell healthcare provider right away if have signs and symptoms of low white blood cell counts or infections, such as fever and chills. Liver problems: Abemaciclib can cause serious liver problems. Healthcare provider should do blood tests to check liver before and during treatment with abemaciclib. If develop liver problems during treatment with abemaciclib, healthcare provider may reduce dose or stop treatment. Tell healthcare provider right away if have any of the following signs and symptoms of liver problems: -feeling very tired -pain on the upper right side of your stomach area (abdomen) -loss of appetite -bleeding or bruising more easily than normal Blood clots in veins, or in the arteries of lungs.abemaciclib may cause serious blood clots that have led to death. Tell healthcare provider right away if get any of the following signs and symptoms of a blood clot: -pain or swelling in your arms or legs -shortness of breath -chest pain -rapid breathing -rapid heart rate				

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
51.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Abemaciclib 200 mg Tablet	Abemaciclib INN 200 mg	Anticancer	Abemaciclib is a kinase inhibitor indicated: in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. • as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.	**Contraindications:** None. **Side Effects:** Diarrhea: Diarrhea is common with abemaciclib treatment and may sometimes be severe. Diarrhea may cause to develop dehydration or an infection. The most common time to develop diarrhea is during the first month of abemaciclib treatment. If anyone develop diarrhea during treatment with abemaciclib, healthcare provider may tell to temporarily stop taking abemaciclib, stop treatment, or decrease dose. -If have any loose stools, right away tell healthcare provider, start taking an antidiarrheal medicine (such as loperamide), and drink more fluids. Low white blood cell counts (neutropenia): Low white blood cell counts are common during treatment with abemaciclib and may cause serious infections that can lead to death. Healthcare provider should check white blood cell counts before and during treatment. If develop low white blood cell counts during treatment with abemaciclib, healthcare provider may tell to temporarily stop taking abemacicliob, decrease dose, or wait before starting next month of treatment. Tell healthcare provider right away if have signs and symptoms of low white blood cell counts or infections, such as fever and chills. Liver problems: Abemaciclib can cause serious liver problems. Healthcare provider should do blood tests to check liver before and during treatment with abemaciclib. If develop liver problems during treatment with abemaciclib, healthcare provider may reduce dose or stop treatment. Tell healthcare provider right away if have any of the following signs and symptoms of liver problems: -feeling very tired -pain on the upper right side of your stomach area (abdomen)	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						-loss of appetite -bleeding or bruising more easily than normal Blood clots in veins, or in the arteries of lungs.abemaciclib may cause serious blood clots that have led to death. Tell healthcare provider right away if get any of the following signs and symptoms of a blood clot: -pain or swelling in your arms or legs -shortness of breath -chest pain -rapid breathing -rapid heart rate				
52.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Daratumumab 100mg/5ml Injection	Daratumumab INN 100mg/5ml	Anticancer	Daratumumab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.	**Contraindications:** None. **Side Effects:** **Infusion reactions:** Infusion reactions are common with daratamumab and can be severe. Your healthcare provider may temporarily stop your infusion or completely stop treatment with daratamumab if you have infusion reactions. Tell healthcare provider right away if get any of the following symptoms: b) shortness of breath or trouble breathing c) dizziness or lightheadedness (hypotension) d) cough e) wheezing f) throat tightness g) runny or stuffy nose h) headache i) itching j) nausea k) vomiting l) chills m) fever **Changes in blood tests:** Daratamumab can affect the results of blood tests to match blood type. These changes can last for up to 6 months after final dose of daratamumab. Healthcare provider will do blood tests to match blood type before start treatment with	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						daratamumab. **Decreases in blood cell counts:** Daratamumab can decrease white blood cell counts which help fight infections and blood cells called platelets which help to clot blood.				
53.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Daratumumab 400mg/20ml Injection	Daratumumab INN 400mg/20ml	Anticancer	Daratumumab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.	**Contraindications:** None. **Side Effects:** **Infusion reactions:** Infusion reactions are common with daratamumab and can be severe. Your healthcare provider may temporarily stop your infusion or completely stop treatment with daratamumab if you have infusion reactions. Tell healthcare provider right away if get any of the following symptoms: n) shortness of breath or trouble breathing o) dizziness or lightheadedness (hypotension) p) cough q) wheezing r) throat tightness s) runny or stuffy nose t) headache u) itching v) nausea w) vomiting x) chills y) fever **Changes in blood tests:** Daratamumab can affect the results of blood tests to match blood type. These changes can last for up to 6 months after final dose of daratamumab. Healthcare provider will do blood tests to match blood type before start treatment with daratamumab. **Decreases in blood cell counts:** Daratamumab can decrease white blood cell counts which help fight infections and blood cells called platelets which help to clot blood.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
54.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Atezolizumab 1200mg/20ml Injection for Intravenous Use	Atezolizumab INN 1200mg/20ml	Anticancer	**Locally Advanced or Metastatic Urothelial Carcinoma** Atezolizumab is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: • are not eligible for cisplatin-containing chemotherapy, or • have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. **Metastatic Non-Small Cell Lung Cancer** Atezolizumab is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have	**Contraindications:** None **Side Effects: The most common side effects of atezolizumab in people with urothelial carcinoma include:** • feeling tired • decreased appetite • nausea • constipation • urinary tract infection • diarrhea • fever **The most common side effects of atezolizumab in people with non-small cell lung cancer include:** • feeling tired • decreased appetite • shortness of breath • cough • nausea • muscle or bone pain • constipation Atezolizumab may cause fertility problems in females, which may affect the ability to have children. Patients should talk to their healthcare provider if they have concerns about fertility. These are not all the possible side effects of atezolizumab. Patients should ask their healthcare provider or pharmacist for more information.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving atezolizumab.					
55.	General Pharmaceutical Ltd., Gazipur	Fluvoxamine Maleate BP 100mg Tablet	Fluvoxamine Maleate BP 100mg	Antidepressants	Fluvoxamine Maleate Tablets are indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder (OCD)	**Contra-indication :**Coadministration of tizanidine, thioridazine, alosetron, pimozide Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with Fluvoxamine Maleate Tablets or within 14 days of stopping treatment with Fluvoxamine Maleate Tablets. Do not use Fluvoxamine Maleate Tablets within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Fluvoxamine Maleate Tablets in a patient who is being treated with linezolid or intravenous methylene blue **Side –Effects**: Most reactions in controlled trails with adult OCD and depression patients were nausea, somnolence, insomnia, asthenia, nervousness, dyspepsia, abnormal ejaculation, sweating, anorexia, termor and vomiting. Using the above rule, the following events were also identified: anorgasmia, deacresed libido, dry mouth, rhinitis, taste perbversion, and urinary frequiency in patients with OCD and agitation, depression dysmenorrhea, flatulence, hyperkinesia and rash in pediatric patients with OCD	50mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
56.	Ziska Pharmaceuticals Ltd.	L-tryptophan 500 mg Capsule	L-tryptophan USP 500mg	Antidepressants	Treatment resistant depression (used alone or as adjunct to other antidepressant drugs)	**Contraindications:** History of eosinophilia myalgia syndrome following use of Tryptophan **Side effects:** Asthenia, dizziness, eosinophilia myalgia syndrome, headache, myalgia, myopathy, nausea, oedema, somnolence, suicidal ideation & behavior	New	BNF-75 Page-370	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
57.	a) Pacific Pharmaceuticals Limited BSCIC, Kanchpur, Sonargaon, Narayangonj b) Square Formulations Ltd., Gorai, Tangail c) Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Empagliflozin 25mg + Linagliptin 5mg Tablet	Empagliflozin INN 25 mg + Linagliptin INN 5 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 Empagliflozin and Linagliptin is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Combination of Empagliflozin and Linagliptin on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.	**Contraindications:** Empagliflozin & Linagliptin INN Tablet is contraindicated in patients with Severe renal impairment, end-stage renal disease, or dialysis. A history of serious hypersensitivity reaction to Empagliflozin, Linagliptin, or any of the excipients in this product such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity. **Side Effects :** The common adverse effect reported associated with the treatment of combination of Empagliflozin & Linagliptin are pancreatitis, heart failure, hypotension, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis and pyelonephritis, hypoglycemia with concomitant use with insulin and insulin secretagogues, genital mycotic infections, hypersensitivity reactions, increased low-density lipoprotein cholesterol (ldl-c), severe and disabling arthralgia, bullous pemphigoid.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
58.	a) Pacific Pharmaceuticals Limited BSCIC, Kanchpur, Sonargaon, Narayangonj b) Square Formulations Ltd., Gorai, Tangail	Empagliflozin 10mg + Linagliptin 5 mg Tablet	Empagliflozin INN 10 mg + Linagliptin INN 5 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 Empagliflozin and Linagliptin is appropriate. Empagliflozin is indicated to reduce the risk of	**Contraindications:** Empagliflozin & Linagliptin INN Tablet is contraindicated in patients with Severe renal impairment, end-stage renal disease, or dialysis. A history of serious hypersensitivity reaction to Empagliflozin, Linagliptin, or any of the excipients in this product such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity. **Side Effects :** The common adverse effect reported	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	c) Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204				cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Combination of Empagliflozin and Linagliptin on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.	associated with the treatment of combination of Empagliflozin & Linagliptin are pancreatitis, heart failure, hypotension, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis and pyelonephritis, hypoglycemia with concomitant use with insulin and insulin secretagogues, genital mycotic infections, hypersensitivity reactions, increased low-density lipoprotein cholesterol (ldl-c), severe and disabling arthralgia, bullous pemphigoid.				
59.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Teneligliptin 20mg Film Coated Tablet	Teneligliptin INN 20mg	Antidiabetic	It is a Type 2 diabetes mellitus- The drug product should be used only in patients who have not sufficiently responded to either of the following treatments: • Diet and/or exercise therapy alone. • Use of sulfonylureas in addition to diet and/or exercise therapy. • Use of thiazolidinediones in addition to diet and/or exercise therapy.	**Contraindications:** Hypersensitivity**,** Severe ketosis, diabetic coma or history of diabetic coma, type 1 diabetic patient, Patients with severe infection, surgery, severe trauma (blood sugar control should preferably be done by insulin). **Side effects:** Abdominal bloating, abdominal discomfort, nausea, abdominal pain, flatulence, Proteinuria, urine ketone-positive, Eczema, rash, itching, allergic dermatitis.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
60.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Semaglutide 1.34mg/ml Pre-filled Pen for Injection	Semaglutide INN 1.34mg/ml	Antidiabetic	It is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitations of Use:** 1. Not recommended as first-	**Contraindications:** 1. Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known hypersensitivity to this or any of the product components **Side-effects/Toxicity:** The most common adverse	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					line therapy for patients inadequately controlled on diet and exercise. 2. Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy. 3. Not indicated for use in type 1 diabetes mellitus or treatment of diabetic ketoacidosis	reactions, reported in ≥5% of patients treated with this are: nausea, vomiting, diarrhea, abdominal pain and constipation.				
61.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Gliclazide 80mg + Metformin Hydrochloride 500mg Film Coated Tablet	Gliclazide BP 80mg + Metformin Hydrochloride BP 500mg	Antidiabetic	Gliclazide + Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2diabetes mellitus.	**Contraindications:** Type-1 diabetes mellitus, renal or hepatic failure, alcoholism, type-2 diabetes complicated by severe ketosis and acidosis, diabetic precoma and coma, patients undergoing surgery, after severe trauma or during infections, chronic obstructive pulmonary disease, coronary heart disease, cardiac failure, peripheral vascular disease, known hypersensitivity to any of the ingredients. **Side effects:** **Gastrointestinal disturbances -** Nausea, diarrhea, gastric pain, constipation, vomiting, metallic taste in mouth. **Dermatological effects -** Rash, pruritus, urticaria, erythema and flushing. **Miscellaneous -** Headache and dizziness. Gliclazide appears to be associated with a low incidence of hypoglycaemia. Impaired gastrointestinal absorption of vitamin B_{12} and folic acid has been associated with long term Metformin therapy.	Gliclazide 60mg Tablet Metformin HCl BP 500mg Tablet		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
62.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 5mg + Metformin Hydrochloride Extended Release 1000mg Tablet	Empagliflozin INN 5mg + Metformin Hydrochloride EP 1000mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. **Limitations of Use:** Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. • Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. • Hepatic impairment, acute alcohol intoxication, alcoholism **Adverse reactions:** Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache	Empagliflozin 10mg & 25 mg Tablet Metformin Hydrochloride 500mg, 850mg, 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
63.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 10 mg + Metformin Hydrochloride Extended Release 1000 mg Tablet	Empagliflozin INN 10 mg + Metformin Hydrochloride EP 1000 mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitations of Use: Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. • Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. • Hepatic impairment, acute alcohol intoxication, alcoholism Adverse reactions: Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache	Empagliflozin 10mg & 25 mg Tablet Metformin Hydrochloride 500mg, 850mg, 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
64.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 12.5 mg + Metformin Hydrochloride Extended Release 1000 mg film coated Tablet	Empagliflozin INN 12.5mg + Metformin Hydrochloride EP 1000mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitations of Use: Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. • Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. • Hepatic impairment, acute alcohol intoxication, alcoholism **Adverse reactions:** Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache	Empagliflozin 10mg & 25 mg Tablet Metformin Hydrochloride 500mg, 850mg, 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
65.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 25 mg + Metformin Hydrochlorude Extended Release 1000 mg Tablet	Empagliflozin INN 25 mg + Metformin Hydrochlorude EP 1000mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitations of Use: Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis)• Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. • Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock.• Hepatic impairment, acute alcohol intoxication, alcoholism Adverse reactions: Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache	Empagliflozin 10mg & 25 mg Tablet Metformin Hydrochloride 500mg, 850mg, 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
66.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 5 mg Film Coated Tablet	Ertugliflozin L-Pyroglutamic Acid INN 6.48mg eq. to Ertugliflozin 5 mg	Antidiabetic	It is a sodium glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** • Severe renal impairment, end-stage renal disease, or dialysis. • History of serious hypersensitivity reaction to the active substances. **Adverse Reaction:** The most common adverse reactions associated with Ertugliflozin (incidence ≥ 5%) were female genital mycotic infections	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
67.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 15 mg Film Coated Tablet	Ertugliflozin L-Pyroglutamic Acid INN 19.43mg eq. to Ertugliflozin 15 mg	Antidiabetic	It is a sodium glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	Contraindication: • Severe renal impairment, end-stage renal disease, or dialysis. • History of serious hypersensitivity reaction to the active substances. Adverse Reaction: The most common adverse reactions associated with Ertugliflozin (incidence ≥ 5%) were female genital mycotic infections	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
68.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 2.5 mg + Metformin Hydrochloride 500mg Film Coated Tablet	Ertugliflozin L-Pyroglutamic Acid INN 3.24mg eq. to Ertugliflozin 2.5 mg + Metformin Hydrochloride EP 500 mg	Antidiabetic	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin	Contraindication: • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin. Adverse reactions: • The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.	Metformin Hydrochloride 500mg, 850mg & 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					and metformin. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.					
69.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 2.5 mg + Metformin Hydrochloride 1000mg Film Coated Tablet	Ertugliflozin L-pyroglutamic acid INN 3.24mg eqv. to Ertugliflozin 2.5 mg + Metformin Hydrochloride EP 1000 mg	Antidiabetic	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin. Adverse reactions: • The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.	Metformin Hydrochloride 500mg, 850mg & 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
70.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 7.5 mg + Metformin Hydrochloride 500mg Film Coated Tablet	Ertugliflozin L-Pyroglutamic Acid INN 9.71mg eqv. to Ertugliflozin 7.5 mg + Metformin Hydrochloride EP 500 mg	Antidiabetic	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing	**Contraindication:** • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin. Adverse reactions: • The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with	Metformin Hydrochloride 500mg, 850mg & 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.				
71.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 7.5 mg + Metformin Hydrochloride 1000mg Film Coated Tablet	Ertugliflozin L-pyroglutamic acid INN 9.71mg eqv. to Ertugliflozin 7.5 mg + Metformin Hydrochloride EP 1000 mg	Antidiabetic	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** • Severe renal impairment, end stage renal disease, or dialysis.• Metabolic acidosis, including diabetic ketoacidosis. • History of serious hypersensitivity reaction to ertugliflozin or metformin. Adverse reactions:• The most common adverse reactions associated with ertugliflozin (incidence ≥5%) were female genital mycotic infections. • Most common adverse reactions associated with metformin (incidence ≥5%): diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.	Metformin Hydrochloride 500mg, 850mg & 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
72.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 5 mg + Sitagliptin 100 mg Film Coated Tablet	Ertugliflozin L-Pyroglutamic Acid INN 6.47mg eqv. to Ertugliflozin 5 mg + Sitagliptin Phosphate Monohydrate INN 128.5mg eqv. to Sitagliptin 100 mg Tablet	Antidiabetic	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Limitations of Use: • Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Has not been studied in patients with a history of pancreatitis.	**Contraindication:** • Severe renal impairment, end stage renal disease, or dialysis. • History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema. • History of serious hypersensitivity reaction to ertugliflozin. Adverse reactions: • Most common adverse reactions associated with ertugliflozin (LQFLGHQFH•5%): female genital mycotic infections. • Most common adverse reactions associated with sitagliptin (LQFLGHQFH •5%): upper respiratory tract infection, nasopharyngitis and headache. In the add-on to sulfonylurea and add-on to insulin studies, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo.	Sitagliptin 25 mg , 50mg & 100mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
73.	Square Formulations Ltd., Gorai, Tangail	Ertugliflozin 15 mg + Sitagliptin 100 mg Film Coated Tablet	Ertugliflozin L-Pyroglutamic Acid INN 19.42mg eqv. to Ertugliflozin 15 mg + Sitagliptin phosphate monohydrate INN 128.5mg eqv. to Sitagliptin 100 mg Tablet	Antidiabetic	It is a combination of ertugliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, and sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Limitations of Use: • Not for the treatment of type 1 diabetes mellitus or diabetic	**Contraindication:** • Severe renal impairment, end stage renal disease, or dialysis.• History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema. • History of serious hypersensitivity reaction to ertugliflozin.**Adverse reactions:** • Most common adverse reactions associated with ertugliflozin (LQFLGHQFH•5%): female genital mycotic infections. • Most common adverse reactions associated with sitagliptin (LQFLGHQFH •5%): upper respiratory tract infection, nasopharyngitis and headache. In the add-on to sulfonylurea and add-on to insulin studies, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo.	Sitagliptin 25 mg , 50mg & 100mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					ketoacidosis. • Has not been studied in patients with a history of pancreatitis.					
74.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 5mg + Metformin 500mg Film Coated Tablet	Empagliflozin INN 5mg + Metformin Hydrochloride EP 500 mg	Antidiabetic	It is a combination of empagliflozin and metformin HCl indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. **Limitation of use:** It is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	**Contraindications:** • Renal Impairment, ESRD, or on dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side effects:** • Most common adverse reactions associated with empaglifloz in (5% or greater incidence) were urinary tract infection and female genital mycotic infections. • Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.	Metformin 500mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
75.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 5mg + Metformin Hydrochloride 1000mg Tablet	Empagliflozin INN 5mg + Metformin Hydrochloride BP 1000mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults	Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. • Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. • Hepatic impairment, acute alcohol intoxication,	Empagliflozin 10mg & 25 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitations of Use: Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis	alcoholism Adverse reactions: Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache				
76.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 12.5mg + Metformin 500 mg Film Coated Tablet	Empagliflozin INN 12.5mg + Metformin EP 500 mg	Antidiabetic	It is a combination of empagliflozin and metformin HCl indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. **Limitation of use:** It is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	**Contraindications:** • Renal Impairment, ESRD, or on dialysis • Metabolic acidosis, including diabetic ketoacidosis • History of serious hypersensitivity reaction to empagliflozin or metformin **Side effects:** • Most common adverse reactions associated with empaglifloz in (5% or greater incidence) were urinary tract infection and female genital mycotic infections. • Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.	Metformin 500mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
77.	Square Formulations Ltd., Gorai, Tangail	Empagliflozin 12.5mg + Metformin Hydrochloride 1000mg Tablet	Empagliflozin INN 12.5mg + Metformin Hydrochloride EP 1000mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitations of Use: Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis	Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis)• Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severeinfection,shock.• Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock.• Hepatic impairment, acute alcohol intoxication, alcoholism **Adverse reactions:** Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache	Empagliflozin 10mg & 25 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
78.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Desmopressin Acetate 0.83mcg/0.1ml Nasal Spray	Desmopressin Acetate INN 0.83mcg eq. to desmopressin 0.75mcg/0.1ml Spray	Antidiuretic Hormone	IT is a vasopressin analog indicated for treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. **Limitation of Use:** Not studied in patients younger than 50 years of age.	**Contraindications:** 1 Hyponatremia or a history of hyponatremia 2.Polydipsia 3.Primary nocturnal enuresis 4. Concomitant use with loop diuretics or systemic or inhaled glucocorticoids 5.Estimated glomerular filtration rate below 50 mL/min/1.73 m2 6.Syndrome of inappropriate antidiuretic hormone secretion (SIADH) 7.During illnesses that can cause fluid or electrolyte imbalance (4) 8.New York Heart Association (NYHA) Class II-IV congestive heart failure 7.Uncontrolled hypertension **Side-effects/Toxicity:** Common adverse reactions in clinical trials (incidence >2%) included nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension/ blood pressure increased, back pain, epistaxis, bronchitis and dizziness.	Desmopressin 360mcg/1ml oral solution	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
79.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Desmopressin Acetate 1.66 mcg/0.1 ml Nasal Spray	Desmopressin acetate INN 1.66mcg eq. to desmopressin 1.5mcg/0.1ml Spray	Antidiuretic Hormone	It is a vasopressin analog indicated for treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. **Limitation of Use:** Not studied in patients younger than 50 years of age.	**Contraindications:** 1 Hyponatremia or a history of hyponatremia 2.Polydipsia 3.Primary nocturnal enuresis 4. Concomitant use with loop diuretics or systemic or inhaled glucocorticoids 5.Estimated glomerular filtration rate below 50 mL/min/1.73 m2 6.Syndrome of inappropriate antidiuretic hormone secretion (SIADH) 7.During illnesses that can cause fluid or electrolyte imbalance (4) 8.New York Heart Association (NYHA) Class II-IV congestive heart failure 7.Uncontrolled hypertension	Desmopressin 360mcg/1ml Oral solution	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						Side-effects/Toxicity: Common adverse reactions in clinical trials (incidence >2%) included nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension / blood pressure increased, back pain, epistaxis, bronchitis and dizziness				
80.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Lamotrigine 2 mg Chewable Dispersible Tablet	Lamotrigine BP 2 mg	Antiepileptic	Epilepsy—adjunctive therapy in patients aged 2 years and older: partial-onset seizures. primary generalized tonic-clonic seizures. generalized seizures of Lennox-Gastaut syndrome. Epilepsy—monotherapy in patients aged 16 years and older: Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single AED. **Bipolar disorder:** Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy. **Limitations of Use:** Treatment of acute manic or mixed episodes is not recommended. Effectiveness of Lamotrigine in the acute treatment of mood episodes has not been established.	**Contraindication:** Hypersensitivity to the drug or its ingredients **Side Effects:** Epilepsy: Most common adverse reactions (incidence ≥10%) in adults were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash. Additional adverse reactions (incidence ≥10%) reported in children included vomiting, infection, fever, accidental injury, diarrhea, abdominal pain, and tremor. Bipolar disorder: Most common adverse reactions (incidence >5%) in adults were nausea, insomnia, somnolence, back pain, fatigue, rash, rhinitis, abdominal pain, and xerostomia.	25mg, 50mg & 100mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
81.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Lamotrigine 5 mg Chewable dispersible tablet	Lamotrigine BP 5 mg	Antiepileptic	**Epilepsy—adjunctive therapy in patients aged 2 years and older:** 1. partial-onset seizures. 2. primary generalized tonic-clonic seizures. 3. generalized seizures of Lennox-Gastaut syndrome. **Epilepsy—monotherapy in patients aged 16 years and older:** Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single AED. **Bipolar disorder:** Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy. **Limitations of Use**: Treatment of acute manic or mixed episodes is not recommended. Effectiveness of LAMICTAL in the acute treatment of mood	Contraindication:Hypersensitivity to the drug or its ingredients Side Effects: Epilepsy: Most common adverse reactions (incidence ≥10%) in adults were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash. Additional adverse reactions (incidence ≥10%) reported in children included vomiting, infection, fever, accidental injury, diarrhea, abdominal pain, and tremor. Bipolar disorder: Most common adverse reactions (incidence >5%) in adults were nausea, insomnia, somnolence, back pain, fatigue, rash, rhinitis, abdominal pain, and xerostomia.	25mg, 50mg & 100mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					episodes has not been established.					
82.	Acme Laboratories Ltd., Dhamrai, Dhaka	Brivaracetam 25mg Film Coated Tablet	Brivaracetam INN 25 mg	Anti-epileptic	It is indicated in the treatment of partial-onset seizures in patients 4 years of age & older.	**Contraindication:** It is contraindicated in hypersensitivity to Brivaracetam or any of the inactive ingredients. **Side Effects:** Adults: Most common adverse reactions (at least 5% for Brivaracetam and at Least 2% more frequently than placebo) are somnolence/sedation, dizziness, fatigue, and nausea/vomiting. **Pediatric Patients:** Most common adverse reactions are similar to those seen in adult patients. **WARNINGS AND PRECAUTIONS**: - Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. - Neurological Adverse Reactions: Monitor for somnolence and fatigue, and advise patients not to drive or operate machinery until they have gained sufficient experience on it. - Psychiatric Adverse Reactions: Behavioral reactions including psychotic symptoms, irritability, depression, aggressive behavior, and anxiety; monitor patients for symptoms. - Hypersensitivity: Bronchospasm and Angioedema: Advise patients to seek Immediate medical care. Discontinue and do not restart BRIVIACT if hypersensitivity occurs. Withdrawal of Antiepileptic Drugs: this drug should be gradually withdrawn.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
83.	Acme Laboratories Ltd., Dhamrai, Dhaka	Brivaracetam 50 mg Film Coated Tablet	Brivaracetam INN 50 mg	Anti-epileptic	It is indicated in the treatment of partial-onset seizures in patients 4 years of age & older.	**Contraindication:** It is contraindicated in hypersensitivity to Brivaracetam or any of the inactive ingredients. **Side Effects:** Adults: Most common adverse reactions (at least 5% for Brivaracetam and at Least 2% more frequently than placebo) are somnolence/sedation, dizziness, fatigue, and nausea/vomiting. **Pediatric Patients:** Most common adverse reactions are similar to those seen in adult patients. **WARNINGS AND PRECAUTIONS**: - Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. - Neurological Adverse Reactions: Monitor for somnolence and fatigue, and advise patients not to drive or operate machinery until they have gained sufficient experience on it. - Psychiatric Adverse Reactions: Behavioral reactions including psychotic symptoms, irritability, depression, aggressive behavior, and anxiety; monitor patients for symptoms. - Hypersensitivity: Bronchospasm and Angioedema: Advise patients to seek Immediate medical care. Discontinue and do not restart BRIVIACT if hypersensitivity occurs. Withdrawal of Antiepileptic Drugs: this drug should be gradually withdrawn.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
84.	Acme Laboratories Ltd., Dhamrai, Dhaka	Brivaracetam 10mg/ml Oral Solution	Brivaracetam INN 10mg/ml	Anti-epileptic	It is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. As the safety of this injection in pediatric patients has not	**Contraindication:** It is contraindicated in hypersensitivity to Brivaracetam or any of the inactive ingredients. **Side Effects:** Adults: Most common adverse reactions (at least 5% for Brivaracetam and at Least	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					been established, This injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older)	2% more frequently than placebo) are somnolence/sedation, dizziness, fatigue, and nausea/vomiting. **Pediatric Patients:** Most common adverse reactions are similar to those seen in adult patients. **WARNINGS AND PRECAUTIONS**: - Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and ideation. - Neurological Adverse Reactions: Monitor for somnolence and fatigue, and advise patients not to drive or operate machinery until they have gained sufficient experience on it. - Psychiatric Adverse Reactions: Behavioral reactions including psychotic symptoms, irritability, depression, aggressive behavior, and anxiety; monitor patients for symptoms. - Hypersensitivity: Bronchospasm and Angioedema: Advise patients to seek Immediate medical care. Discontinue and do not restart BRIVIACT if hypersensitivity occurs. Withdrawal of Antiepileptic Drugs: this drug should be gradually withdrawn.				
85.	Navana Pharmaceuticals, Narayanganj	Itraconazole 10 mg/mL oral solution	Itraconazole USP 10 mg/mL oral solution	Antifungal	It is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients: 1. Blastomycosis, pulmonary and extrapulmonary 2. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis, and	**CONTRAINDICATIONS:** • Itraconazole oral solution is contraindicated in patients with a known hypersensitivity to the drug or its excipients. • Caution should be used in prescribing itraconazole to patients with hypersensitivity to other azoles. • Itraconazole oral solution should not be administered to patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF except for the treatment of life-threatening or other	100 mg capsule	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					3. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. Specimens for fungal cultures and other relevant laboratory studies (wet mount, histopathology, serology) should be obtained before therapy to isolate and identify causative organisms. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, antiinfective therapy should be adjusted accordingly. It is also indicated for the treatment of the following fungal infections in non-immunocompromised patients: 1. Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and 2. Onychomycosis of the fingernail due to ermatophytes (tinea unguium). Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be	serious infections • Itraconazole is contraindicated in pregnant women except for the treatment of life-threatening cases of systemic mycoses, where the potential benefits outweigh the potential harm to the foetus. **Side Effect:** dizziness, headache, nausea, vomiting, diarrhoea, abdominal pain, constipation, dyspepsia .				

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					obtained to confirm the diagnosis of onychomycosis.					
86.	Ziska Pharmaceuticals Ltd.	Ketoconazole 2%, Zinc Pyrithione 1% and Aloe-vera 10% Lotion	Ketoconazole BP 2% + Zinc Pyrithione INN 1% + Aloe-vera USP 10%	Antifungal and anti-seborrheic agent	In the treatment of anti-dandruff, seberrhoeic dermatitis, candidiasis, candidura infections, sperificial, and deep mycosis, dry scalp Skin and psoriasis	**Contraindications**: The drug is contraindicated in patients who are taking terfenadine or astemizole, cisapride, triazolam and hypersensitivity. **Side effects:** Possible side effects are Dizziness, Headache, Nausea, Vomiting, Diarrhea, Anorexia, Gynecomastia, Loss of hair, Libido, Leucopenia, Pruritis, Psychiatric problems etc. .	Ketoconazole 20 mg/ml Shampoo		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
87.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Voriconazole 200mg/Vial Injection	Voriconazole USP 200mg/Vial	Anti-fungal Drugs	It is an azole antifungal indicated for use in the treatment of: • Invasive aspergillosis •Candidemia (nonneutropenics) and disseminated candidiasis in skin, abdomen, kidney, bladder wall, and wounds • Esophageal candidiasis • Serious infections caused by Scedosporium apiospermum and Fusarium species including Fusarium solani, in patients intolerant of, or refractory to, other therapy	**Contra-indication :** Hypersensitivity to voriconazole or its excipients • Coadministration with terfenadine, astemizole, cisapride, pimozide or quinidine, sirolimus due to risk of serious adverse reactions • Coadministration with rifampin, carbamazepine, long-acting barbiturates, efavirenz, ritonavir, rifabutin, ergot alkaloids, and St. John's Wort due to risk of loss of efficacy **Side-effect:** Most common adverse reactions (incidence ≥2%): visual disturbances, fever, nausea, rash, vomiting, chills, headache, liver function test abnormal, tachycardia, hallucinations	50mg, 200mg, Tablet & 200mg/5ml suspension	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
88.	a) Eskayef Pharmaceuticals Limited, Tongi, Gazipur b) Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Latanoprostene Bunod 0.024% Ophthalmic Solution	Latanoprostene Bunod INN 0.024gm/100ml	Antiglaucoma	It is a prostaglandin analog indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.	**Contraindications:** None. **Side effects:** Most common ocular adverse reactions with incidence ≥ 2% are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%).	Latanoprost 0.005% Eye Drops	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
89.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Netarsudil 0.02% Ophthalmic Solution	Netarsudil INN 0.02gm/100ml	Antiglaucoma	It is a Rho kinase inhibitor indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.	**Contraindications:** None. **Side effects:** The most common adverse reaction is conjunctival hyperemia (53%). Other common adverse reactions, approximately 20% include: corneal verticillata, instillation site pain, and conjunctival hemorrhage.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
90.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka	Netarsudil 0.2mg/ml Ophthalmic solution	Netarsudil Dimesylate INN 0.0280mg eq. to 0.2mg Netarsudil /ml	Antiglaucoma	It is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocularhypertension.	**Contraindications:** None **Side Effects** : The most common adverse reaction is conjunctival hyperemia (53%). Other common adverse reactions, approximately 20% include: corneal verticillata, instillation site pain, and conjunctival hemorrhage.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
91.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Phenylephrine 1.016% + Ketorolac 0.288% Intraocular Solution	Phenylephrine USP 1.016gm + Ketorolac USP 0.2888gm/100ml	Antihistamin + NSAIDS	It is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for **:** • Maintaining pupil size by preventing intraoperative miosis. • Reducing postoperative pain.	**Contraindications:** None. **Side effects:** The most common reported adverse reactions (≥2%) are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.	Phenylephrine Hydrochloride 5% + Tropicamide 0.8% Eye Drops	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
92.	ACI Ltd.	(Brompheniramine Maleate 0.020 g + Dextromethorphan Hydrobromide 0.100 g + Phenylephrine Hydrochloride 0.050 g) / 100 ml Syrup	(Brompheniramine Maleate USP 0.020 g + Dextromethorphan Hydrobromide BP 0.100 g + Phenylephrine Hydrochloride USP 0.050g) / 100 ml	Antihistamine	It is indicated for relieves of symtomps including nasal sinus congestion, blocked/runny nose,itchy water eyes, sneezing, dry irritating cough	**Contraindications:** This combination is contraindicated in patients with known hypersensitivity to any of the ingredients. **Side Effects :**The common side effects of this combination are dizziness, feeling nervous and excitable, not able to sleep and feeling sleepy,hives, difficult breathing;swelling of the face,lips, tongue or throat.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
93.	Concord Pharmaceuticals Ltd.	Bilastine 20 mg Tablet	**Bilastine INN 20 mg**	Antihistamine	Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors.indicated in allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.	**Contraindicaion:** Bilastine is contraindicated in patients with: • hypersensitivity to bilastine or to any ingredient in the formulation or component of the container. For a complete listing of ingredients and components . • a history of QT prolongation and/or torsade de pointes, including congenital long QT syndromes **Adverse Reactions:** The most common treatment-emergent adverse reactions reported in the double-blind Phase 3 studies involving 931 subjects treated with bilastine 20 mg were related to the central nervous system (headache, dizziness and somnolence) and the gastrointestinal system (abdominal pain upper).	New	BNF-75 Page: 275	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
94.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Ebastine 10mg + Montelukast 10mg Tablet	Ebastine BP 10mg + Montelukast Sodium BP 10.40mg eq. to Montelukast 10mg	Antihistamine	Ebastine and Montelukast combination is indicated for the prophylaxis and chronic treatment of Asthma, Exercise-Induced Bronchoconstriction & Hay fever Allergic Rhinitis	**Contraindications:** Hypersensitivity to the combination of Ebastine & Montelucast is a contraindication. In addition, the combination of Ebastine & Montelucast shuld not be used in the conditions of, cardiac arrhythmias, lactation and pregnancy. any component of this product. **Side effects:** The common side effects of the combination are nausea, diarrhea, diarrhea, dryness in mouth, vomiting, skin rash,, headache, drowsiness, flu-like symptoms.	Ebastine 10 mg Tablet & 5mg/5ml Syrup		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
95.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Phenylephrine HCl 10 mg + Pyrilamine Maleate 16 mg Chewable Tablet	Phenylephrine Hydrochloride BP 10 mg+ Pyrilamine Maleate INN 16 mg	Antihistamine + Nasal decongestant	Nasal congestion associated with the common cold, sinusitis allergic rhinitis and other respiratory tract infections	**Contraindications:** It is contraindicated for use in the treatment of lower respiratory tract symptoms, including asthma. Phenylephrine is contraindicated in patients with hypertension or with peripheral vascular insufficiency **Side Effect**s: Drowsiness sedation, dryness of mucous membranes, and gastrointestinal effects.	Phenylephrine Hydrochloride 5% + Tropicamide 0.8% Eye Drops		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
96.	a) Eskayef Pharmaceuticals Limited, Tongi, Gazipur b) Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna c) Aristopharma Ltd.; Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Bisoprolol Fumarate 5.00mg + Amlodipine 5mg Film Coated Tablet	Bisoprolol Fumarate USP 5.00mg + Amlodipine Besilate BP 6.935mg eq. to 5mg Amlodipine	Antihypertensive	It is indicated for the treatment of hypertension, alone or with other Antihypertensive agents. (Amlodipine+Bisoprolol) may also be used as initial therapy in patients who are likely to need multiple Antihypertensive agents to achieve their blood pressure goals. It is also used to treat angina pectoris, stable chronic heart failure.	**Contraindications:** Combination of Amlodipine and Bisoprolol is contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients. **Side effects:** The common side effects include edema, upper respiratory tract infection, hypotension, dizziness, headache, nausea, vomiting, diarrhoea, constipation, hypersensitivity reactions (itching, flush, rash) etc.	Bisoprolol 5.00mg & 10mg Tablet Amlodipine 5mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
97.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Amlodipine 5 mg + Valsartan 160 mg + Hydrochlorothiazide 12.5mg Tablet	Amlodipine Besilate BP 7mg eqv. to 5mg Amlodipine + Valsartan USP 160 mg + Hydrochlorothiazide BP 12.5 mg	Antihypertensive	Amlodipine, a dihydropyridine calcium channel blocker (DHP CCB), valsartan, an angiotensin II receptor blocker (ARB), and hydrochlorothiazide, a thiazide diuretic. This combination is indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes, and myocardial infarctions	**Contraindications:**Anuria, Hypersensitivity to sulfonamide-derived drugs, Known hypersensitivity to any component, Do not coadminister aliskiren with this product in patients with diabetes. **Side-effect:** Most common adverse events (≥2% incidence) are dizziness, peripheral edema, headache, dyspepsia, fatigue, muscle spasms, back pain, nausea and nasopharyngitis	Amlodipine 10mg + Hydrochlorothiazide 25mg + Valsartan 160mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
98.	Sun Pharmaceutical (Bangladesh) Ltd.	Olmesartan Medoxomil 20mg + Amlodipine 5mg + Hydrochlorothi azide 12.5mg Tablet	Olmesartan Medoxomil BP 20 mg + Amlodipine Besylate 6.940 mg eq. to Amlodipine 5 mg +	Antihypertensive	Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets is a combination of an angiotensin 2 receptor blocker, a dihydropyridine	**Contraindications:** Anuria; Hypersensitivity to sulfonamide-derived drugs (4). Do not co administer aliskiren with olmesartan medoxomil, amlodipine and hydrochlorothiazide in patients with diabetes **Side Effects:** Most common adverse reactions (incidence ≥2%) are dizziness, peripheral edema,	Amlodipine 5mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			Hydrochlorothiazide BP 12.5 mg		calcium channel blocker, and a thiazide diuretic indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets is not indicated for initial therapy.	headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling				
99.	Sun Pharmaceutical (Bangladesh) Ltd.	Olmesartan Medoxomil 40mg + Amlodipine 5mg + Hydrochlorothi azide 12.5mg Tablet	Olmesartan Medoxomil BP 20 mg + Amlodipine Besylate 6.940 mg eqv. to Amlodipine 5 mg + Hydrochlorothiazide BP 12.5 mg	Antihypertensive	Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets is a combination of an angiotensin 2 receptor blocker, a dihydropyridine calcium channel blocker, and a thiazide diuretic indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets is not indicated for initial therapy.	**Contraindications:** Anuria; Hypersensitivity to sulfonamide-derived drugs (4). Do not co administer aliskiren with olmesartan medoxomil, amlodipine and hydrochlorothiazide in patients with diabetes **Side Effects:** Most common adverse reactions (incidence ≥2%) are dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling	Amlodipine 5mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
100.	Drug International Ltd 252,Tongi I/A Tongi, Gazipur	Cilnidipine 10 mg + Olmesartan Medoxomil 20mg Tablet	Cilnidipine INN 10 mg + Olmesartan Medoxomil BP 20mg	Anti-Hypertensive	It is used in the treatment of high blood pressure	**Contraindication:** It is contraindicated for the patients with hypersensitivity to Cilnidipine&Olmesartan or any other components of this product. Cardiogenic Shock; Recent MI Or Acute Unstable Angina; Severe Aortic Stenosis. **Side effect/ Toxicity**: Dizziness; Flushing; Headache; Hypotension; Peripheral Oedema; Tachycardia; Palpitations; GI Disturbances; Increased Micturition Frequency; Lethargy; Eye Pain; Depression; Ischaemic Chest Pain; Cerebral Or Myocardial Ischaemia; Transient Blindness; Rashes; Fever; Abnormal Liver Function; Gingival Hyperplasia; Myalgia; Tremor; Impotence	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
101.	Healthcare Pharmaceutical ltd., Rajendrapur , Gazipur	Apremilast 20 mg Film coated tablet	Apremilast INN 20mg	Anti-Inflammatory	Indicated for the treatment of 1. Adult patients with active psoriatic arthritis 2.Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	**Contraindications:** Known hypersensitivity to apremilast or any excipients in formulation **Side-Effects:** 1. InPsoriatic Arthritis: The most common adverse reactions (≥5%) are Diarrhea, nausea, and headache. 2. In Psoriasis: The most common adverse reactions (≥5%) are diarrhea, nausea, upper respiratory tract infection, and headache, including tension headache	10mg & 30mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
102.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Etoricoxib 60mg + Thiocolchicoside 4mg Film Coated Tablet	Etoricoxib INN 60mg + Thiocolchicoside INN 4mg	Anti-inflammatory and Muscle Relaxant	It is used medically to treat orthopedic, traumatological and rheumatologic disorders as well as to treat muscular spasms. It is also used to control the pain and swelling suffered by individuals with four medical conditions: • Rheumatoid arthritis • Gout	**Contraindication:** Inflammatory bowel disease, severe kiere congestive heart failure, Active peptic ulceration, cerebrovascular disease, Lactation child, Adolescent < 16 years. **Side effects:** Side effects of Etoricoxib and Thiocolchicoside are most likely to be minor. Like Constipation, diarrhea, dizziness. If you suffer from serious side effects, then concern your doctor as soon as possible.	Etoricoxib 60mg Tablet Etoricoxib 90mg Tablet Etoricoxib 120mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					• Osteoarthritis • Ankylosing spondylitis					
103.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Etoricoxib 60mg + Thiocolchicoside 8mg Film Coated Tablet	Etoricoxib INN 60mg + Thiocolchicoside INN 8mg	Anti-inflammatory and Muscle Relaxant	It is used medically to treat orthopedic, traumatological and rheumatologic disorders as well as to treat muscular spasms. It is also used to control the pain and swelling suffered by individuals with four medical conditions: • Rheumatoid arthritis • Gout • Osteoarthritis • Ankylosing spondylitis	**Contraindication:** Inflammatory bowel disease, severe kiere congestive heart failure, Active peptic ulceration, cerebrovascular disease, Lactation child, Adolescent < 16 years. **Side effects:** Side effects of Etoricoxib and Thiocolchicoside are most likely to be minor. Like Constipation, diarrhea, dizziness. If you suffer from serious side effects, then concern your doctor as soon as possible.	Etoricoxib 60mg Tablet Etoricoxib 90mg Tablet Etoricoxib 120mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
104.	Navana Pharmaceuticals, Narayanganj	Sumatriptan Succinate 85mg+Naproxen Sodium 500 mg Tablet	Sumatriptan Succinate BP 119 mg eq. to 85mg Sumatriptan + Naproxen Sodium BP 500 mg	Antimigraine	It is a combination of sumatriptan, a serotonin (5-HT) 1b/1d receptor agonist (triptan), and naproxen sodium, a non-steroidal antiinflammatory drug, indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. Not indicated for the prophylactic therapy of migraine attacks. Not indicated for the treatment of cluster headache. .	**Contraindications:** History of coronary artery disease or coronary vasospasm. History of coronary artery bypass graft surgery.(Wolff-Parkinson-White syndrome or other cardiac accessory conduction, pathway disorders. History of stroke, transient ischemic attack, or hemiplegic or basilar migraine. Peripheral vascular disease. Ischemic bowel disease. Uncontrolled hypertension. **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.	Naproxen 250, 500 mg Tablet & Sumatriptan 50mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
105.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fesoterodine Fumarate 8mg Extended Release Tablet	Fesoterodine Fumarate INN 8mg	Antimuscarinic agent	It is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.	**Contraindications:** It is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma. Toviaz is also contraindicated in patients with known hypersensitivity to the drug or its ingredients or to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules. **Side effects:** Dry mouth, Constipation, Dyspepsia, Nausea.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
106.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Arsenic Trioxide 10mg/10ml injection	Arsenic Trioxide INN 10mg/10ml	Antineoplastic Agent	It is an arsenical indicated: • In combination with tretinoin for treatment of adults with newly-diagnosed low-risk acute promyelocytic leukemia (APL) whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression. • For induction of remission and consolidation in patients with APL who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.	**Contra-indication** : Hypersensitivity to arsenic **Side-effect**: The most common adverse reactions (greater than 30%) were leukocytosis, neutropenia, thrombocytopenia, nausea, vomiting, diarrhea, abdominal pain, hepatic toxicity, fever, rigors, fatigue, insomnia, tachycardia, QTc prolongation, edema, hyperglycemia, hypokalemia, hypomagnesemia, dyspnea, cough, rash or itching, sore throat, arthralgia, headaches, paresthesia, and dizziness	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
107.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Tretinoin 10mg capsule	Tretinoin USP 10mg	Antineoplastic Agent	Its indicated for the induction of remission in patients with acute promyelocytic leukemia (APL), French-AmericanBritish (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RARα gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated. VESANOID is for the induction of remission only. The optimal consolidation or maintenance regimens have not been defined, but all patients should receive an accepted form of remission consolidation and/or maintenance therapy for APL after completion of induction therapy with VESANOID	**Contra-indication:** VESANOID is contraindicated in patients with a known hypersensitivity to VESANOID, any of its components, or other retinoids. VESANOID should not be given to patients who are sensitive to parabens, which are used as preservatives in the gelatin capsule Side effect: Virtually all patients experience some drug-related toxicity, especially headache, fever, weakness, and fatigue. These adverse effects are seldom permanent or irreversible nor do they usually require interruption of therapy. Some of the adverse events are common in patients with APL, including hemorrhage, infections, gastrointestinal hemorrhage, disseminated intravascular coagulation, pneumonia, septicemia, and cerebral hemorrhage. The following describes the adverse events, regardless of drug relationship, that were observed in patients treated with VESANOID	0.025% Cream 0.05% Cream	USFDA	"শুধুমাত্র বিশেষজ্ঞ চিকিৎসকের প্রেসক্রিকশনের ভিত্তিতে ব্যবহার করতে হবে" এই বাক্যটি মোড়কের গায়ে মুদ্রিত করতে হবে, এই শর্তে অনুমোদন করা যেতে পারে।	"শুধুমাত্র বিশেষজ্ঞ চিকিৎসকের প্রেসক্রিকশনের ভিত্তিতে ব্যবহার করতে হবে" এই বাক্যটি মোড়কের গায়ে মুদ্রিত করতে হবে, এই শর্তে অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
108.	a) Nipro JMI Pharma Ltd., Comilla b) Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Lorcaserin HCl 10mg Film Coated Tablet	Lorcaserin HCl Hemihydrate INN 10.40 mg eq. 10 mg Lorcaserin HCl	Anti-Obesity	Lorcaserin hydrochloride is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients 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) **Limitations of use:** The safety and efficacy of coadministration of Lorcaserin hydrochloride with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established The effect of Lorcaserin hydrochloride on cardiovascular morbidity and mortality has not been established	**Contraindications:** It is contraindicated in Pregnancy. **Side Effects:**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।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
109.	Ziska Pharmaceuticals Ltd.	Naltrexone HCl 8.0mg + Bupropion HCl 90mg Extended Release Tablet	Naltrexone HCl USP 8mg + Bupropion HCl USP 90 mg	Antiobesity agent	Adjunct in obesity (in conjunction with dietary measures and increased physical activity in individuals with a body mass index (BMI) of 30 kg/m^2 or more or in individuals with a BMI of 27 kg/m^2 or more in the presence of one or more weight related co-morbidity)	**Contraindications:** Uncontrolled hypertension **Side effects:** Most common adverse reactions (greater than or equal to 5%): nausea, constipation, headache, vomiting, dizziness,insomnia, dry mouth and diarrhea.	Naltrexone 25 mg & 50 mg tablet, Bupropion 150 mg SR Tablet	BNF-75 Page-90	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
110.	ACI Ltd.	Undenatured Type-2 Collagen 40.00 mg Capsule	Undenatured Type-2 Collagen INN 40.00 mg	Anti-Osteoporotic agent	It is indicated for to treat joint pain associated with many types of arthritis like osteoarthritis and rheumatoid arthritis and surgeryas well as back pain, neck pain and pain following injury.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to any of the ingredients. **Side Effects:** The most common sid effects include nausea, heartburn. Diarrhea and constipation, drowsiness, skin reactions and headache.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
111.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Astaxanthin 6mg+ Blueberry extract 160mg + Lutein 6mg Soft Gelatin Capsule	Astaxanthin Oleoresin 5% INN 120mg eq. to 6mg Astaxanthin + Blueberry Extract INN 160mg + Lutein INN 6mg	Antioxidant	Astaxanthin is indicated to- 1. Strong antioxidant 2. Improves cardiovascular health (Atherosclerosis, reduce cholesterol). 3. Improves immune function. 4. Improves condition of skin 5. Protects skin from damage caused by sun (Reduce wrinkles, pimples and other signs of aging) 6. Improves recovery from central nervous system	**Contra-indication:** Contraindicated for those with known allergies to Astaxanthin. **Side-effect:** No severe side effects have been reported yet for astaxanthin. Possible side effects of ginkgo biloba include: Nausea, Diarrhea, Dizziness, Headaches, Stomach ache, Restlessness, Vomiting	Astaxanthin 2mg, 4mg soft gelatin capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					injuries 7. Protects from Parkinson 's disease, Dementia and Alzheimer's 8. Protects eyes from cataracts and macular degeneration. 9. Reduces inflammation (Arthritis) 10. Reduces risk of infertility Also Astaxnthin effectively reduce oxidative damage to DNA, decrease the risk for many types of cancer and stabilize blood sugar. Blueberry is used for preventing cataracts and glaucoma and for treating ulcers, urinary tract infections (UTIs), multiple sclerosis (MS), chronic fatigue syndrome (CFS), colic, fever, varicose veins, and hemorrhoids. Blueberry is also used for improving circulation, and as a laxative.				
112.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Trihexyphenidyl Hydrochloride 1mg Tablet	Trihexyphenidyl Hydrochloride USP 1mg	Antiparkinsonian	It is indicated as an adjunct in the treatment of all forms of parkinsonism (postencephalitic, arteriosclerotic, and idiopathic). It is often useful as adjuvant therapy when	**Contraindication:** This is contraindicated in patients with hypersensitivity to trhexyphenidyl HCl or to any Of the tablet or elixir ingredients. It is also contraindicated in patients with narrow angle glaucoma. Blindness after long-term use due to narrow angle glaucoma has been reported.	2mg & 5mg Tablet		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					treating these forms of parkinsonism with-levodopa. Additionally, it is indicated for the control of extrapyramidal disorders caused by central nervous system drgs such as the dibenzoxazepines, phenothiazines, thioxanthenes, and butyophenones.	**Side- effect:** Minor side effects, such as dress of the mouth, blurred vision, dizziness, mild nausea or nervousness, wil be experienced by 30 tö 50 percent of all patients. These sensations, however, are much less troublesome with ARTANE than with belladonna alkaloids and are usually less disturbing than unalleviated parkinsonism. Such reactions tend to become less pronounced, and even to disappear, as treatment continues. Even before these reactions have remitted spontaneously, they may often be controlled by careful adjustnent of dosage form, amount of drg, or interval between doses.Isolated instaces of suppurative parotitis secondar to excessive dress of the mouth, skin rashes, dilatation of the colon, paralytic ileus, and certain psychiatrc manifestations such as delusions, hallucinations, and paranoia, all of which ilay occur with any of the atropine-like drugs, have been reported rarely with ARTANEQ. Potential side effects associated with the use of any atropine-like drugs, including ARTANE,include cogntive dysfuctions, including confusion and memory impairment; constipation,drowsiness, urnary hesitancy or retention, tachycardia, dilation of the pupil, increasedintraocular pressure,' choreiform movements, weakness, vomiting, and headache. ,Exacerbation ofparkinsonism with abrupt treatment withdrawal has been reported. Neuroleptic malignant syndrome with abrupt treatment withdrawal has been reported.The occurence of angle-closure glaucoma in patients receiving trhexyphenidyl Hei has been reported (blindness has been reported in some cases). Paradoxical sinus bradycardia, dry skin,and cycloplegia have been reported.. In addition to adverse events seen in adults, the				

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						following adverse events have been reported in the literatue in pediatrc patients: hyperkinesia, psychosis, forgetfulness, weightloss,restlessness, chorea, and sleep alterations.				
113.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Aspirin 81mg + Omeprazole 40mg Delayed Release Tablet	Aspirin USP 81mg + Omeprazole USP 40mg	Anti-platelet agent and PPI	It is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. The aspirin component of this combination indicated for: Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli. Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris.	**Contraindications:** • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. • In pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's syndrome. • Known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles or to any of the excipients of this combination. • Patients receiving rilpivirine-containing products. **Side effects:** Most common adverse reactions in adults (≥2%) are: gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain.	Aspirin 75mg Tablet Omeprazole 40mg Capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					Use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated. Limitations of Use: Not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction or before percutaneous coronary intervention. Has not been shown to reduce the risk of gastrointestinal bleeding due to aspirint. It is not interchangeable with the individual components of aspirin and Omeprazole.					
114.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Aspirin 325mg + Omeprazole 40mg Delayed Release Tablet	Aspirin USP 325mg + Omeprazole USP 40mg	Anti-Platelet agent and PPI	It is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. The aspirin component of this combination indicated for: Reducing the combined	**Contraindications:** • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. • In pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's syndrome. • Known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles or to any of the excipients of this combination. • Patients receiving rilpivirine-containing products. **Side effects:** Most common adverse reactions in adults (≥2%) are: gastritis, nausea, diarrhea, gastric	Aspirin 75mg Tablet Omeprazole 40mg Capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli. Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris. Use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated. Limitations of Use: Not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction or before percutaneous coronary intervention. Has not been shown to reduce the risk of gastrointestinal bleeding due to aspirint. It is not interchangeable with the individual components of aspirin and Omeprazole.	polyps, and non-cardiac chest pain.				
115.	Drug International Ltd	Ticagrelor Tablet	Ticagerol INN 60	Anti-platelet drug	**Ticagrelor** is indicated to	**Contraindication:Ticagrelor** is contraindicated in	90 mg	BNF-75	অনুমোদন করা	অনুমোদন করা

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	252,Tongi I/A Tongi,Gazipure		mg		reducetherate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction). It has been shown to reduce the rate of cardiovascular death, myocardial infarction or stroke compared to clopidogrel. In patients treated with PCI, it also reduces the rate of stent thrombosis.	patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage. It is also contraindicated in patients with hypersensitivity to Ticagrelor or any component of the product. **Side effect**:Bleeding is the most commonly reported adverse reaction. Others adverse effects include hypertension, fatigue, headache, back pain, dizziness, nausea etc.		Page: 213	যেতে পারে।	হল।
116.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Aspirin 81mg + Omeprazole 40 mg Delayed release Tablet	Aspirin BP 81mg + Omeprazole BP 40mg	Antiplatelet + Anti-Ulserant	The combination of aspirin and omeprazole, is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. The aspirin component is indicated for: • Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli • Reducing the combined risk	This combination is contraindicated in: Patients with known allergy to aspirin and other nonsteroidal anti-inflammatory drug products (NSAIDs) and in patients with the syndrome of asthma, rhinitis, and nasal polyps. Aspirin may cause severe urticaria, angioedema, or bronchospasm (asthma). • Pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's syndrome with concomitant use of aspirin in certain viral illnesses. • This combination is contraindicated in patients with known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles, or to any of the excipients in the formulation. • Proton pump inhibitor (PPI)–containing products, including this combination, are contraindicated in patients receiving rilpivirine-containing products.	Aspirin 75mg Tablet Omeprazole 40mg Capsule	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

<table>
<tr><th>SI</th><th>Name of the Manufacturer</th><th>Name of the Drug</th><th>Generic Name</th><th>Therapeutic Class</th><th>Indication</th><th>Contra-indication & Side-effect</th><th>Status (New Molecule/ Existing)</th><th>USFDA/BNF/ MHRA Reference</th><th>টেকনিক্যাল সাব-কমিটির মতামত</th><th>সভার সিদ্ধান্ত</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>of death and nonfatal MI in patients with a previous MI or unstable angina pectoris

• Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris

• Use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated.

The omeprazole component is indicated for decreasing the risk of developing aspirin-associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.</td><td>Side Effects
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. This combination 325 mg/40 mg was studied primarily in two randomized, double-blind controlled clinical trials (n=524) of 6 months duration. Table 1 lists adverse reactions that occurred in >2% of patients in the this combination arm and were more common than in the control arm, consisting of 325 mg of enteric coated (EC)-aspirin.

<table><tr><th>Preferred Term</th><th>Aspirin +Omeprazole 325 mg/40 mg once daily (n=521) %</th><th>EC-Aspirin 325 mg once daily (n=524) %</th></tr><tr><td>Gastritis</td><td>18</td><td>16</td></tr><tr><td>Nausea</td><td>3</td><td>2</td></tr><tr><td>Diarrhea</td><td>3</td><td>2</td></tr><tr><td>Gastric Polyps</td><td>2</td><td>1</td></tr><tr><td>Non-Cardiac chest pain</td><td>2</td><td>1</td></tr></table>*Adverse reactions occurring in ≥2% of Aspirin+Omeprazole -treated patients and more common than in the control arm</td><td></td><td></td><td></td><td></td></tr>
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Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						In Study 1 and Study 2 combined, 7% of patients taking this combination discontinued due to adverse reactions compared to 11% of patients taking EC-aspirin alone. The most common reasons for discontinuations due to adverse reactions in the this combination treatment group were upper abdominal pain (<1%, n=2), diarrhea (<1%, n=2) and dyspepsia (<1%, n=2). *Less Common Adverse Reactions* In THIS COMBINATION-treated patients in the clinical trials there were 2 patients with upper GI bleeding (gastric or duodenal) and 2 patients with lower GI bleeding (hematochezia and large intestinal hemorrhage) and one additional patient experienced obstruction in the small bowel.				
117.	Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Levosulpiride 25mg Tablet	Levosulpiride INN 25mg	Antipsychotic	It is a 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, and dyskinesia hyperprolactinemia .	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
118.	General Pharmaceutical Ltd., Gazipur	Olanzapine 6mg + Fluoxetine Hydrochloride 25mg Capsule	Olanzapine BP 6mg + Fluoxetine Hydrochloride BP 27.95mg eq. to 25mg Fluoxetine	Antipsychotic	Ccombines olanzapine, an atypical antipsychotic and fluoxetine, a selective serotonin reuptake inhibitor, indicated for acute treatment of: • Depressive Episodes Associated with Bipolar I	**Contra-indication :** Do not use with an MAOI or within 14 days of discontinuing an MAOI due to risk of drug interaction. At least 5 weeks should be allowed after stopping SYMBYAX before starting treatment with an MAOI (4, 7.1) Do not use with pimozide due to risk of risk of drug interaction or QTc prolongation (4, 7.9) Do not use with thioridazine due to QTc interval prolongation or	Olanzapine 5mg 10mg Tablet Fluoxetine 20mg Capsule & 0.4% Oral Solution	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					Disorder in adults (1.1) • Treatment Resistant Depression (Major Depressive Disorder in adults who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode)	potential for elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing **Side –Effects:** Most common adverse reactions are disturbance in attention, dry mouth, fatigue, hypersomnia, increased appetite, peripheral edema, sedation, somnolence, termor, vision blurred, and weight increased.				
119.	General Pharmaceutical Ltd., Gazipur	Olanzapine 12mg + Fluoxetine Hydrochloride 25mg Capsule	Olanzapine BP 12.0 mg + Fluoxetine Hydrochloride BP 27.95mg eq. to 25mg Fluoxetine	Antipsychotic	Ccombines olanzapine, an atypical antipsychotic and fluoxetine, a selective serotonin reuptake inhibitor, indicated for acute treatment of: • Depressive Episodes Associated with Bipolar I Disorder in adults (1.1) • Treatment Resistant Depression (Major Depressive Disorder in adults who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode)	**Contra-indication :** Do not use with an MAOI or within 14 days of discontinuing an MAOI due to risk of drug interaction. At least 5 weeks should be allowed after stopping SYMBYAX before starting treatment with an MAOI (4, 7.1) Do not use with pimozide due to risk of risk of drug interaction or QTc prolongation (4, 7.9) Do not use with thioridazine due to QTc interval prolongation or potential for elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing **Side –Effects:** Most common adverse reactions are disturbance in attention, dry mouth, fatigue, hypersomnia, increased appetite, peripheral edema, sedation, somnolence, termor, vision blurred, and weight increased.	Olanzapine 5mg Tablet & 10mg Tablet Fluoxetine 20mg Capsule & Oral Solution	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
120.	Delta Pharma Ltd.	Paracetamol 500 mg + Phenylephrine HCl 6.10mg Tablet	Paracetamol BP 500mg + Phenylephrine HCl BP 6.10 mg	Antipyretic & Analgesic	For relief of symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion and lowering of temperature.	**Contra-indications:** ▪ Hypersensitivity to any of the active substances or any other ingredient. ▪ Severe coronary heart disease and cardiovascular disorders. ▪ Hypertension, Hyperthyroidism. ▪ Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors. **Side-effects**: Adverse effects of paracetamol are	Paracetamol 500mg + Caffeine 65mg	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						rare, but hypersensitivity including skin rash may occur. Phenylephrine HCl High blood pressure with headache, vomiting, probably only in overdosage. Rarely, palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males.				
121.	Delta Pharma Ltd.	Paracetamol 500mg + Phenylephrine HCl 5mg + Caffeine 25mg Tablet	Paracetamol BP 500 mg+ Phenylephrine HCl 5 mg+ Caffeine 25 mg Tablet	Antipyretic & Analgesic .	It is recommended for the relief of sinus pain and the symptoms of colds and influenza, including fatigue and drowsiness.	**Contra-indications:** ▪ Concomitant use of other sympathomimetic decongestants ▪ Phaeochromocytoma ▪ Closed angle glaucoma ▪ Known hypersensitivity to paracetamol or any of the other constituents. Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, and heart disease. Patients taking tricyclic antidepressants, or beta-blocking drugs and those who are taking or who have taken within the last two weeks monoamine oxidase inhibitors **Side-effects**: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. Phenylephrine HCl High blood pressure with headache, vomiting, probably only in overdosage. Rarely, palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males. Caffeine Adverse reactions identified through post-marketing use with caffeine are Nervousness and anxiety Irritability, Restlessness and Excitability Dizziness. The frequency of these reactions is unknown.	Paracetamol 500mg + Caffeine 65mg	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
122.	Incepta	Baricitinib	Baricitinib INN 2	Antirheumatic	It is indicated for the treatment	**Contraindications:** None.	New	USFDA	প্রয়োজন নেই	প্রয়োজন নেই

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	2 mg Tablet	mg.		of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. **Limitation of Use:** Use of OLUMIANT in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.	**Side Effects:** Adverse reactions (greater than or equal to 1%) include: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.			বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	বিধায় আবেদন নামঞ্জুর করা হল।
123.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Baricitinib 4 mg Tablet	Baricitinib INN 4 mg	Antirheumatic	It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. **Limitation of Use:** Use of OLUMIANT in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.	**Contraindications:** None. **Side Effects:** Adverse reactions (greater than or equal to 1%) include: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
124.	Eskayef Pharmaceuticals Limited,	Phenol 1.4% Oral Liquid Spray	Phenol BP 1.4gm/100ml	Antiseptic + Disinfectant	It is indicated for sore throat, mouth irritation.	**Contraindications:** Hypersensitivity **Side effects:** Rash, Hives, Itching, Redness,	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Tongi,Gazipur.					Swollen, Blistered or peeling skin.			নামঞ্জুর করা যেতে পারে।	নামঞ্জুর করা হল।
125.	Ziska Pharmaceuticals Ltd.	Alverine citrate 60 mg + Simeticone 300mg Capsule	Alverine citrate BP 60mg + Simeticone BP 300 mg	Antispasmodics	Abdominal pain in irritable bowel syndrome	**Contraindications:** Hypersensitivity to simethicone, alverine citrate or to any of the excipients of Avarin. Patients with intestinal obstruction or paralytic ileus. Pregnancy and lactation. Children <12 years.**Side effects:** Dizziness, Headaches, Difficulty breathing, Swelling of the face, wheeze, Dry mouth, Weakness, Decreased blood pressure can occur. Rash (very rare)	Alverine citrate BP 60mg Tablet & 120mg Capsule Simethicone 67mg/ml pediatric drops Simethicone 40 mg Chewable Tablet	BNF-75 Page-46	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
126.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Dextromethorphan Hydrobromide 0.20gm + Phenylephrine Hydrochloride 1.0gm + Chlorpheniramine Maleate 0.04gm/100ml Syrup	Dextromethorphan Hydrobromide USP 0.20gm + Phenylephrine Hydrochloride USP 1.0gm + Chlorpheniramine Maleate USP 0.04gm/100ml	Antitussive + Sympathomimetic + Antihistamine	It is used for the relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.	**Contraindications:** Hypersensitivity, Monoamine oxidase (MAO) inhibitor therapy. **Side effects:** Sedation, dizziness, diplopia, vomiting, diarrhea, nausea, anorexia, heartburn, dry mouth, headache, nervousness, weakness, polyuria and dysuria.	Dextromethorphan Hydrobromide 0.40gm + Phenylephrine HCl 0.20gm + Triprolidine HCl 0.05gm/100ml Syrup	-	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
127.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Dextromethorphan Hydrobromide 0.1gm + Guaifenesin 2.0gm + Phenylephrine Hydrochloride 0.05gm/100ml Syrup	Dextromethorphan Hydrobromide USP 0.1gm + Guaifenesin USP 2.0gm + Phenylephrine Hydrochloride USP 0.05gm/100ml	Antitussive + Expectorant + Sympathomimetic	It Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes. Temporarily relieves these symptoms occurring with a cold, nasal congestion, cough due to minor throat and bronchial irritation.	**Contraindications:** Hypersensitivity, Concomitant use with MAO inhibitors. **Side effects:** Mood changes, Severe headache, Fast or uneven heart rate, Severe dizziness or anxiety.	Dextromethorphan Hydrobromide 0.40gm + Phenylephrine HCl 0.20gm + Triprolidine HCl 0.05gm/100ml Syrup		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
128.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Sucralfate 10gm/100ml Oral Suspension	Sucralfate USP 10gm/100ml	Antiulcerant	It is indicated in the short-term (up to 8 weeks) treatment of active duodenal ulcer	Contraindications: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Side Effects: the following signs or symptoms that may be related to a very bad side effect: Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Signs of high blood sugar like confusion, feeling sleepy, more thirst, hungrier, passing urine more often, flushing, fast breathing, or breath that smells like fruit.	500mg and 1.0gm Tablet 20gm/100ml Oral Suspension	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
129.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Chloral Hydrate 2.866gm/100ml Oral Solution	Chloral Hydrate BP 2.866gm /100ml	Anxiolytics	• Chloral Hydrate Oral Solution is used for the short-term treatment of severe insomnia which is interfering with normal daily life and where other therapies have failed . • Chloral Hydrate Oral Solution Should be used as an adjunct to non-Pharmacological therapies. • In children aged 2-11 years treatment should be as an adjunct to behavioural therapy and sleep hygiene management , and usually for duration of less than 2 weeks. The use of hypnotics in	**Contraindication:** Chloral Hydrate Oral Solution should not be used in patients with a marked hepatic or renal impairment, or in patients with severe cardiac disease. Should not be used in patients susceptible to acute attacks of porphyria. **Side-effect:** Gastric irritation , abdominal distension and flatulence may occur . Excitement, tolerance, allergic skin reactions,headache and ketonuria have occasionally been reported. There is a danger of abuse or chronic intoxication and the possibility that habituation may develop. In such patients gastritis and parenchymatous renal injury may develop . After long term use, sudden withdrawal may result in delirium. Elderly patients are more susceptible to the undesirable effects of hypnotic medications such as Chloral Hydrate Oral Solution and are therefore more susceptible to ataxia, Confusion , falls and injuries.			প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					children and adolescents is not generally recommended and if used should be under the supervision of a medical specialist.					
130.	Square Formulations Ltd., Gorai, Tangail	Doxofylline 400mg + Montelukast 10mg Tablet	Doxofylline INN 400mg + Montelukast Sodium USP 10.400mg eq. to 10mg of Montelukast	Bronchodilator	It is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: • Asthma • Hay fever • Exercise-induced asthma • Chronic asthma • Seasonal allergic rhinitis • Perennial allergic rhinitis • Doxovent M Tablet may also be used for purposes not listed here.	**Contraindication:** Contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients.It should not be used if you have thû conditions:Allergic reactions, Asthma exacerbations, Hypersensitivity,Lactation, Pregnancy **Side effect:** The following is a list of possible side-effects that may occur from all constituting ingredients of Doxovent M Tablet. This is not a comprehensive list. These side-effects are possible, but do not always occur. Nausea, Vomiting, Epigastric pain, Palpitations, Headache, Insomnia	Doxophylline 400 mg Tablet, Montelukast 10mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
131.	Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Nifedipine 0.30g + Lidocaine Hydrochloride 1.50 g /100g Cream	Nifedipine USP 0.30g + Lidocaine Hydrochloride USP 1.50 g /100g	Ca Channel Blocker & Loacal Anesthetic	Lidocaine is a topical anesthetic and Nifedipine works in a anal fissure by blocking the action of calcium on blood vessels of anus. As a result. Blood vessels are relaxed which allows fissure to relieves pain.	**Contraindications:** This combinateion is contraindicated in patients with a known hypersensitivity to any of the ingredients contained in this product. **Side effects**: During or immediately after treatment , the skin at the site of treatment may develop erythema or edema or may be the locus of abnormal sensation.	Nifedipine 5 mg, 10mg & 20mg Capsule Lidocaine Hydrochloride 20mg/ml , 40mg/ml Injection		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
132.	Beacon Pharmaceuticals Ltd, Kathali,	Etelcalcetide 5mg/ml Injection	Etelcalcetide Hydrochloride INN 5.77mg eq. to 5mg	Calcimimetic	It is a calcium-sensing receptor agonist indicated for: Secondary	**Contra-indication**: It is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Bhaluka, Mymensingh		Etelcalcetide/ml		hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. **Limitations of Use**: It has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.	**Side-effect**: The most common adverse reactions (≥ 5%) were blood calcium decreased, muscle spasms, diarrhea, nausea, vomiting, headache, hypocalcemia, and paresthesia				
133.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Etelcalcetide 10mg/2ml Injection	Etelcalcetide Hydrochloride INN 11.54mg eq. to 10mg Etelcalcetide/2ml	Calcimimetic	It is a calcium-sensing receptor agonist indicated for: Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. **Limitations of Use**: It has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.	**Contra-indication**: It is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients **Side-effect**: The most common adverse reactions (≥ 5%) were blood calcium decreased, muscle spasms, diarrhea, nausea, vomiting, headache, hypocalcemia, and paresthesia	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
134.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lisdexamfetamine Dimesylate 30mg Capsule	Lisdexamfetamine Dimesylate INN 30mg	CNS Stimulant	It is a central nervous system (CNS) stimulant indicated for the treatment of : • Attention Deficit Hyperactivity Disorder (ADHD) • Moderate to Severe Binge	**Contraindications:** Known hypersensitivity to amphetamine products and is also contraindicated with monoamine oxidase (MAO) inhibitor, or within 14 days of the last MAO inhibitor dose. **Side effects:** The most frequent adverse reactions leading to discontinuation were insomnia,	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					Eating Disorder (BED) in adults. **Limitation of Use:** It is not indicated for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of this drug for the treatment of obesity have not been established.	tachycardia, irritability, hypertension, headache, anxiety and dyspnea. The most common adverse reactions (incidence ≥5% and at a rate at least twice placebo) reported in children, adolescents, and/or adults were anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, and vomiting.				
135.	a) Eskayef Pharmaceuticals Limited, Tongi, Gazipur b) Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Flibanserin 100mg Film Coated Tablet	Flibanserin INN 100mg	CNS Agent	It is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:• A co-existing medical or psychiatric condition, • Problems within the relationship, or • The effects of a medication or other drug substance. **Limitations of Use:** • It is not indicated for the treatment of HSDD in postmenopausal women or in men. • It is not indicated to enhance sexual performance.	**Contraindications:** Alcohol, Hepatic impairment, Moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors. **Side effects:** Most common adverse reactions (incidence ≥2%) are dizziness, somnolence, nausea, fatigue, insomnia, and dry mouth.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
136.	Incepta	Triamcinolone Acetonide	Triamcinolone	Corticosteroid	It is an extended-release	**Contraindications:** Patients with hypersensitivity to	40 mg/ml	USFDA	অনুমোদন করা	অনুমোদন করা

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	32mg/vial extended-release injectable suspension for Intra-articular Use	Acetonide BP 32mg/vial		synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. **Limitations of Use:** It is not intended for repeated use.	triamcinolone acetonide or any component of the product. **Side-effects/Toxicity:** Most commonly reported adverse reactions (incidence ≥1%) in clinical studies include sinusitis, cough and contusions.	Injection 0.1% Oral Paste 4mg Tablet		যেতে পারে।	হল।
137.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Levodropropizine 30mg/5ml Syrup	Levodropropizine BP 0.60gm/100ml	Cough suppressant	It is indicated for the symptomatic treatment of cough.	**Contraindications:** It should not be used in those cases where it is known or hypersensitivity is suspected to the active ingredient, or in patients with bronchial hypersecretion, where function mucociliary reduced syndrome (Kartagener, dyskinesia ciliary) in severe liver or kidney failure. **Side effects:** The sometimes may occur gastrointestinal disorders (nausea, vomiting, heartburn, abdominal discomfort, diarrhea), central nervous system (exhaustion, dizziness, drowsiness, mental confusion, numbness, dizziness and headache), cardiovascular system (palpitations) and, rarely, have been observed dermatological allergic reactions.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
138.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Brimonidine Tartrate 0.025% Ophthalmic Solution	Brimonidine Tartrate BP 0.025gm/100ml	Decongestant	It is an alpha adrenergic agonist indicated for lowering intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	**Contraindications:** Neonates and infants (under the age of 2 years). **Side effects:** Most common adverse reactions occurring in approximately 10 to 30% of patients receiving brimonidine ophthalmic solution 0.2% included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.	Brimonidine Tartrate 0.2 % Eye Drops	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
139.	Navana Pharmaceuticals, Narayanganj	Oxymetazoline Hydrochloride 0.05% Nasal Spray	Oxymetazoline Hydrochloride USP 0.05%	Decongestant	For the fast relief of stuffy noses due to head colds and hay fever.	**Contraindication:** Hypersensitivity to any of the ingredients, patients with cardiovascular disease, hyperthyroidism, angle closure glaucoma or	• 0.05% & 0.025% Nasal Drops	MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						prostatic enlargement **Side Effects:** Occasionally may cause local irritation and dryness of the mouth and throat. Prolonged use may cause rebound congestion and rhinitis medicamentosa.				
140.	Ziska Pharmaceuticals Ltd.	Alitretinoin 10 mg soft Gelatin capsule	Alitretinoin INN 10 mg	Dermatological Agent	Severe chronic hand eczema refractory to high potency topical corticosteroids in adults	**Contraindications:** Hypervitaminosis A, uncontrolled hyperlipidemia, uncontrolled hypothyroidism **Side effects:** Alopecia, anaemia, arthralgia, dry eyes, dryness of lips, dryness of skin, erythema, eye kinase, raised serum concentration, of triglycerides and of cholesterol.	New	BNF-75 Page-1193	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
141.	Ziska Pharmaceuticals Ltd.	Alitretinoin 30 mg soft Gelatin capsule	Alitretinoin INN 30 mg	Dermatological Agent	Severe chronic hand eczema refractory to high potency topical corticosteroids in adults	**Contraindications:** Hypervitaminosis A, uncontrolled hyperlipidemia, uncontrolled hypothyroidism **Side effects:** Alopecia, anaemia, arthralgia, dry eyes, dryness of lips, dryness of skin, erythema, eye kinase, raised serum concentration, of triglycerides and of cholesterol.	New	BNF-75 Page: 1193	"শুধুমাত্র বিশেষজ্ঞ চিকিৎসকের প্রেসক্রিকশনের ভিত্তিতে ব্যবহার করতে হবে" এই বাক্যটি মোড়কের গায়ে মুদ্রিত করতে হবে, এই শর্তে অনুমোদন করা যেতে পারে।	"শুধুমাত্র বিশেষজ্ঞ চিকিৎসকের প্রেসক্রিকশনের ভিত্তিতে ব্যবহার করতে হবে" এই বাক্যটি মোড়কের গায়ে মুদ্রিত করতে হবে, এই শর্তে অনুমোদন করা হল
142.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Tolvaptan 30mg Tablet	Tolvaptan INN 30mg	Diuretic agent	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	**Contra-indication :** 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	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH) Limitations: • Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Tolvaptan • It has not been established that Tolvaptan provides a symptomatic benefit to patients	• Do not administer to patients who are anuric as no benefit is expected **Side-effect:** Most common adverse reactions (≥ 5% placebo) are thirst, dry mouth, asthenia, constipation, pollakiuria or polyuria, and hyperglycemia				
143.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Tolvaptan 15mg Tablet	Tolvaptan INN 15mg	Diuretic agent	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) Limitations: • Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Tolvaptan	**Contra-indication :** 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-effect:** Most common adverse reactions (≥ 5% placebo) are thirst, dry mouth, asthenia, constipation, pollakiuria or polyuria, and hyperglycemia	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					• It has not been established that Tolvaptan provides a symptomatic benefit to patients					
144.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Potassium Citrate 508.305mg + Sodium Citrate Anhydrous 197.80mg + Sodium Chloride 484.957mg + Anhydrous Glucose (Dextrose) 5.7gm/Sachet	Potassium Citrate USP 508.305mg + Sodium Citrate Anhydrous USP 197.80mg + Sodium Chloride BP 484.957 mg + Anhydrous Glucose (Dextrose) BP 5.7 gm/Sachet	Electrolytes	It is a hydration solution specially formulated with the optimal balace of sugar and electrolytes needed to help replenish vital fluids, minerals, and nutrients, which, when lost, can lead to dehydration caused by vomiting, diarrhea, exercise, travel and heat exhaustion.	**Contraindications:** No information **Side effects:** None	New		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
145.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Urea 10.00 gm + Liquid Paraffin 10.00gm + Propylene Glycol 10.00 gm + Lactic Acid 10.00 gm/100gm Cream	Urea BP 10.00 gm + Liquid Paraffin BP 10.00gm + Propylene Glycol 10.00 gm + Lactic Acid BP 10.00 gm/100gm	Emollient & Protectives	It is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: • Wrinkles and lines • Dry skin conditions • Mild to severe forms of dry, scaly skin • Dry skin • Psoriasis • Burns • Rough skin • Hyperkeratotic surface lesions • Moisturex Cream may also be used for	Contraindications: Hypersensitivity, perforation of tympanic membrane, premature infants Side-effects: Common side effects may include: • Erosion • Stinging • Burning • Itching • Inflammation of chinchilla middle ears • Contact dermatitis • Mild lactic acidosis	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
146.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	L-Asparaginase INN 5,000IU/vial (As Lyophilized powder)	L-Asparaginase INN 5,000IU/vial (As Lyophilized powder)	Enzyme	It is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia	**Contra-indication**: Serious allergic reactions to Elspar or other Escherichia coli-derived L-asparaginases Side effect: Most common adverse reactions are allergic reactions (including anaphylaxis), hyperglycemia, pancreatitis, central nervous system (CNS) thrombosis, coagulopathy, hyperbilirubinemia, and elevated transaminases.	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
147.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	L-Asparaginase INN 10,000IU/vial (As Lyophilized powder)	L-Asparaginase INN 10,000IU/vial (As Lyophilized powder)	Enzyme	It is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia	Contra-indication: Serious allergic reactions to Elspar or other Escherichia coli-derived L-asparaginases Side effect: Most common adverse reactions are allergic reactions (including anaphylaxis), hyperglycemia, pancreatitis, central nervous system (CNS) thrombosis, coagulopathy, hyperbilirubinemia, and elevated transaminases.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
148.	Square Formulations Ltd., Gorai, Tangail	Amylase 15,000 Units + Lipase 3000 Units + Protease 9,500 Units Capsule	Pancrelipase EC Pellets Ph. Grade 83.67mg contains Amylase 15,000 USP Units + Lipase 3000 USP Units + Protease 9,500 USP Units	Enzymes	It is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.	Contraindication: None. Warnnigns: Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement. Exercise caution when doses of PANCREAZE exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day). To avoid irritation of oral mucosa, do not chew PANCREAZE or retain in the mouth Exercise caution when prescribing PANCREAZE to patients with gout, renal impairment, or hyperuricemia. There is theoretical risk of viral transmission with all pancreatic enzyme products.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
149.	Square Formulations Ltd., Gorai, Tangail	Amylase 1,20,000 Units + Lipase 24000 Units + Protease 76,000 Units Capsule	Pancrelipase EC Pellets Ph. Grade 669.36mg (contains Amylase 1,20,000 USP Units + Lipase 24,000 USP Units + Protease 76,000	Enzymes	It is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.	Contraindication: None. Warnnigns: Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement. Exercise caution when doses of PANCREAZE exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day).	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			USP Units)			To avoid irritation of oral mucosa, do not chew PANCREAZE or retain in the mouth Exercise caution when prescribing PANCREAZE to patients with gout, renal impairment, or hyperuricemia. There is theoretical risk of viral transmission with all pancreatic enzyme products including PANCREAZE.				
150.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Sildenafil 50 mg + Dapoxetine 30 mg Tablet	Sildenafil Citrate BP 70.25mg eq. to 50 mg Sildenafil + Dapoxetine Hydrochloride INN 33.58mg eq. to 30 mg Dapoxetine	Erectile dysfunction	It is used to achieve and maintain erections and delay premature ejaculation in men. This medication is used to treat men with persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes and simultaneously have also to be treated for erectile dysfunction (ED).	Sildenafil & Dapoxetine combination was shown to potentiate the hypotensive effects of nitrates and its administration to patients who are using organic nitrates, either regularly and or intermittently, in any form is therefore contraindicated. 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 of significant valvular disease. - Concomitant treatment with monoamine oxidase inhibitors (MAOIs), thioridazine. Similarly, MAOIs or thioridazine should not be administered within 7 days after Dapoxetine has been discontinued. - Concomitant treatment with serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) or other medicinal/herbal products with serotonergic effects or within 14 days of discontinuing treatment with these medicinal/herbal products. **Side Effects:**mmediate call your emergency when you face sign of allergy such as pimples; difficulty in breathing; face swelling, lips, tongue, or gullet. If you become faint or disgusted, or have pain, anesthetized, or itchy in your chest, arms, neck, or jaw during sexual activity, call your doctor. You could have these serious side effects of Suhagra	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						Force: sudden vision loss; ringingin you rears,or sudden hearing loss; chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea, sweating, general ill feeling; irregular heartbeat; swelling in your hands, ankles, or feet; shortness of breath; vision changes; feeling light-headed, fainting; or Penis erection that is painful or lasts 4 hours or longer				
151.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Patiromer 16.80gm/Sachet Powder For Suspension	Patiromer Sorbitex Calcium INN 33.60gm eq. to 16.80gm Patiromer/Sachet	Exchange Resin /Potassium Binder	It is a potassium binder indicated for the treatment of hyperkalemia. **Limitations of use:** It should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.	**Contraindications:** Known hypersensitivity to Veltassa or any of its components. **Side effects:** Most common adverse reactions (incidence ≥2%) are constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
152.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Guaifenesin 2.0gm/100ml syrup	Guaifenesin USP 2.0gm/100ml	Expectorant	It helps loosen phlegm and thin bronchial secretions, symptomatic relief of deep chesty coughs, expectorant for productive cough.	**Contraindications:**Hypersensitivity (allergy) to the active substance or to any of the ingredients. **Side effects:** Occasionally been reported to cause gastrointestinal (stomach) discomfort, nausea and vomiting, particularly in high doses.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
153.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Dextromethorphan Hydrobromide 0.40gm +Guaifenesin 4.0gm +Phenylephrine 0.10gm/100ml Suspension	Dextromethorphan Hydrobromide BP 0.40gm +Guaifenesin BP 4.0gm +Phenylephrine HCl BP 0.1218gm eq. to 0.10gm/100ml	Expectorant	This combination medication is used to temporarily treat cough, chest congestion, and stuffy nose symptoms caused by the common cold, flu, allergies, hay fever, or other breathing illnesses (e.g., sinusitis, bronchitis). Guaifenesin is an expectorant that helps to thin and loosen mucus in the lungs, making it easier to cough up the mucus. Dextromethorphan is a cough	**Contraindications:** Some medicines can cause unwanted or dangerous effects when used together. Not all possible interactions are listed in this medication guide. Taking this medicine with other drugs that make you sleepy or slow your breathing can worsen these effects. Ask your doctor before taking this medicine with a sleeping pill, narcotic pain medicine, muscle relaxer, or medicine for anxiety, depression, or seizures. **Side Effects:** Dizziness, headache, nausea, nervousness, or trouble sleeping may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly.If your doctor has prescribed this drug, remember that your doctor has prescribed it	Dextromethorphan Hydrobromide 0.40gm + Phenylephrine HCl 0.20gm + Triprolidine HCl 0.05gm/100ml Syrup		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					suppressant that affects a certain part of the brain (cough center), reducing the urge to cough. This product also contains a decongestant, which helps relieve stuffy nose symptoms. This medication is usually not used for ongoing coughs from smoking, asthma, other long-term breathing problems (e.g., emphysema), or coughs with a lot of mucus, unless directed by your doctor.	because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.Tell your doctor if any of these unlikely but serious side effects occur: mental/mood changes (e.g., confusion, hallucinations), shaking (tremors), weakness.Tell your doctor if any of these rare but very serious side effects occur: fast/slow/irregular heartbeat.				
154.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Dextromethorphan Hydrobromide 0.40gm +Guaifenesin 4.0gm +Phenylephrine 0.10gm/100ml Pediatric Drop	Dextromethorphan Hydrobromide BP 0.40gm +Guaifenesin BP 4.0gm +Phenylephrine HCl BP 0.1218gm eq. to 0.10gm/100ml	Expectorant	This combination medication is used to temporarily treat cough, chest congestion, and stuffy nose symptoms caused by the common cold, flu, allergies, hay fever, or other breathing illnesses (e.g., sinusitis, bronchitis). Guaifenesin is an expectorant that helps to thin and loosen mucus in the lungs, making it easier to cough up the mucus. Dextromethorphan is a cough suppressant that affects a certain part of the brain (cough center), reducing the urge to cough. This product also contains a decongestant, which helps relieve stuffy nose symptoms. This medication is usually not	**Contraindications:** Some medicines can cause unwanted or dangerous effects when used together. Not all possible interactions are listed in this medication guide. Taking this medicine with other drugs that make you sleepy or slow your breathing can worsen these effects. Ask your doctor before taking this medicine with a sleeping pill, narcotic pain medicine, muscle relaxer, or medicine for anxiety, depression, or seizures. **Side Effects:** Dizziness, headache, nausea, nervousness, or trouble sleeping may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. If your doctor has prescribed this drug, remember that your doctor has prescribed it because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor if any of these unlikely but serious	Dextromethorphan Hydrobromide 0.40gm + Phenylephrine HCl 0.20gm + Triprolidine HCl 0.05gm/100ml Syrup		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					used for ongoing coughs from smoking, asthma, other long-term breathing problems (e.g., emphysema), or coughs with a lot of mucus, unless directed by your doctor.	side effects occur: mental/mood changes (e.g., confusion, hallucinations), shaking (tremors), weakness. Tell your doctor if any of these rare but very serious side effects occur: fast/slow/irregular heartbeat.				
155.	Navana Pharmaceuticals, Narayanganj	Guaifenesin BP 2.0gm + Levomenthol BP 22.0mg/100ml Syrup	Guaifenesin BP 2.0g + Levomenthol BP 22.0mg/100ml	Expectorant	It is indicated for the symptomatic relief of cough.	**Contraindication:** This product is contraindicated in individuals with known hypersensitivity to the product, or any of its components **Side Effects:** Hypersensitivity, Rash, Diarrhoea, Nausea & Vomiting	Diphenhydramine Hydrochloride 14mg + Guaifenesin 100mg + Levomenthol 1.10mg/5ml syrup	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
156.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bromhexine Hydrochloride 0.08gm + Guaifenesin 2.0gm/100ml Syrup	Bromhexine Hydrochloride BP 0.08gm + Guaifenesin USP 2.0gm/100ml	Expectorant + Mucolytic Agent	It is indicated for the Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.	**Contraindications:** Children under 2 years of age. **Side effects:** Nausea, Vomiting**,** Hypersensitivity**.**	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
157.	a) Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh b) Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka c) Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Linaclotide 290mcg Capsule	Linaclotide INN 290mcg	Gastrointestinal Agent	It is a guanylate cyclase-C agonist indicated in adults for treatment of: • Irritable bowel syndrome with constipation (IBS-C) • Chronic idiopathic constipation (CIC)	**Contra-indication :** • Pediatric patients up to 6 years of age. • Patients with known or suspected mechanical gastrointestinal obstruction **Side-effect:** Most common adverse reactions (incidence of at least 2%) reported in IBS-C or CIC patients are diarrhea, abdominal pain, flatulence and abdominal distension	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
158.	Navana Pharmaceuticals, Narayanganj	Domperidone 30mg SR Capsule	Domperidone INN 30 mg	Gastroprokinetic	1. The dyspeptic symptom complex that is often associated with delayed gastric emptying, Gastroo-esophageal reflux and Eesophagitis: - Epigastric sense of fullness, early satiety, feeling of abdominal distension, upper abdominal pain; - Bloating, eructation, flatulence; - Nausea and vomiting; - Heartburn with or without regurgitations of gastric contents in the mouth. 2. Nausea and vomiting of functional, organic, infectious or dietetic origin or induced by radiotherapy or drug therapy. A specific indication is nausea and vomiting induced by dopamine agonists, as used in Parkinson's disease (such as L-dopa and bromocriptine).	**Contraindications:**Known hypersensitivity to Domperidone or any of the excipients • Prolactin-releasing pituitary tumour (prolactinoma) • Co-administration with medicines that prolong the QTc interval. • It should not be used in the presence of gastrointestinal haemorrhage, mechanical obstruction, or perforation. **Side-effects:** Generally well tolerated. Most common side effects are somnolence, dizziness, dry mouth and blurring of vision.	10 mg tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
159.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Deflazacort 1mg Tablet	Deflazacort INN 1mg	Glucocorticoid	Asthma and other airway Diseases, Rheumatoid arthritis, juvenile chronic arthritis, pemphigus, uveitis, nephritic, syndrome,Immune suppression in transplantation, anaphylaxis, severe,hypersensitivity reactions, dermatomyositis, mixed connective, tissue disease, polyarteritis nodosa,	**Contraindications**: Systemic infection; live virus vaccines in those receiving immunosuppressive doses. **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.	6mg, 24mg, 30mg Tablet & 120mg/100ml Suspention		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					bullous pemphigoid, ulcerative colitis, optic neuritis, autoimmune haemolytic anaemia, idiopathic, thrombocytopenic, purpura, acute and lymphatic leukaemia, malignant lymphoma.					
160.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Deflazacort 18 mg Tablet	Deflazacort INN 18mg	Glucocorticoid	Asthma and other airway Diseases, Rheumatoid arthritis, juvenile chronic arthritis, pemphigus, uveitis, nephritic, syndrome,Immune suppression in transplantation, anaphylaxis, severe,hypersensitivity reactions, dermatomyositis, mixed connective, tissue disease, polyarteritis nodosa, bullous pemphigoid, ulcerative colitis, optic neuritis, autoimmune haemolytic anaemia, idiopathic, thrombocytopenic, purpura, acute and lymphatic leukaemia, malignant lymphoma.	Contraindications: Systemic infection; live virus vaccines in those receiving immunosuppressive doses. 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.	6mg, 24mg Tablet & 120mg/100ml Suspention	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
161.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Follicle Stimulating Hormone (FSH) (Urofollitropin) 150 IU/Vial Lyophilized Injection	Follicle Stimulating Hormone (FSH) (Urofollitropin) BP 150IU/Vial	Hormone	Ovulation Induction FSH administered IM or SC with HCG in a sequential manner, which is indicated for ovulation indication in patients who have previously received pituitary suppression. Multi-follicular Development During ART FSH administered	**Contraindications:** Tumours of the ovary, breast, uterus, pituitary or hypothalamus. Pregnancy or lactation. Undiagnosed vaginal bleeding. Hypersensitivity to the active substance or to any of the excipients. Primary ovarian failure. Fibroid tumors of the uterus incompatible with pregnancy. Primary testicular failure. **Side effects:** FSH sometimes excites the ovaries	FSH 50IU, 75IU, 100IU	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					IM in conjunction with HCG is indicated for multiple follicular developments (controlled ovarian stimulation) during ART cycles in patients who have previously received pituitary suppression. Polycystic Ovarian Syndrome (OCOS). Used to treat Polycystic Ovarian Syndrome (PCOS) related infertility. IN Women; Starting dose of 150 to 225 international units (IU) of FSH is administered intramuscularly for at least the first 4 days of treatment. Subsequent doses are adjusted based upon ovarian response as determined by ultrasound evaluation of follicular growth and serum estradiol levels. Final Oocyte (egg) maturation is induced with a dose of 7500-10,000 international units of HCG Oocyte (egg) retrieval is performed 34 to 36 hours later Polycystic Ovarian Hyperstimulation (PCOS). FSH injections are therefore given each morning as an intramuscular injection. It is best to start with the lowest dose of FSH per day (using 75 IU per day). There doses	too much. This may cause pelvic pain or breathing problems. It may also make you urinate less. In rare cases, patients with this problem have had serious lung problems, including fluid in the lungs, troublebreathing, and worsening of asthma blood clots and strokes, severe pelvic pain, chest pain, or abdominal pain, Nausea, Vomiting, Sudden weight gain, Bloating, Trouble, breathing. FSH may cause twins or multiple births. The most common side effects with FSH are headache, vaginal bleeding, nausea, and hot flashes. Sometimes there is a reaction at the spot where you give yourself the injection. This can include bruising, pain, or redness.				

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					are used for 4 to 6 days at a time. The ovarian response is determined by measuring oestrogen levels in the blood. When the oestrogen beings to rise, the FSH is successfully growing an egg or eggs. If there is no response to a dose of FSH in 5-6 days of injections the dose will be increased. The normal dose increments are 75 units, 112 units, 150 units and 225 units per day. Most patients respond with 50 to 150 IU per day. However it is very important that increments are only made cautiously.					
162.	Healthcare Pharmaceutical ltd., Rajendrapur , Gazipur	Diacerein capsule	Diacerein 50mg capsule	Interleukin-1 receptor antagonist, Antirheumatic agent	Treatment of Osteoarthritis & Rheumatoid arthritis.	**Contraindications:** Should not be administered to patients with known hypersensitivity to the drug or those with previous episodes of hypersensitivity to Anthraquinone derivatives **Side-Effects:** May cause mild to moderate laxative effects in few patients which is transient and goes once the patients is accustomed to the medication	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
163.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	(Sodium Picosulfate 10.00mg+ Magnesium Oxide 3.50gm + Anhydrous Citric Acid 12.0gm)/160ml Bottle	(Sodium Picosulfate BP 10.00mg+ Magnesium Oxide BP 3.50gm + Anhydrous Citric Acid BP 12.0gm)/160ml	Laxative	it is a combination of sodium picosulfate, a stimulant laxative, and magnesium oxide and anhydrous citric acid, which form magnesium citrate, an osmotic laxative, indicated for cleansing of the colon as a preparation for colonoscopy in adul	**Contra-indication** : Patients with severely reduced renal function (creatinine clearance less than 30 mL/minute) • Gastrointestinal (GI) obstruction or ileus • Bowel perforation • Toxic colitis or toxic megacolon • Gastric retention • An allergy to any of the ingredients in CLENPIQ Side-effect: Most common adverse reactions (>1%)	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						are nausea, headache, and vomiting				
164.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	PEG-3350 210 gm + Sodium chloride 5.6gm + Sodium Bicarbonate 2.86 gm + Potassium Chloride 0.74gm/Bottle Oral Solution and Bisacodyl 5mg Delayed-Release Tablet	PEG-3350 BP/Ph. EUR 210 gm + Sodium chloride BP/Ph. EUR 5.6gm + Sodium Bicarbonate BP/Ph. EUR 2.86 gm + Potassium Chloride BP/Ph. EUR 0.74gm/Bottle and Bisacodyl Extended Release USP 5mg	laxatives	This preparation is indicated for cleansing of the colon as a preparation for colonoscopy in adults.	**Contraindications:** The PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride and bisacodyl delayed-release tablet, is contraindicated in the following conditions: Gastrointestinal (GI) obstruction Bowel perforation Toxic colitis and toxic megacolon Gastric retention Ileus **Side-effects:** Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in clinical studies of another drug and may not reflect the rates observed in practice. In a clinical study of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride and (5 mg vs. 10 mg) bisacodyl delayed-release tablet, overall discomfort, abdominal fullness, abdominal cramping, nausea, and vomiting, were the most common adverse reactions (>3%). The data in Table 1 reflects the 154 patients that received PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride and 5 mg bisacodyl tablet vs. the 154 patients that received PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride and 10 mg bisacodyl tablets. The PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride and 5 mg bisacodyl delayed-release tablet, population was 29-87 years of age, 49% male, 51% female, 13% African American, 83% White, 5% Hispanic requiring a colonoscopy. The demographics of the comparator group were similar.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
165.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Prucalopride 1mg Tablet	Prucalopride succinate INN 1.049 mg eqv. to 1.00mg Prucalopride	Laxativves	This is a selective serotonin (5-HT4) receptor agonist which is indicated for symptomatic treatment of chronic constipation in adults especially in women when other laxatives fail to provide adequate relief.	**Contraindications:** - Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. - 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	New	BNF-75 Page: 59	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						megacolon/megarectum. **Side Effects:** The most frequently reported adverse reactions associated with Prucalopride therapy are headache (17.8%) and gastrointestinal symptoms (abdominal pain (13.7%), nausea (13.7%) and diarrhoea (12.0%)				
166.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Prucalopride 2mg Tablet	Prucalopride succinate INN 2.098 mg eqv. to 2.00mg Prucalopride	Laxativves	This is a selective serotonin (5-HT4) receptor agonist which is indicated for symptomatic treatment of chronic constipation in adults especially in women when other laxatives fail to provide adequate relief.	**Contraindications:** - Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. - 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. **Side Effects:** The most frequently reported adverse reactions associated with Prucalopride therapy are headache (17.8%) and gastrointestinal symptoms (abdominal pain (13.7%), nausea (13.7%) and diarrhoea (12.0%)	New	BNF-75 Page: 59	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
167.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Ferric Pyrophosphate Citrate eq. to Iron (III) 27.20 mg/5ml IV Infusion	Ferric Pyrophosphate Citrate Solution INN eq. to Iron (III) 27.20mg/5ml	Mineral	It is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).	None. **PREGNANCY:** Pregnancy Category C. There are no adequate and well-controlled studies of Ferric Pyrophosphate Citrate in pregnant women. Use of Ferric Pyrophosphate Citrate during pregnancy only if the potential benefit justifies the potential risk to the fetus. **LACTATION:** It is not known if ferric pyrophosphate citrate is present in human milk. Because many drugs are excreted in human milk and because of the potential for adverse events in nursing infants, a decision should be made whether to discontinue nursing or to avoid it, taking into account the	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						importance of iron to the mother and the known benefits of nursing. **Side Effects:** The most common adverse reactions in controlled clinical studies include: headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, procedural hypotension, muscle spasms, pain in extremity, back pain, and dyspnea.				
168.	Square Formulations Ltd., Gorai, Tangail	Calcium L-5 Methyltetrahydrofolate 1.00mg Tablet	Calcium L-5 Methyltetrahydrofolate USP 1.00mg	Mineral	Folic acid is the man-made form of folate. Folate is a B-vitamin naturally found in some foods. It is needed to form healthy cells, especially red blood cells. Folic acid supplements may come in different forms (such as L-methylfolate, levomefolate, methyltetrahydrofolate). They are used to treat or prevent low folate levels. Low folate levels can lead to certain types of anemia. Conditions that can cause low folate levels include poor diet, pregnancy, alcoholism, liver disease, certain stomach/intestinal problems, kidney dialysis, among others. Women of childbearing age should receive adequate amounts of folic acid either through their diet or supplements to prevent infant spinal cord birth defects.	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to pregabalin or any of it's component.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
169.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Elemental Zinc 0.4gm/100ml Syrup	Zinc Gluconate USP 2.80gm eqv. to Elemental Zinc 0.4gm/100ml	Minerals	It is a nutrient that people need to stay healthy. Zinc is found in cells throughout the body. It helps the immune system fight off invading bacteria and viruses. The body also needs zinc to make proteins and DNA, the genetic material in all cells. During pregnancy, infancy, and childhood, the body needs zinc to grow and develop properly. Zinc also helps wounds heal and is important for proper senses of taste and smell.	**Contra-indication:** The following drugs can interact with or be made less effective by zinc gluconate. Tell your doctor if you are using any of these: a blood thinner such as warfarin (Coumadin); methyltestosterone (Android, Methitest, Oreton); penicillamine (Cuprimine, Depen); risedronate (Actonel); a tetracycline antibiotic such as demeclocycline (Declomycin), doxycycline (Adoxa, Doryx, Oracea, Vibramycin), minocycline (Dynacin, Minocin, Solodyn, Vectrin), or tetracycline (Brodspec, Panmycin, Sumycin, Tetracap); or an antibiotic such as ciprofloxacin (Cipro), ofloxacin (Floxin), norfloxacin (Noroxin), levofloxacin (Levaquin), and others. **Side-effect:** Frequency not defined; may vary with different salts. Adverse reactions reported with excess dietary zinc (IOM, 2001). Central nervous system: Headache Endocrine & metabolic: Copper deficiency, decreased HDL cholesterol, decreased LDL cholesterol Gastrointestinal: Abdominal cramps, decreased appetite, diarrhea, epigastric pain, gastrointestinal distress, nausea, vomiting Hematologic & oncologic: Immunodeficiency	10 mg/5 ml Syrup 20 mg/5 ml Syrup		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
170.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Iron 14 mg + Folic Acid 200 mcg + Cyanocobalamin 3mcg + Ascorbic Acid 100 mg Effervescent Tablet	Dried Ferrous Sulphate USP 43.523mg eq. to Elemental Iron 14 mg + Folic Acid USP 200 mcg + Cyanocobalamin USP 3mcg +	Minerals + Vitamins	It is indicated for the treatment of all anemias that are responsive to oral iron therapy. These include: hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, post-	Contraindications: Hypersensitivity, Hemolytic anemia, Hemochromatosis, Haemosiderosis. Side effects: Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			Ascorbic Acid USP 100 mg		surgical convalescence, and dietary needs.	both oral and parenteral administration of folic acid.				
171.	Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Erdosteine 175mg/5ml Powder for Suspension	Erdosteine INN 175mg/5ml	Mucolytic	Erdosteine is priparily indicated in conditions like acute exacerbation of chronic bronchitis, and can also be given in adjunctive therapy as an alternative drug of choice in respiratory tract disorders.	to any of the excipients or to free SH – group containing products. Hepatic disorders and abnormalities (e.g. increase of serum alkaline phosphatase, transaminases, etc.). Renal insufficiency (creatinine clearance <25mL/min). Homocystinuria (the active substance is partially metabolised to homocysteine and there are no data concerning administration of erdosteine in case of congenital errors of the Metabolism of aminoacids, especially in those patients obliged to follow a methionine-free dietary regimen). Phenylketonuria (only for powder for suspension due to the presence of aspartame in this presentation). **Side effects:** Gastric burning, nausea and rarely diarrhea.	300mg Capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
172.	Ziska Pharmaceuticals Ltd.	Vitamin C 500 mg + Vitamin B1 (Thiamine Mononitrate) 50 mg + Vitamin B2 (Riboflavin) 25 mg + Vitamin B6 (Pyridoxine HCl) 10 mg + Vitamin B12 5 mcg + Niacinamide 50 mg + Calcium Pantothenate 20 mg Tablet	Vitamin C BP 500 mg + Vitamin B1 (Thiamine Mononitrate) BP 50 mg + Vitamin B2 (Riboflavin) BP 25 mg + Vitamin B6 (Pyridoxine HCl) BP 10 mg + Vitamin B12 BP 5mcg + Niacinamide BP 50 mg + Calcium Pantothenate BP 20 mg	Multivitamin	Nutritional supplement to help promote increased energy & enhance the immune system. Treatment of vit B-complex & vit C deficiencies.	**Contraindications:** If the patient is allergic to any ingredient of the product. **Side effects:** Nausea, flushing of the face, arms & chest, itching, abdominal cramps, diarrhea & nose bleeds.	Ascorbic Acid 175 mg + Calcium d-Pantothenate 25 mg + Cynocobalamin 5 mcg + Folic Acid 500 mcg + Nicotinamide100 mg + Pyridoxine Hydrochloride 10 mg + Riboflavin 25 mg + Vitamin B 150 mg		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
173.	Opsonin Phatrma Ltd	**Firmvit Syrup** Vitamin (A+D3) Water	Vitamin (A+D3) Water Miscible Type 100/20 BP 10 mg	Multi-Vitamin	Promotes muscle growth. Weight gain and calcium	The Products are contraindicated in patients with a know hypersensitivity to any of the ingredients of the	Folic Acid 250 mcg + L-Lysine		প্রয়োজনীয় রেফারেন্স নেই	প্রয়োজনীয় রেফারেন্স নেই

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
		Miscible Type 100/20 10 mg (eq. to Vitamin A 1000 IU & Vitamin D3 200 IU) + Ascorbic Acid 15mg + dl-Alpha Tocopheryl Acetate USP 5 mg (eq. to Vitamin E 5IU) + Pyridoxine HCl 500mcg + Thiamine HCl 500mcg + Riboflavin Sodium Phosphate 500mcg + Nicotinamide 6mg + Cyanocobalamin 0.9mcg + Calcium Pantothenate 2.174mg + L-Lysine 100mg/ 5ml Syrup	(equivalent to Vitamin A 1000 IU & Vitamin D3 200 IU)+ Ascorbic Acid BP 15mg +dl-Alpha Tocopheryl Acetate USP 5 mg (equivalent to Vitamin E 5 IU) + Pyridoxine Hydrochloride BP 500 mcg + Thiamine Hydrochloride BP 500 mcg +Riboflavin Sodium PhosphateBP 500 mcg +Nicotinamide BP 6mg +Cyanocobalamin BP 0.9 mcg + Calcium Pantothenate BP2.174 mg + L-Lysine USP 100mg/5ml		retention: Helps to enhance body geight and weight gain: Ensures good eye sight: Necessary for the normal process in protein, fat carbohydrate metabolism: for RBC formation and correct functioning of nervous system & proper food assimilation and for proper cell functioning and pretect body cell from free radical	products. Side effects: Generally well tolerated	50 mg + Nicotinamide 2.5 mg + Vitamin A 1500 IU + Vitamin B1 250 mcg + Vitamin B12 2 mcg + Vitamin B2 250 mcg + Vitamin B6 250 mcg + Vitamin C 50 mg + Vitamin D3 100 IU + Vitamin E 10 IU Tablet		বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	বিধায় আবেদন নামঞ্জুর করা হল।
174.	Square Formulations Ltd., Gorai, Tangail	Eperisone Hydrochloride 150mg Sustained Release Capsule	Eperisone Hydrochloride sustained release pellets 50% w/w Ph. Grade 300mg eqv. to Eperisone Hydrochloride INN 150mg	Muscle Relaxat	Improvement of muscular hypertonic symptoms in the following diseases Cervical syndrome, periarthritis of the shoulder, lumbago. Spastic paralysis in the following disease: Cerebrovascular disease, spastic spinal paralysis, cervical spondylosis, postoperative sequelae (including cerebrospinal tumor), sequelae to trauma (spinal trauma, head injury),amyotrophic lateral	It is contraindicated in patients with known hypersensitivity to the drug. Warnings : Interaction with alcohol is unknown Eprisan 150mg Capsule SR may be unsafe to use during pregnancy. Drug should not be used during lactation.	50 mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					sclerosis, cerebral palsy, spinocerebellar degeneration, spinal vascular diseases and other encephalomyelopathies.					
175.	Aristopharma Ltd.; Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Atropine Sulfate 0.01g/100 ml Ophthalmic Solution	Atropine Sulfate USP 0.01g/100 ml	Mydriatic and Cycloplegic Agent	Atropine Sulfate Ophthalmic Solution 0.01% is indicated to control progression of myopia. It is used to widen the pupil before an eye exam or eye surgery. It is used to treat eye swelling. It is used to treat lazy eye (amblyopia).	**Contraindications:** Patients with glaucoma or a tendency toward glaucoma, and with hypersensitivity to belladonna alkaloids. **Side effects**: May be occasional with stinging sensation on instillation. May cause allergy (itch, irritation and redness), blurring of near vision and glare in some children.	Atropine Sulphate 1 mg/ml 0.6 mg/ml Injection Injection 1% Eye Drops		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
176.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Pregabalin 82.5mg SR Tablet	Pregabalin BP 82.5mg	Neuropathic Pain Agent	Pregabalin extended-release tabletis indicated for the management of: • Neuropathic pain associated with diabetic peripheral neuropathy • Postherpetic neuralgia Pregabalin extended-release tabletshould be administered once daily after an evening meal. Pregabalin extended-release tabletshould be swallowed whole and should not be split, crushed, or	Known hypersensitivity to Pregabalin or any of its components. Most common adverse reactions reported in greater than or equal to 4% of patients treated with Pregabalin extended-release tabletare dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain.	Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg Capsule	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					chewed. When discontinuing Pregabalin extended-release tablet, taper gradually over a minimum of 1 week. **Neuropathic Pain Associated with Diabetic Peripheral Neuropathy** Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of Pregabalin extended-release tabletis 330 mg once daily. Although Pregabalinwas studied at 600 mg/day, there was no evidence that this dose conferred additional significant benefit and this dose was less well tolerated. In view of the dose -dependent adverse reactions with Pregabalin, treatment with doses above 330 mg/day is not recommended for Pregabalin extended-release tablet. **Postherpetic Neuralgia** Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week					

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					based on individual patient response and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 330 mg once daily and who are able to tolerate Pregabalin extended-release tablet, may be treated with up to 660 mg once daily. In view of the dose-dependent adverse reactions and the higher rate of treatment discontinuation due to adverse reactions,dosing above 330 mg/day should be reserved only for those patients who have on-going pain and are tolerating 330 mg daily. The maximum recommended dose of Pregabalin extended-release tablet is 660 mg once daily.					
177.	Popular Pharmaceuticals Ltd. 164 Tongi I/A, Tongi, Gazipur	Pregabalin 165mg SR Tablet	Pregabalin BP 165mg	Neuropathic Pain Agent	Pregabalin extended-release tabletis indicated for the management of: • Neuropathic pain associated with diabetic peripheral	Known hypersensitivity to Pregabalin or any of its components. Most common adverse reactions reported in greater than or equal to 4% of patients treated with Pregabalin extended-release tabletare dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain.	Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg Capsule	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					• neuropathy • Postherpetic neuralgia Pregabalin extended-release tabletshould be administered once daily after an evening meal. Pregabalin extended-release tabletshould be swallowed whole and should not be split, crushed, or chewed. When discontinuing Pregabalin extended-release tablet, taper gradually over a minimum of 1 week. **Neuropathic Pain Associated with Diabetic Peripheral Neuropathy** Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of Pregabalin extended-release tabletis 330 mg once daily. Although Pregabalinwas studied at 600 mg/day, there was no evidence that this dose conferred additional significant benefit and this dose was less well tolerated. In view					

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					of the dose -dependent adverse reactions with Pregabalin, treatment with doses above 330 mg/day is not recommended for Pregabalin extended-release tablet. **Postherpetic Neuralgia** Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 330 mg once daily and who are able to tolerate Pregabalin extended-release tablet, may be treated with up to 660 mg once daily. In view of the dose-dependent adverse reactions and the higher rate of treatment discontinuation due to adverse reactions,dosing above 330 mg/day should be reserved only for those patients who have on-going pain and are tolerating 330 mg daily. The maximum recommended dose of Pregabalin extended-					

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					release tablet is 660 mg once daily.					
178.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Paracetamol 250mg + Aspirin 250mg + Caffeine 65mg Film Coated Tablet	Paracetamol BP 250mg + Aspirin USP 250mg + Caffeine USP 65mg	NSAID + Analgesic + CNS Stimulant	It is used 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		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
179.	Navana Pharmaceuticals, Narayanganj	Ferric Citrate 1 gm Tablet	Ferric Citrate INN 1.0gm eq. to 210 mg Iron	Phosphate binder	It is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis.	**Contraindication:** Iron overload syndromes **Side Effect:** Diarrhea, discolored feces, constipation, nausea and vomiting	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
180.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Sodium Zirconium Cyclosilicate INN 5gm/Sachet Powder for Oral suspension	Sodium Zirconium Cyclosilicate INN 5gm/Sachet	Potassium binder	It is a potassium binder indicated for the treatment of hyperkalemia in adults. **Limitation of Use**: It should not be used as an	**Contra-indication : None** **Side-effect:** Most common adverse reactions with it: mild to moderate edema	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					emergency treatment for life-threatening hyperkalemia because of its delayed onset of action					
181.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Sodium Zirconium Cyclosilicate 10.000g/Sachet Powder for Oral suspension	Sodium Zirconium Cyclosilicate INN 10.000g/Sachet	Potassium binder	It is a potassium binder indicated for the treatment of hyperkalemia in adults. **Limitation of Use**: It should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action	**Contra-indication : None** **Side-effect:** Most common adverse reactions with LOKELMA: mild to moderate edema	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
182.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Patiromer 25.20gm/Sachet Powder For Suspension	Patiromer Sorbitex Calcium INN 50.40gm eq. to 25.20gm Patiromer/Sachet	Potassium Binder	It is a potassium binder indicated for the treatment of hyperkalemia. **Limitations of use:** It should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.	**Contraindications:** Known hypersensitivity to Veltassa or any of its components. **Side effects:** Most common adverse reactions (incidence ≥2%) are constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
183.	a) Eskayef Pharmaceuticals Limited, Tongi, Gazipur b) Aristopharma Ltd.; Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka-1204	Vonoprazan 10mg Film Coated Tablet	Vonoprazan INN 10mg	Potassium-Competitive Acid Blocker	Vonoprazan Fumarate is a first-in-clas potassium-competitive acid blocker. It inhibits H+, K+-ATPase activities in a reversible and potassium-competitive manner with potency of inhibition approximately 350 times higher than the proton pump inhibitor, Lansoprazole. Vonoprazan Fumarate tablet	**Contraindications:** Caution is necessary when oral vonoprazan Fumarate is used in patients with the following conditions and frequent monitoring is necessary: Liver/Renal disorders, allergic rections (itch, rash, etc.) or in those who are taking any other medicinal products, over-the-counter medicines & dietary supplements as well as other prescription medicines. Caution is also necessary for women who are pregnant & breastfeeding. **Side-effects:** The most commonly reported adverse	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					is indicated in the treatment of Gastroduodenal Ulcer, Secondary prevention of Reflux Esophagitis, Secondary prevention of lowdose aspirin or non-steroidal antiinflammatory drug induced Peptic Ulcer, in combination with Clarithromycin and Amoxicillin for the eradication of Hlicobacter pylori.	reactions include constipation, diarrhea, enlarged feeling				
184.	a) Eskayef Pharmaceuticals Limited, Tongi, Gazipur b) Square Formulations Ltd., Gorai, Tangail c) Aristopharma Ltd. Plot No.21, Road No.11, Shampur-Kadamtali I/A Dhaka	Vonoprazan 20mg Film Coated Tablet	Vonoprazan INN 20mg	Potassium-Competitive Acid Blocker	Vonoprazan Fumarate is a first-in-clas potassium-competitive acid blocker. It inhibits H+, K+-ATPase activities in a reversible and potassium-competitive manner with potency of inhibition approximately 350 times higher than the proton pump inhibitor, Lansoprazole. Vonoprazan Fumarate tablet is indicated in the treatment of Gastroduodenal Ulcer, Secondary prevention of Reflux Esophagitis, Secondary prevention of lowdose aspirin or non-steroidal antiinflammatory drug induced Peptic Ulcer, in combination with Clarithromycin and Amoxicillin for the eradication of Hlicobacter pylori.	**Contraindications:** Caution is necessary when oral vonoprazan Fumarate is used in patients with the following conditions and frequent monitoring is necessary: Liver/Renal disorders, allergic rections (itch, rash, etc.) or in those who are taking any other medicinal products, over-the-counter medicines & dietary supplements as well as other prescription medicines. Caution is also necessary for women who are pregnant & breastfeeding. **Side-effects:** The most commonly reported adverse reactions include constipation, diarrhea, enlarged feeling	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
185.	UniMed &	Pirfenidone 534 mg Tablet	Pirfenidone BP	Respiratory Agent	It is a pyridone indicated for	**Contraindication:** None	267mg Capsule	USFDA	অনুমোদন করা	অনুমোদন করা

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	UniHealth Manufacturers Ltd. B.K Bari, Gazipur Sadar, Gazipur		534 mg		the treatment of idiopathic pulmonary fibrosis	**Adverse Reactions :** The most common adverse reactions (≥10%) are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastro-esophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia	& 801mg Tablet		যেতে পারে।	হল।
186.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Rh0 (D) Immune Globulin Intravenous (Human) 1500 IU (300 mcg)/2ml prefilled syringe for injection	Rh0 (D) Immune Globulin (As Rho (D) Immune Globulin ready to fill sterile solution) INN 1500 IU (300 mcg)/2ml prefilled syringe	Rh Immune Globulin	Suppression of rhesus (Rh) isoimmunization in: • Pregnancy and obstetric conditions in non-sensitized, Rh0(D)-negative women with an Rh-incompatible pregnancy, including: o Routine antepartum and postpartum Rh prophylaxis o Rh prophylaxis in obstetric complications or invasive procedures • Incompatible transfusions in Rh0(D)-negative individuals transfused with blood components containing Rh0(D)-positive red blood cells (RBCs) Immune thrombocytopenic purpura (ITP) Raising platelet counts in Rh0(D)-positive, non-splenectomized adults with chronic ITP	**Contraindications:** Anaphylactic or severe systemic reaction to human immune globulin products **Side-effects**: **Suppression of Rh Isoimmunization.** Most common adverse reactions are nausea, dizziness, headache, injection-site pain, and malaise **Immune thrombocytopenic purpura (ITP) :** Most common adverse reactions are chills, pyrexia/increased body temperature, headache, and mild extravascular hemolysis (increased bilirubin, decreased Hemoglobin.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
187.	Navana Pharmaceuticals, Narayanganj	Loteprednol etabonate 0.5% + Moxifloxacin 0.5% Eye Drops	Loteprednol etabonate 0.5gm + Moxifloxacin HCl 0.545gm eq. to 0.5gm	Steroid + Antibiotic	It is indicated for – • Ocular infection & inflammation (steroid-responsive inflammation) • Prevents pre and post	Hypersensitivity to Loteprednol / Moxifloxacin is a contraindication. In addition, Loteprednol / Moxifloxacin should not be used if you have the following conditions: • Allergic reactions	Loteprednol 0.5% Eye Drops, Moxifloxacin		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			Moxifloxacin/100ml		conjunctivitis • Reduces symptoms of bacterial conjunctivitis • Active against allergic conjuctivitis	• Anxiety • Fungal infections of ocular structures • Hypersensitivity • Insomnia • Mycobacterial eye infection • Nervousness • Viral infections of the cornea and conjunctiva	0.5% Eye Drops Loteprednol Etabonate 0.5% + Tobramycin 0.3% Eye Drops			
188.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Ketoconazole 2.00gm + Zinc Pyrithione 1.00gm + Aloe extract 10.00gm/100gm Shampoo	Ketoconazole BP 2.00gm + Zinc Pyrithione Ph. Grade 1.00gm + Aloe extract BP 10.00gm/100gm	Topical Anti-Fungal	It is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: • Fungal infections • Seborrhoeic dermatitis of the scalp • Dandruff • Dry skin • Wounds • Radiation induced skin damage • Skin aging • Minor skin infections • Microbial infections of living surface	**Contraindications:** It is contra-indicated for use in the following conditions: • Astemizole • Cisapride • Hypersensitivity • Porphyria • Preexisting liver disease • Terfenadine Side effects: • lockade of synthesis of hormones from adrenal glands, Itching of skin, Indigestion, Skin burning sensation, Dryness, Folliculitis	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
189.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Hydrocortisone 0.50gm + Dimeticone 350 10.00gm + Nystatin 3.00gm + Benzalkonium chloride 0.20gm/100gm Cream	Hydrocortisone BP 0.50gm + Dimeticone 350 BP 10.00gm + Nystatin BP 3.00gm + Benzalkonium chloride BP 0.20gm/100gm	Topical Corticosteroid Combinations	Effective preparation to reduce mixed infection with inflammation specially, in the folding areas of body Suitable for children affected by mixed infections with inflammation (as Hydrocortisone is a mild steroid) Eases the soreness and	**Contraindications:** It is contra-indicated for use in the following conditions: • Hypersensitivity to nystatin, hydrocortisone, dimeticone 350, benzalkonium • rosacea • perioral dermatitis • untreated bacterial, fungal or viral skin infections • ulcerated skin	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					treats the infections in intertrigo and inflamed nappy rash. Treats various skin diseases mixed with Candida infections: Eczema, Seborrhoeic dermatitis, Pruritis ani & vulvae etc.	Side effects: Thinning of the skin, irreversible striae atrophicae, telangiectasia, acne or worsening of acne, rosacea, mild depigmentation				
190.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Selenium 100mcg/2ml Solution Injection	Sodium Selenite Pentahydrate BP 333mcg eq. to 100mcg Selenium/2ml	Trace element	It is indicated Proven selenium deficiency that cannot be offset from food sources.	**Contra-indication :** Hypersensitivity to any component of the product **Side-effect:** None to know.	New	BNF-75 Page: 1006	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
191.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Selenium 500mcg/10ml Injection	Sodium Selenite Pentahydrate BP 1665mcg eqv. to Selenium 500mcg/10ml	Trace element	It is indicated Proven selenium deficiency that cannot be offset from food sources.	Contra-indication : Hypersensitivity to any component of the product Side-effect: General disorders and administration site conditions.After intramuscular administration local pain has been reported.	New	BNF-75 Page: 1006	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
192.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Fesoterodine Fumarate 4mg Extended Release Tablet	Fesoterodine Fumarate INN 4mg	Urinary Antispasmodic	It is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.	**Contraindications:** It is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma. Toviaz is also contraindicated in patients with known hypersensitivity to the drug or its ingredients or to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules. **Side effects:** Dry mouth, Constipation, Dyspepsia, Nausea.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
193.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Phenylephrine Hydrochloride 10mg Tablet	Phenylephrine Hydrochloride BP 10 mg	Vasoconstrictor	Nasal congestion, Hypotensive states, Paroxysmal supraventricular tachycardia, Mydriasis, Conjunctival decongestant.	Contraindication: Hypertension, ventricular tachycardia. Oral: use with or within 14 days of MAOI therapy. Ophthalmic: narrow-angle glaucoma. Side Effects: Anxiety, reflex bradycardia,	Phenylephrine Hydrochloride 10mg/ml Injection		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						tachycardia, arrhythmias, headache, cold extremities/gangrene, hypertension, nausea, vomiting, sweating, weakness, fear, restlessness, insomnia, confusion, irritability, psychotic states, dyspnoea, anorexia, palpitations, extravasation causing tissue necrosis and sloughing, mydriasis, difficulty in micturition and urinary retention, piloerection, increased salivation, hyperglycaemia, lactic acidosis. Ophthalmic solutions may liberate pigment granules from the iris, corneal clouding/damage. Potentially Fatal: Increase in cardiac contractility, which may lead to angina or cardiac arrest; severe hypertension leading to cerebral haemorrhage or pulmonary oedema.				
194.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Phenylephrine Hydrochloride 2.5mg/5ml Paediatric drops	Phenylephrine Hydrochloride BP 2.5mg/5ml	Vasoconstrictor	Nasal congestion, Hypotensive states, Paroxysmal supraventricular tachycardia, Mydriasis, Conjunctival decongestant.	**Contraindication:** Hypertension, ventricular tachycardia. Oral: use with or within 14 days of MAOI therapy. Ophthalmic: narrow-angle glaucoma. **Side Effects:** Anxiety, reflex bradycardia, tachycardia, arrhythmias, headache, cold extremities/gangrene, hypertension, nausea, vomiting, sweating, weakness, fear, restlessness, insomnia, confusion, irritability, psychotic states, dyspnoea, anorexia, palpitations, extravasation causing tissue necrosis and sloughing, mydriasis, difficulty in micturition and urinary retention, piloerection, increased salivation, hyperglycaemia, lactic acidosis. Ophthalmic solutions may liberate pigment granules from the iris, corneal clouding/damage. Potentially Fatal: Increase in cardiac contractility, which may lead to angina or cardiac arrest; severe hypertension leading to cerebral haemorrhage or pulmonary oedema.	Phenylephrine Hydrochloride 10mg/ml Injection		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
195.	**Concord**	**Benfotiamine 100mg +**	**Benfotiamine BP**	Vitamin	**This Tablet is used for the**	**Contraindication:This Tablet should not be used**	**New**		প্রয়োজনীয়	প্রয়োজনীয়

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceuticals Ltd.	**alpha lipoic acid 100 mg + Mecobalamin 0.5mg + Pyridoxine hydrochloride 50mg Tablet**	**100 mg + alpha lipoic acid BP 100 mg + Mecobalamin BP 0.5 mg + Pyridoxine Hydrochloride BP 50 mg**		**treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: Adjunct therapy in severe muscle tightness , Loss of sensation , Diabetic polyneuropathy, Inadequate dietary intake , Pain in extremities , Eye diseases , Decrease in muscle mass , Prevention of complications of diabetes , Thiamine deficiency , Weight loss , Burning mouth syndrome , Low hemoglobin , Drug-induced deficiency**	**if you have the following conditions: Allergic to Saw Palmetto , Asthma or other breathing disorder , Heart disease , Heart rhythm disorder , History of stomach ulcer , Hypersensitivity , Kidney or Liver problems , Liver disease , Low blood sugar , Thyroid disorder, sensitivity** **Adverse Reactions: The most commonly reported side-effects of tablet are vomiting, diarrhea, biliousness, eczema, moderate skin rash, and nausea.**			রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
196.	Drug International Ltd 252,Tongi I/A Tongi, Gazipur	Vitamin E Soft Capsule	Vitamin E USP 600 IU	Vitamin	Vitamin E is indicated in the prevention and treatment of vitamin E deficiency. There is a possible need for supplimentation of Vitamin E in the diet of pregnant & lactating women and for new born infants where anemia can arise as a result of insufficiency of Vitamin-E. Vitamin E has been tried in the treatment of various disorders including angina pectoris, hypercholesterolemia, intermittent claudicating, fibrocystic breast disease, cancer, nocturnal leg cramps, osteoarthritis etc. Vitamin-E	**Contraindication:** Vitamin E is contraindicated in patients with known hypersensitivity to Vitamin E or any other components of this product. **Side effect:** Nausea, flatulence or diarrhoea may occur. High dose Vitamin E (generally more than 400 mg daily) has been associated with a variety of minor side effects, including hypertension, fatigue, diarrhoea, myopathy and thrombophlebitis.	200 IU & 400 IU Soft Capsule	BNF-75 Page: 1024	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					has also been claimed to enhance athletic performance.					
197.	Incepta Pharmaceutics Ltd.; Zirabo, Savar, Dhaka.	Cholecalciferol equivalent to vitamin D3 10000IU Tablet	Dry Vitamin D3 100 INN 110.00 mg eq. to 10000IU Vitamin D3/Cholecalciferol USP	Vitamin	Colecalciferol Tablets are essential for absorption of calcium and necessary for healthy and strong bones. Cholecalciferol Tablets are indicated for use in the treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia.	**Contraindication:** Colecalciferol Tablets are contraindicated in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D **Side effects:** Generally all nutrition supplements are considered to be safe and well tolerable. However, few side-effects can generally occur including hypercalcaemia syndrome or calcium intoxication, occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation with the administration of colecalciferol.	1000IU, 2000IU 4000IU Tablet	BNF-75 Page: 1019	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
198.	Navana Pharmaceuticals, Narayanganj	Beta-Carotene 1.6mg + Vitamin B_1 3 mg + Vitamin B_2 3.4 mg + Nicotinamide 20mg + Pantothenic Acid 5 mg +Vitamin B_6 10 mg + Vitamin C 120 mg + Vitamin E 13.8 mg + Copper 2 mg+ Iodine 0.15mg+ Iron 35 mg+ Magnesium 50 mg+ Zinc 15 mg Morning Tablet	Beta-Carotene BP 1.6 mg + Vitamin B_1 (As Thiamine mononitrate) BP 3 mg + Vitamin B_2 (As Riboflavin) BP 3.4 mg+Nicotinamide BP 20 mg+ Pantothenic Acid (As Calcium D pantothenate) USP 5 mg + Vitamin B_6(As Pyridoxine HCl) BP 10 mg+ Vitamin C (As Ascorbic acid) BP 120 mg + Vitamin E (As alpha tocopheryl acetate) USP 13.8 mg + Copper Ph. Grade (As Cupric oxide) 2 mg+ Iodine (As	Vitamin -Mineral	Vitamin-Mineral Supplement Tablets for Prenatal/Postpartum use.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to any of the ingredients in the formulation **Side Effect:** Constipation, Nausea, Fatigue, diarrhea	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			Potassium iodide) USP 0.15 mg+ Iron (As dried ferrous fumarate) BP 35 mg+ Magnesium (As heavy Manganiese oxide) BP 50 mg + Zinc (As zinc oxide) USP 15 mg							
199.	Navana Pharmaceuticals, Narayanganj	Folic Acid 1.1 mg+ Vitamin B12 12µg + Vitamin D3 600 IU + Calcium 300 mg Evening Tablet	Folic Acid USP 1.1 mg+ Vitamin B12 (As Cyanocobalamin) Ph. Gr. 12µg+ Vitamin D3 (As cholecalciferol) USP 600 IU + Calcium (As Calcium carbonate) USP 300 mg	Vitamin -Mineral	Vitamin-Mineral Supplement Tablets for Prenatal/Postpartum use.	**Contraindication:**It is contraindicated in patients with known hypersensitivity to any of the ingredients in the formulation **Side Effect:** Constipation, Nausea, Fatigue, diarrhea	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
200.	Navana Pharmaceuticals, Narayanganj	Folic Acid 5 mg+ Vitamin B12 12µg + Vitamin D3 600 IU + Calcium 300 mg Evening Tablet	Folic Acid USP 5 g+ Vitamin B12 (As Cyanocobalamin) Ph. Gr 12µg+ Vitamin D3 (As Cholecalciferol) USP 600 IU + Calcium (As Calcium carbonate) USP 300 mg	Vitamin -Mineral	Vitamin-Mineral Supplement Tablets for Prenatal/Postpartum use.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to any of the ingredients in the formulation **Side Effect:** Constipation, Nausea, Fatigue, diarrhea	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
201.	Square	Myo-inositol 2000mg +	Myo-inositol BP	Vitamin	It is indicated for the treatment	**Contraindications:**	Inositol 500mg,		প্রয়োজনীয়	প্রয়োজনীয়

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Melatonin 1mg + Folic 0.20mg/Sachet	2000mg + Melatonin BP 1mg + Folic BP 0.20mg		of women suffers from PCOS (Polycystic Ovary Syndrome) and to improve fertility.	This combination is contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients.	700mg Tablet Melatonin 3 mg Tablet		রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
202.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Elemental Calcium 800mg + Colecalciferol 10mg + Vitamin k_2 180mcg Tablet	Calcium Carbonate CS 90 Ph. Grade 2222.22mg eq. to 800mg of Elemental Calcium + Colecalciferol (1 lac IU/gm) BP 10mg (Dry Vitamin D_3 1000 IU) + Vitamin K_2 (menaquinone-7) Ph. Grade 90mg eq. to Vitamin k_2 180mcg	Vitamin & Minerals	It is indicated to support healthy bones, Vitamin D, Vitamin K or Calcium Deficiency in adults and postmenopausal women. Moreover 186inerali Calcium Delivery.Vitamin D is required for optimal calcium and phosphorous absorption. Vitamin D is required to maintain normal blood levels of calcium and phosphate, which are in turn needed for the normal 186ineralization of bone, muscle contraction, nerve conduction, and general cellular function in all cells of the body as well as bone growth and maintenance of bone density. Vitamin K is responsible for the carboxylation of the bone protein, osteocalcin, to its active form. Osteocalcin regulates the function of calcium in bone turnover /bone 186ineralization/bone	**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.	Calcium 500mg + Vitamin D3 200 IU	TGA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					development. MK-7 may play a role in bone health.; MK-7 may be involved in (bone health/maintenance of healthy bone/normal bone/bone health). May help to increase bone mineral density. For optimal delivery of calcium into the bones. More than 99% of total body calcium is stored in the bones and teeth. Clinically trialled dose of Vitamin K2 (MK-7) which may help decrease bone loss in postmenopausal women Supplementation of K2 (MK-7) may help decrease bone loss in postmenopausal women; Maintaining adequate Vitamin K2 (MK-7) levels may help decrease bone loss in post-menopausal women. Calcium is essential for bone mineralisation. D3 is the preferred form of vitamin D/ the form found in the human body. Vitamin D is required for optimal calcium and phosphorous absorption. Adequate serum vitamin D level is required for bone and muscle health. Vitamin D is important for absorption of calcium and phosphorous from the small intestine, extracellular calcium					

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					homeostasis and mineralisation of the skeleton.					
203.	Beximco Pharmaceuticals Ltd.	Cholecalciferol (Vitamin D3) 200IU / 0.5 ml	Each 0.5ml syrup contains Cholecalciferol 200IU USP equivalent to 5 mcg of vitamin D3.	Vitamins & minerals	Vitamin D is essential for normal bone growth and development and to maintain bone density. Vitamin D acts as a hormone and increases reabsorption of Calcium and Phosphorus by the kidneys and increased bone turnover. Prevention and Treatment of vitamin D deficiency states.	**Contraindications:** ● Hypersensitivity to the active substance (cholecalciferol) or to any of the excipients • Hypercalcaemia and/or hypercalciuria ● Nephrolithiasis (Renal calculi) ● Hypervitaminosis ● Severe renal impairment **Side effects:** Few side-effects can generally occur including hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of hypercalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation with the administration of Cholecaciferol.	Cholecalciferol 40000 IU capsule, Cholecalciferol 20000 IU capsule, Cholecalcigerol 2000 IU tablet	BNF-75 Page: 1020	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
204.	Beximco Pharmaceuticals Ltd.	Cholecalciferol 50,000 IU Capsule	Cholecalciferol (As vitamin D_3 1,00,000 IU/g) USP 500.000mg eq.to Vitamin D_3 50, 000 IU	Vitamins & minerals	Prevention and Treatment of vitamin D deficiency states.	**Contraindications:** ● Hypersensitivity to the active substance (cholecalciferol) or to any of the excipients • Hypercalcaemia and/or hypercalciuria ● Nephrolithiasis (Renal calculi) ● Hypervitaminosis ● Severe renal impairment **Side effects:** Few side-effects can generally occur including hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of hypercalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation with the administration of Cholecaciferol.	Cholecalciferol 40000 IU capsule, Cholecalciferol 20000 IU capsule, Cholecalciferol 2000 IU tablet	BNF-75 Page: 1020 MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
205.	M/S Radiant Pharmaceuticals Limited. Tongi ,Gazipur	Elemental Calcium 600mg + Colecalciferol 1000IU + Ascorbic Acid 45.0mg + Magnesium 50mg + Zinc 7.5mg + Manganese 1. + Copper 0.5mg + Collagen	Calcium Carbonate (Coral Calcium) USP 1500.00mg eq. to 600mg of Calcium + Colecalciferol (Vitamin D3) BP 10.00mg eq. to 1000 IU of Colecalciferol +	Vitamin & Minerals	Indicated for the prevention and treatment of vitamin & minerals deficiencies.	**Contraindication**: The use of calcium supplement with Vitamins, minerals and Collagen (UC II) preparations tablets is contraindicated in patients with known hypersensitivity to any of the ingredients of the tablet. Periodic checks of plasma calcium levels and urinary calcium excertion should be made	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
		10mg Tablet	Ascorbic Acid (Vitamin C, coated) USP 45.0 mg + Magnesium Oxide (Heavy) USP 82.50mg eq. to 50mg of Magnesium + Zinc Oxide BP 9.33mg eq. to 7.5mg of zinc + Manganese Sulphate USP 5.535mg eq.to 1.8mg of Manganese + Cupric Oxide USP 0.62575mg eq.to 0.5mg of Copper + Collagen (UC-II) PH grade 10mg			in patients with mild to moderate renal failure or mild hypercalciuria. **Side effects:** This calcium supplement with vitamins, minerals and collagen (UCII) preparations is generally well tolerated. However, Mild and transient effect of gastrointestinal disturbance, like constipation, flatulence, nausea, diarrhea may be seen in some individuals. Following administration of vitamin D Supplements may cause skin rash in some rare cases. Hypercalciuria has been with long-term use at high dosage. .				
206.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka	Menthol 0.44gm + Zinc Oxide 20.6gm /100 gm ointment	Menthol USP 4.4 mg + Zinc oxide BP 206 mg	Analgesic	Indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of the long-term use of this product in the treatment of other disorders have not been established.	**Contraindication:** Use of the product should be discontinued if hypersensitivity to any of the ingredients is noted. **Side-effects:** Hives,itching,troble in breathing, pruritis,wheezing,tightness in the chest	Calamine 15% + Zinc Oxide 5% Lotion Zinc Oxide 7.5% Ointment Zinc Oxide 40% Ointment		ফর্মূলেশন সঠিক নয় বিধায় ঔষধটির আবেদন নামঞ্জুর করা যেতে পারে।	ফর্মূলেশন সঠিক নয় বিধায় ঔষধটির আবেদন নামঞ্জুর করা হল।
207.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur	Dexketoprofen 25mg + Tramadol Hydrochloride 75mg Tablet	Dexketoprofen Trometamol INN 36.90mg eq. to 25mg Dexketoprofen + Tramadol Hydrochloride BP 75mg	Analgesic	It is indicated for the treatment of moderate to severe acute pain	**Contraindications:** The contraindications reported for dexketoprofen and tramadol as single agents should be taken into account. Dexketoprofen must not be administered in the following cases: • hypersensitivity to dexketoprofen, to any other NSAID, or to any of the excipients listed in section; • patients in whom substances with a similar action (e.g. acetylsalicylic acid, or other NSAIDs) precipitate attacks of asthma, bronchospasm, acute rhinitis, or cause nasal polyps, urticaria or angioneurotic oedema; • known photoallergic or phototoxic reactions during treatment with ketoprofen or fibrates;	New	BNF-76 Page-466,467	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						• patients with active peptic ulcer/gastrointestinal haemorrhage or any history of gastrointestinal bleeding ulceration or perforation; • patients with history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; • patiens with chronic dyspepsia; • patients who have other active bleedings or bleeding disorders; • patients with Crohn's disease or ulcerative colitis; • patients with severe heart failure; • patients with moderate to severe renal dysfunction (creatinine clearance <59 ml/min); • patients with severely impaired hepatic function (Child-Pugh C); • patients with haemorrhagic diathesis and other coagulation disorders; • Patients with severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake). Tramadol must not be administered in the following cases: • hypersensitivity to tramadol or to any of the excipients listed in section 6.1; • in acute intoxication with alcohol, hypnotics, analgesics, opioids or psychotropic medicinal products; • in patients receiving MAO inhibitors, or who have taken them within the last 14 days (see section ; • in patients with epilepsy not adequately controlled by treatment (see section 4.4); • severe respiratory depression Skudexa is contraindicated during pregnancy				

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						and lactation. Undesirable effects: In clinical studies the most commonly observed adverse reactions were vomiting, nausea and dizziness (2.9%, 2.7% and 1.1% of patients, respectively). Dexketoprofen Gastrointestinal: The most commonly-observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Oedema, hypertension and cardiac failure have been reported in association with NSAIDs treatment. As with other NSAIDs the following undesirable effects may appear aseptic meningitis, which might predominantly occur in patients with systemic lupus erythematosus or mixed connective tissue disease; haematological reactions (purpura, aplastic and haemolytic anaemia, and rarely agranulocytosis and medullar hypoplasia). Bullous reactions including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (very rare). Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increase in the risk of arterial thrombotic events (for example				

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						myocardial infarction or stroke) Tramadol The most commonly reported adverse reactions due to tramadol are nausea and dizziness, both occurring in more than 10% of patients. If the recommended doses are considerably exceeded and other centrally depressant substances are administered concomitantly respiratory depression may occur. Worsening of asthma has been reported, though a causal relationship has not been established. Epileptiform convulsions occurred mainly after administration of high doses of tramadol or after concomitant treatment with drugs, which can lower the seizure threshold or themselves induce cerebral convulsions . Symptoms of withdrawal reactions, similar to those occurring during opiate withdrawal, may occur as follows; agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms. Other symptoms that have very rarely been seen with tramadol discontinuation include: panic attacks, severe anxiety, hallucinations, paraesthesias, tinnitus, and unusual CNS symptoms (i.e. confusion, delusions, depersonalisation, derealisation, paranoia).				
208.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Iron (III) isomaltoside 1000 (100 mg/vial injection.)	Iron (III)isomaltoside 1000 INN 200mg eq. to elemental iron 100 mg	Antianemic	Iron isomaltoside is indicated in adults for the treatment of iron deficiency in patients with chronic kidney disease on dialysis, when oral iron preparations are ineffective or cannot be used.	**Contraindication:** Active rheumatoid arthritis,asthma,eczema,history of allergic disorder. **Side-effects:** **Uncommon**:Abdominalpain,anaphylaxis, blurredvision,constipation,cramps,dysphonia,fever,flushing,injection-site reaction,nausea,numbness,pruritis,rash,	Elemental Iron 50mg/2.5ml 100 mg/5ml 200 mg/10ml Injection	BNF 76 Page: 989	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						vomiting. **Rare**:Altered mental status,angioedema, arythmias,chest pain,diarrhoea, dizziness,hypotension ,malaise,myalgia,restlessness,seizures,swetting, tachycardia.**Veryrare:**haemolysis,headache,hypertension,palpitation,transient deafness.				
209.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Iron (III)isomaltoside 1000 200 mg/Vial injection	Iron (III)isomaltoside 1000 INN 400mg eq. to elemental Iron 200 mg	Antianemic	Iron isomaltoside is indicated in adults for the treatment of iron deficiency in patients with chronic kidney disease on dialysis, when oral iron preparations are ineffective or cannot be used.	**Contraindication:** Active rheumatoid arthritis,asthma,eczema,history of allergic disorder. **Side-effects:** **Uncommon**:Abdominalpain,anaphylaxis,blurred vision,constipation,cramps,dysphonia,fever,flushing,injection-site reaction,nausea, numbness, pruritis, rash, vomiting.**Rare**:Altered mental status,angioedema,arythmias,chest pain,diarrhoea,dizziness,hypotension,malaise,myalgia,restlessness,seizures,swetting, tachycardia. **Veryrare:**haemolysis, headache, hypertension,palpitation,transient deafness.	Elemental Iron 50mg/2.5ml 100 mg/5ml 200 mg/10ml		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
210.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Iron (III)isomaltoside 1000 500 mg/vial injection.	Iron (III)isomaltoside 1000 INN 1000mg eq. to elemental iron 500mg/Vial	Antianemic	Iron isomaltoside is indicated in adults for the treatment of iron deficiency in patients with chronic kidney disease on dialysis, when oral iron preparations are ineffective or cannot be used.	**Contraindication:** Active rheumatoid arthritis, asthma, eczema, history of allergic disorder. **Side-effects:** **Uncommon**:Abdominalpain,anaphylaxis, blurredvision,constipation,cramps,dysphonia,fever,flushing,injection-site reaction,nausea,numbness,pruritis,rash, vomiting.**Rare**:Altered mental status,angioedema ,arythmias,chest pain,diarrhoea, dizziness,hypotension, malaise, myalgia,restlessness,seizures ,swetting,tachycardia.**Veryrare:**haemolysis,hea	Elemental Iron 50mg/2.5ml 100 mg/5ml 200 mg/10ml		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						dache,hypertension,palpitation,transient deafness.				
211.	Opsonin Pharma Limited, Rupatoli, Barisal.	Montelukast 4 mg /5 ml Syrup	Montelukast BP 4 mg/5 ml	Antiashmatic	It is leukotriene receptor antagonist indicated for: Prophylaxis and chronic treatment of asthma in patients 12 months of age and older. Acute prevention of exercise-induced bronchoconstriction (EIB) in patients 6 years of age and older. Relief of symptoms of allergic rhinitis (AR): Seasonal allergic rhinitis (PAR) in patients 6 months of age and older.	**Contraindication:** Hypersensitivity to any component of this product. **Side-effects:** Most common adverse reactions (incidence ≥5% and greater than placebo listed in descending order of frequency): Upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis	Montelukast 5 mg & 10 mg Tablet, 4 mg Granules		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
212.	Opsonin Pharma Limited, Rupatoli, Barisal.	Doxophylline 400 mg + Montelukast 10 mg Tablet	Doxophylline INN 400 mg + Montelukast sodium BP 10 mg	Antiasthmatic	It is used for the treatment, control, prevention & improvement of the following diseases, conditions and symptoms: Asthma Hay fever, Exercise-induced asthma, Chronic asthma, Seasonal allergic, Rhinitis, Perennial allergic rhinitis.	**Contraindication:** Contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients. It should not be used if you have the following conditions: Allergic reaction, Asthma exacerbations, Hypersensitivity Lactation, Pregnancy **Side-effects:** The following is a list of possible side-effects that may occur from all constituting ingredients of tablet. This is not a comprehensive list. These side-effects are possible, but do not always occur.Nausea, Vomiting, Epigastric pain Palpitations, Headache, Insomnia	Doxophylline 400 mg tablet, Montelukast 10 mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
213.	a) Beacon Pharmaceuticals Ltd. Kathali,	Eravacycline 50mg/vial	Eravacycline Diydrochloride INN 63.50mg eq. to Eravacycline	Antibiotic	It is a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections	**Contra-indication:** Known hypersensitivity to eravacycline, tetracycline-class antibacterial drugs, or any of the excipients in Eravacycline.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Bhaluka, Mymensingh b) Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka		50mg/vial		in patients 18 years of age and older. **Limitations of Use**: It is not indicated for the treatment of complicated urinary tract infections (cUTI). To reduce the development of drug-resistant bacteria and maintain the effectiveness of Eravacycline and other antibacterial drugs, Eravacycline should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	**Side-effect:** Most common adverse reactions (incidence ≥ 3%) are infusion site reactions, nausea, and vomiting				
214.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Ozenoxacin INN 1% Cream	Ozenoxacin INN 1.0gm/100gm	Antibiotic	Indicated for topical treatment of Impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older	**Contraindication:** None. **Side-effects:** Adverse reactions (rosacea and seborrheic dermatitis) were reported in 1 adult patient treated with Ozenoxacin.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
215.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Cefoperazone 1000mg + Sulbactam 1000mg/vial Injection	Cefoperazone Sodium USP 1034.08mg (on anhydrous basis) eqv. to 1000mg Cefoperazone + Sulbactam sodium USP 1101.32mg (on anhydrous basis)	Antibiotic	Sulbactam/cefoperazone is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory Tract Infections (Upper and Lower) Urinary Tract Infections (Upper and Lower)Peritonitis, Cholecystitis, Cholangitis,	**Contraindication:** Sulbactam/cefoperazone is contraindicated in patients with known allergy to penicillins, sulbactam, cefoperazone or any of the cephalosporins. **Side effects:** Skin rash, hives, eosinophilia, diarrhea, nausea, vomiting, eye inflammation, blood clotting	Cefoperazone 500 mg/vial Injection & Cefoperazone 1000 mg/vial Injection	European Medicines Agency (EMA)	একক মাত্রায় অনুমোদন রয়েছে এবং অদ্যাবধি একক মাত্রার রেজিসটেন্স এর কোন তথ্যাদি নেই। তাই পদটির প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			eq. to 1000mg Sulbactam/vial		and Other Intra-Abdominal Infections Septicemia Meningitis Skin and Soft Tissue Infections Bone and Joint Infections Pelvic Inflammatory Disease, Endometritis, Gonorrhea, and Other	problem and super infection				
216.	a) Beacon Pharmaceuticals Ltd. Kathali, Bhauka, Mymensingh b) Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cabozantinib 20mg Capsule	Cabozantinib (S)-Malate INN 25.340mg eqv. to Cabozantinib 20mg	Anticancer	It is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer	**Contra-indication:** None **Side-effect:** The most commonly reported adverse drug reactions (≥25%) are diarrhea, stomatitis, palmar-plantar erythrodysesthesia syndrome (PPES), decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, and constipation. The most common laboratory abnormalities (≥25%) are increased AST, increased ALT, lymphopenia, increased alkaline phosphatase, hypocalcemia, neutropenia, thrombocytopenia, hypophosphatemia, and hyperbilirubinemia.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
217.	a) Beacon Pharmaceuticals Ltd. Kathali, Bhauka, Mymensingh b) Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Cabozantinib 80mg Capsule	Cabozantinib (S)-Malate INN 101.36mg eqv. to Cabozantinib 80mg	Anticancer	It is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer	**Contraindication:** None **Side-effect:** The most commonly reported adverse drug reactions (≥25%) are diarrhea, stomatitis, palmar-plantar erythrodysesthesia syndrome (PPES), decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, and constipation. The most common laboratory abnormalities (≥25%) are increased AST, increased ALT, lymphopenia, increased alkaline phosphatase, hypocalcemia,	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						neutropenia, thrombocytopenia, hypophosphatemia, and hyperbilirubinemia.				
218.	Beacon Pharmaceuticals Ltd. Kathali,Bhaluka, Mymensingh	Eribulin Mesylate 1mg/2ml Injection	Eribulin Mesylate INN 1mg/2ml	Anticancer	It is a microtubule inhibitor indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included	**Contra-indication: None** **Side-effect:**The most common adverse reactions (incidence ≥25%) were neutropenia, anemia, asthenia/fatigue, alopecia, peripheral neuropathy, nausea, and constipation	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
219.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Cabozantinib 60mg Tablet	Cabozantinib (S)-malate INN 76.00mg eq. to 60mg Cabozantinib	Anticancer	Cabozantinib is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.	**Contraindication:** Cabozantinib is contraindicated in patients with known hypersensitivity to it or any other components of this product. **Side effects:** The most common side effects of this tablet are- Hemorrhage**,** GI Perforations and Fistulas, Thrombotic Events, Hypertension and Hypertensive Crisis, Diarrhea, Palmar-plantarerythrodysesthesia syndrome, Reversible PosteriorLeukoencephalopathy Syndrome.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
220.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Ruxolitinib Phosphate 5mg Tablet	Ruxolitinib Phosphate INN 6.60mg (Eqv. to 5mg Ruxolitinib)	Anticancer	Ruxolitinib is indicated for treatment of patients with: Myelofibrosis(MF): intermediate or high-risk, including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. Polycythemia Vera: who have had an inadequate response to or are intolerant of hydroxyurea.	**Contraindication:** Ruxolitinib is contraindicated in patients with a history of hypersensitivity to Ruxolitinib or any other components of this product. **Side effects:** The most common side effects are-thrombocytopenia, anemia, neutropenia, risk of infection, bruising, dizziness, headache etc.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
221.	Drug International Ltd (Unit-2)	Ruxolitinib Phosphate 10mg Tablet	Ruxolitinib Phosphate INN 13.20mg (Eqv. to	Anticancer	Ruxolitinib is indicated for treatment of patients with: Myelofibrosis(MF):	**Contraindication:** Ruxolitinib is contraindicated in patients with a history of hypersensitivity to Ruxolitinib or any other	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur		10mg Ruxolitinib)		intermediate or high-risk, including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. Polycythemia Vera: who have had an inadequate response to or are intolerant of hydroxyurea.	components of this product. **Side effects:** The most common side effects are- thrombocytopenia, anemia, neutropenia, risk of infection, bruising, dizziness, headache etc.				
222.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur	Trabectedin INN 1.00 mg/Vial Lyophilized Powder for Injection for Infusion	Trabectedin INN 1.00mg/Vial	Anticancer	Trabectedin is an alkylating drug indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.	**Contraindication:** Trabectedin is contraindicated in patients with hypersensitivity to Trabectedin or any of the excipients. **Side effects:** The most common (≥20%) adverse reactions are nausea, fatigue, vomiting, constipation, decreased appetite, diarrhea, peripheral edema, dyspnea, and headache. The most common (≥5%) grades 3-4 laboratory abnormalities are: neutropenia, increased ALT, thrombocytopenia, anemia, increased AST,	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
223.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Olaparib 100 mg Tablet	Olaparib INN 100 mg	Anticancer	It is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated: • for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. • for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated	**Contraindications:** None **Side Effects:** • Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in <1.5% of patients exposed to Lynparza monotherapy and the majority of events had a fatal outcome. Monitor patients for hematological toxicity at baseline and monthly thereafter. Discontinue if MDS/AML is confirmed. • Pneumonitis: Occurred in <1% of patients exposed to Lynparza, and some cases were fatal. Interrupt treatment if pneumonitis is suspected. Discontinue if pneumonitis is confirmed. • Embryo-Fetal Toxicity: Can cause fetal	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.	harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.				
224.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Olaparib 150 mg Tablet	Olaparib INN 150 mg	Anticancer	It is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated: • for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. • for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.	**Contraindications:** None **Side Effects:** Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in <1.5% of patients exposed to Lynparza monotherapy and the majority of events had a fatal outcome. Monitor patients for hematological toxicity at baseline and monthly thereafter. Discontinue if MDS/AML is confirmed. **Pneumonitis:** Occurred in <1% of patients exposed to Lynparza, and some cases were fatal. Interrupt treatment if pneumonitis is suspected. Discontinue if pneumonitis is confirmed. **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
225.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Pembrolizumab 100mg/4ml injection	Pembrolizumab 100mg/4ml	Anticancer	It is a human programmed death receptor-1 (PD-1)-blocking antibody indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression	**Contra-indication:** None **Side-effect:** Most common adverse reactions (reported in ≥20% of patients) included fatigue, cough, nausea, pruritus, rash, decreased appetite, constipation, arthralgia, and diarrhea	50mg/vial	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon ve					
226.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Alectinib150mg Capsule	Alectinib Hydrochloride INN 161.33mg eqv. to Alectinib150mg	Anticancer	It is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for thisindication may be contingent upon verification and description of clinical benefit in confirmatory trials	**Contra-indication:** None **Side-effect:** The most common adverse reactions (incidence ≥20%) were fatigue, constipation, edema and myalgia.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
227.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Nilotinib 150mg Capsule	Nilotinib Hydrochloride Monohydrate INN 165.45mg eqv. to Nilotinib 150mg	Anticancer	It is a kinase inhibitor indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia	**Contraindication:** Do not use in patients with hypokalemia, hypomagnesemia, or long QT syndrome. **Side-effect:** In CML-CP patients, the most commonly reported drug-related adverse reactions (>10%) were rash, pruritis, nausea, fatigue, headache, constipation, diarrhea and vomiting. The common serious drug-related	200mg Capsule	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					(CML) in adult patients resistant to or intolerant to prior therapy that included imatinib	adverse reactions were thrombocytopenia and neutropenia. In CML-AP patients, the most commonly reported drug-related adverse reactions (>10%) were rash, pruritus and constipation. The common serious drug-related adverse reactions were thrombocytopenia, neutropenia, pneumonia, febrile neutropenia, leukopenia, intracranial hemorrhage, elevated lipase and pyrexia.				
228.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Brentuximab Vedotin 50mg/Vial (as lyophilized powder)	Brentuximab Vedotin INN 50mg/Vial	Anticancer	It is a CD30-directed antibody-drug conjugate indicated for: • The treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates. The treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen. These indications are based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with ADCETRIS	**Contra-indication**: None **Side-effect:** The most common adverse reactions (≥20%) are neutropenia, peripheral sensory neuropathy, fatigue, nausea, anemia, upper respiratory tract infection, diarrhea, pyrexia, rash, thrombocytopenia, cough, and vomiting	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
229.	M/s Beacon Pharmaceuticals Ltd., Kathali,Bhauka,	Vinorelbine 30mg capsule	Vinorelbine Tartrate USP 41.56mg eqv. to Vinorelbine 30mg	Anticancer	First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer	**Contraindication:** With oral use concurrent radiotherapy if treating the liver .long-term oxygen therapy . previous significant surgicalresection of small bowel . previous	10mg/ml & 50mg/5ml injection	BNF-76 Page-906	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Mymensingh				(NSCLC), in combination with cisplatin. As a single agent, for the treatment of patients with metastatic NSCLC	significant surgical resection of stomach **Side-effect:** Common or very common Alopecia . anaemia . appetitedecreased . arthralgia . bone marrow depression (doselimiting) constipation . diarrhoea . dyspnoea . fever .hypertension . hypotension . increased risk of infection .leucopenia . myalgia . nausea . neutropenia (dose-limiting). pain . reflexes absent . stomatitis . thrombocytopenia .vomiting.				
230.	M/s Beacon Pharmaceuticals Ltd., Kathali,Bhauka, Mymensingh	Doxorubicin Hydrochloride 50mg/25ml (as pegylated Liposomal)	Doxorubicin Hydrochloride USP 50mg/25ml	Anticancer	Doxorubicin HCl is indicated as a component of multi-agent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer	**Contraindication:** Severe myelosuppression (baseline neutrophils <1500cells/mm3) or severe hepatic impairment. Cardiac disease (eg, severe myocardial insufficiency, arrhythmias). Recent MI. Previous treatment with max cumulative doses of anthracyclines, anthracenediones **Side-effect:** Alopecia . anaemia . anxiety . appetite decreased. arrhythmias. arthralgia. asthenia.bone marrow depression. breast pain. cachexia.cardiovascular disorder . chest discomfort . chills.constipation. cough. decreased leucocytes. dehydration.depression. diarrhoea. dizziness. drowsiness. dry mouth .dysphagia. dyspnoea. dysuria. electrolyte imbalance.epistaxis. eye inflammation. fever. gastrointestinal discomfort. gastrointestinal disorders. headache.hyperhidrosis . hypersensitivity . hypertension.hyperthermia. hypotension . increased risk of infection influenza like illness. infusion related reaction . insomnia .malaise . mucosal abnormalities . muscle complaints .muscle tone increased . muscle weakness . nail disorder .nausea . nerve disorders . neutropenia . oedema . oral disorders. pain. scrotal erythema . sensation abnormal .sepsis . skin reactions .skin ulcer. syncope. taste	10mg/Vial 50 mg/vial	BNF-76 Page-877	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						altered .thrombocytopenia. vasodilation . vision blurred. vomiting. weight decreased				
231.	M/s Beacon Pharmaceuticals Ltd., Kathali,Bhauka, Mymensingh	Doxorubicin Hydrochloride 20mg/10ml (as pegylated Liposomal)	Doxorubicin Hydrochloride USP 20mg/10ml	Anticancer	Doxorubicin HCl is indicated as a component of multi-agent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer	**Contraindication:** Severe myelosuppression (baseline neutrophils <1500cells/mm3) or severe hepatic impairment. Cardiac disease (eg, severe myocardial insufficiency, arrhythmias). Recent MI. Previous treatment with max cumulative doses of anthracyclines, anthracenediones **Side-effect**: Alopecia . anaemia . anxiety . appetite decreased. arrhythmias. arthralgia. asthenia.bone marrow depression. breast pain. cachexia .cardiovascular disorder . chest discomfort . chills .constipation. cough. decreased leucocytes. dehydration .depression . diarrhoea. dizziness . drowsiness . dry mouth .dysphagia . dyspnoea . dysuria . electrolyte imbalance .epistaxis . eye inflammation . fever . gastrointestinal discomfort. gastrointestinal disorders . headache .hyperhidrosis . hypersensitivity . hypertension.hyperthermia . hypotension . increased risk of infection influenza like illness . infusion related reaction . insomnia .malaise . mucosal abnormalities . muscle complaints .muscle tone increased . muscle weakness . nail disorder .nausea . nerve disorders . neutropenia . oedema . oral disorders . pain . scrotal erythema . sensation abnormal .sepsis . skin reactions . skin ulcer . syncope . taste altered .thrombocytopenia . vasodilation . vision blurred. vomiting. weight decreased		BNF-76 Page-877	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
232.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Idarubicin Hydrochloride 20mg/vial (as Lyophilized Powder)	Idarubicin Hydrochloride 20 mg/vial	Anticaner	Idarubicin PFS Injection in combination with other approved antileukemic drugs is indicated for the treatment of acute myeloid	**Contra-indication:** None **Side-effect:** Approximately 550 patients with AML have received idarubicin in combination with cytarabine in controlled clinical trials	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					leukemia (AML) in adults. This includes French-American-British (FAB) classifications M1 through M7	worldwide. In addition, over 550 patients with acute leukemia have been treated in uncontrolled trials utilizing idarubicin as a single agent or in combination. The table below lists the adverse experiences reported in U.S. Study 2 (see CLINICAL STUDIES) and is representative of the experiences in other studies. These adverse experiences constitute all reported or observed experiences, including those not considered to be drug related. Patients undergoing induction therapy for AML are seriously ill due to their disease, are receiving multiple transfusions, and concomitant medications including potentially toxic antibiotics and antifungal agents.				
233.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Ruxolitinib20mg Tablet	Ruxolitinib Phosphate INN 26.40mg eqv. to Ruxolitinib 20mg	Anticaner	It is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis	**Contra-indication:** None **Side-effect:**The most common hematologic adverse reactions (incidence > 20%) are thrombocytopenia and anemia. The most common non-hematologic adverse reactions (incidence >10%) are bruising, dizziness and headache	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
234.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Roxilitinib 5 mg Tablet	Ruxolitinib Phosphate INN 6.6mg eqv. to Ruxolitinib 5mg	Anticaner	It is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis	**Contra-indication:** None **Side-effect:**The most common hematologic adverse reactions (incidence > 20%) are thrombocytopenia and anemia. The most common non-hematologic adverse reactions (incidence >10%) are bruising, dizziness and headache	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
235.	M/s Beacon	Ruxolitinib10mg Tablet	Ruxolitinib	Anticaner	It is a kinase inhibitor	**Contra-indication:** None	New	USFDA	অনুমোদন করা	অনুমোদন করা

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh		Phosphate INN 13.20mg eqv. to Ruxolitinib10mg		indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia veramyelofibrosis and post-essential thrombocythemia myelofibrosis	**Side-effect:** The most common hematologic adverse reactions (incidence > 20%) are thrombocytopenia and anemia. The most common non-hematologic adverse reactions (incidence >10%) are bruising, dizziness and headache			যেতে পারে।	হল।
236.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Ruxolitinib15mg Tablet	Ruxolitinib Phosphate INN 19.80mg eqv. to Ruxolitinib 15mg	Anticaner	It is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis	**Contra-indication:** None **Side-effect:**The most common hematologic adverse reactions (incidence > 20%) are thrombocytopenia and anemia. The most common non-hematologic adverse reactions (incidence >10%) are bruising, dizziness and headache	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
237.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Ruxolitinib25mg Tablet	Ruxolitinib Phosphate INN 33.00mg eqv. to Ruxolitinib 25mg	Anticaner	It is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.	**Contra-indication:** None **Side-effect:**The most common hematologic adverse reactions (incidence > 20%) are thrombocytopenia and anemia. The most common non-hematologic adverse reactions (incidence >10%) are bruising, dizziness and headache.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
238.	M/s Beacon Pharmaceuticals Ltd. Kathali,Bhauka, Mymensingh	Palifermin 6.25 mg Injection (as Lyophilized Powder)	Palifermin INN 6.25mg/vial	Anticaner	It is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic	**Contra-indication:** it is contraindicated in patients with known hypersensitivity to E coli-derived proteins, palifermin, or any other component of the product **Side-effect:** Most common adverse reactions (incidence ≥20% and 5%≥placebo) are rash,	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					stem cell support. The safety and efficacy of Kepivance™ have not been established in patients with nonhematologic malignancies	fever, elevated serum amylase (Grade 3/4), pruritus, erythema, and edema				
239.	General Pharmaceutical Ltd., Gazipur	Fluoxetine Hydrochloride 40mg Capsule	Fluoxetine Hydrochloride 44.80mg eq. to 40mg Fluoxetine	Antidepressant	Fluoxetine is a selective serotonin reuptake inhibitor indicated for: • Acute and maintenance treatment of Major Depressive Disorder (MDD) in adult and pediatric patients aged 8 to 18 years • Acute and maintenance treatment of Obsessive Compulsive Disorder (OCD) in adult and pediatric patients aged 7 to 17 years • Acute and maintenance treatment of Bulimia Nervosa in adult patients • Acute treatment of Panic Disorder, with or without agoraphobia, in adult patients	**Contraindication:** Do not use with an MAOI or within 14 days of discontinuing an MAOI due to risk of drug interaction. At least 5 weeks should be allowed after stopping Fluoxetine before treatment with an MAOI. Do not use with pimozide due to risk of drug interaction or QTc prolongation • Do not use with thioridazine due to QTc interval prolongation or potential for elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing Fluoxetine. **Side-Effect:** Most common adverse reactions (≥5% and at least twice that for placebo) associated with: Major Depressive Disorder, Obsessive Compulsive Disorder, Bulimia, and Panic Disorder: abnormal dreams, abnormal ejaculation, anorexia, anxiety, asthenia, diarrhea, dry mouth, dyspepsia, flu syndrome, impotence, insomnia, libido decreased, nausea, nervousness, pharyngitis, rash, sinusitis, somnolence, sweating, tremor, vasodilatation, and yawn.	20mg Capsule & 400 mg/100 ml Oral Solution	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
240.	Delta Pharma Ltd.	Trelagliptin 100 mg film coated Tablets	Trelagliptin Succinate INN 133.0 mg eq. to	Antidiabetic	It is usually used to treat type II diabetes mellitus.	**Contra-indications:** • History of previously experienced any	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			Trelagliptin 100 mg			allergic reactions (itch, rash, etc.) to any medicines. • ketosis, diabetic coma or precoma, type 1 diabetes mellitus, severe infection, an injury, renal disorder, pituitary abnormality or adrenal disease. • pre- or post-operative status or weakened • Do not consume an adequate diet • vigorous exercise or taking a large amount of alcohol. • pregnant or breastfeeding. • any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.) **Side-effects:** Nasopharyngitis, rash and itching. Warning and Precautions: • Strictly follow the instructions on dietary/exercise therapy. • This medicine may cause hypoglycemia. Pay close attention to operating dangerous machinery, such as working at heights or driving a car. Tell your family members and other people around you that you are taking this medicine. • When hypoglycemia symptoms occur, take an adequate amount of sugar (e.g., sugar, glucose, soft drinks). If you are taking the medicine concomitantly with an α-glucosidase inhibitor (medicines which delay absorption of sugar such as voglibose and acarbose), ingest glucose in case of any hypoglycemic symptoms.			যেতে পারে।	

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
241.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Empagliflozin 12.5mg + Metformin Hydrochloride Extended Release 1000 mg Tablet	Empagliflozin INN 12.5 mg + Metformin Hydrochloride BP 1000 mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.**Limitations of Use:** Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock.• Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. • Hepatic impairment, acute alcohol intoxication, alcoholism **Adverse reactions:** Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.	Empagliflozin 10mg & 25 mg Tablet Metformin Hydrochloride 500mg, 850mg, 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
242.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Empagliflozin 25 mg + Metformin Hydrochloride Extended Release 1000 mg Tablet	Empagliflozin INN 25 mg + Metformin Hydrochloride BP 1000 mg	Antidiabetic	It is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin hydrochloride, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2	Hypersensitivity to the active substances or to any of the excipients. • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma. • Severe renal failure (GFR <30 ml/min). • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock.• Disease which may cause tissue hypoxia (especially acute disease, or worsening	Empagliflozin 10mg & 25 mg Tablet Metformin Hydrochloride 500mg, 850mg, 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of SYNJARDY on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. **Limitations of Use:** Not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. • Hepatic impairment, acute alcohol intoxication, alcoholism **Adverse reactions**: Most common adverse reactions associated with empagliflozin (5% or greater incidence) were urinary tract infection and female genital mycotic infections. Most common adverse reactions associated with metformin (>5%) are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.				
243.	NIPRO JMI Pharma Ltd.	Empagliflozin 10mg + Linagliptin 5mg Film Coated Tablet	EmpagliflozinIN N 10 mg + Linagliptin INN 5 mg	Antidiabetic	This drug is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate. **Limitation of use:** It is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	**Contraindications:**It is contraindicated in patients with - severe renal impairment, end-stage renal disease, or dialysis. It is also contraindicated in patients with history of serious hypersensitivity reaction to empagliflozin, linagliptin, or any of the excipients in this drug. **Side effects:** The most common adverse reactions associated with this drug (a 5% or greater incidence) were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
244.	NIPRO JMI Pharma Ltd.	Empagliflozin INN 25 mg + Linagliptin INN 5 mg Film Coated Tablet	EmpagliflozinIN N 25 mg + Linagliptin INN 5 mg	Antidiabetic	This drug is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate. **Limitation of use:** It is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	**Contraindications:** It is contraindicated in patients with - severe renal impairment, end-stage renal disease, or dialysis. It is also contraindicated in patients with history of serious hypersensitivity reaction to empagliflozin, linagliptin, or any of the excipients in this drug. **Side effects:** The most common adverse reactions associated with this drug (a 5% or greater incidence) were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
245.	Opsonin Pharma Limited, Rupatoli, Barisal.	Acetylcysteine 200 mg/ml injection	Acetylcysteine USP 200 mg/ml	Antidote	To prevent or lessen hepatic injury from paracetamol overdose	Acetylcysteine is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components in the preparation. **Side-effects:** The most frequently reported adverse events attributed to I.V. acetylcysteine administration were rash, urticaria, and pruritus.The frequency of adverse events has been reported to be between 0.2% and 20.8%, and they most commonly occur during the initial loading dose of acetylcysteine.	Acetylcycteine 600 mg Dispersible/ Effervescent tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
246.	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	Palonosetron 0.25 mg Oral dispersible Tablet	Palonosetron Hydrochloride INN 0.280mg eqv to Palonosetron 0.25 mg	Antiemetic	Palonosetron a serotonin subtype 3 (5-HT3) receptor antagonist, are indicated for: Moderately emetogenic cancer chemotherapy -- prevention of acute nausea and vomiting associated with initial and repeat courses	**Contra-indication:it** is contraindicated in patients known to have hypersensitivity to the drug or any of its components **Side-effect:** No adverse reactions have been reported at an incidence of ≥5% for the 0.5 mg dose. Headache and constipation are the most common adverse reactions but occur less frequently	0.075mg, 0.25mg injection And 0.5mg Tablet And 0.5mg capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
247.	M/s Beacon Pharmaceuticals Ltd., Kathali,Bhauka, Mymensingh	Fosapretitant 150mg/vial	Fosaprepitant Dimeglumine INN 245.30mg eqv to Fosapretitant 150mg/vial	Antiemetic	Its for Injection, in combination with other antiemetic agents, is indicated for the: • 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:** EMEND for Injection is contraindicated in patients who are hypersensitive to EMEND for Injection, aprepitant, and polysorbate 80 or any other components of the product. Aprepitant, when administered orally, is a moderate cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitor following the 3-day antiemetic dosing regimen for CINV. Since fosaprepitant is rapidly converted to aprepitant, fosaprepitant should not be used concurrently with pimozide, terfenadine, astemizole, or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions **Side-effect**: The overall safety of aprepitant was evaluated in approximately 4900 individuals. Since EMEND for Injection is converted to aprepitant, those adverse experiences associated with aprepitant might also be expected to occur with EMEND for Injection. Fosaprepitant (intravenous formulation) In a randomized, open-label, incomplete crossover, bioequivalence study, 66 subjects were dosed with 115 mg of EMEND for Injection intravenously and 72 subjects received 125 mg of aprepitant orally. Systemic exposure of 115 mg of intravenous EMEND for Injection is equivalent to 125 mg oral aprepitant. The following clinical adverse experiences, regardless of causality, were reported in subjects dosed with EMEND for Injection: infusion site pain, 5 (7.6%); infusion site induration, 1(1.5%); headache, 2(3%).	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
248.	Navana Pharmaceuticals Limited	Hyoscine Hydrobromide 300mcg Tablet	Hyoscine Hydrobromide BP 300mcg	Antiemetic	For the prevention of motion sickness	Contraindicated in Glaucoma. Some patients may experience cholinergic signs and symptoms such as dry mouth, dizziness, blurred vision, dilatation of the pupils with loss of accommodation, photophobia, closed angle glaucoma (very rare), urinary disturbances (urinary emergency and retention), reduced bronchial secretions, transient bradycardia (followed by tachycardia, palpitation and arrhythmias), flushing and dryness of the skin, constipation, nausea and vomiting. Other signs and symptoms may include hallucination, high temperature (due to decreased sweating) and confusion. These may occur in all patient groups although certain populations (children and the elderly) are more susceptible to anticholinergic toxicity.	150 mcg chewable Tablet	BNF-76 Page-434 MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
249.	Opsonin Pharma Limited, Rupatoli, Barisal	Palonosetron 0.25mg /5 ml Syrup	Palonosetron Hydrochloride USP 0.25 mg/5 ml	Antiemetic	Indicated for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy.	**Contraindication:** Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. **Side-effects:** The following adverse reactions were reported for palonosetron: Nervous System: <1%: headache, dizziness, and dyskinesia. General: <1%: infusion site pain Dermatological: <1%: allergic dermatitis, skin disorder	Palonosetron 0.5mg Tablet & Capsule, 0 .25 mg/vial Injection & 0.075 mg/1.5 ml		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
250.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka	Simethicone 180 mg soft gelatin capsule	Simethicone USP 180 mg	Antiflautulent	Simethicone is an over-the-counter (OTC) drug that treats symptoms of gas, which may include painful pressure, fullness, and bloating.	**Contraindication:** With severe hypersensitivity to milk proteins. Who have demonstrated hypersensitivity to fluticasone furoate,umeclidinium, vilanterol or any of the excipients **Side-effects:** Simethicone typically does not cause any side effects when taken as	40 mg Chewable Tablet 67 mg/ml Paediatric Drops		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						directedBut the following side effect sometimes occur: abdominal pain, nausea, vomiting and constipation, allergic reactions such as skin rash, pruritus, angioedema, edema of the face, lips, throat and tongue or difficulty breathing.Bowel Dysfunction Bladder Dysfunction				
251.	Incepta Pharmaceuticals Ltd.; Dhamrai Unit, Dhaka	Simethicone 250mg soft gelatin capsule	Simethicone USP 250mg	Antiflautulent	Simethicone is an over-the-counter (OTC) drug that treats symptoms of gas, which may include painful pressure, fullness, and bloating.	**Contraindication:** With severe hypersensitivity to milk proteins. Who have demonstrated hypersensitivity to fluticasone furoate,umeclidinium, vilanterol or any of the excipients **Side-effects:**Simethicone typically does not cause any side effects when taken as directedBut the following side effect sometimes occur: abdominal pain, nausea, vomiting and constipation,allergic reactions such as skin rash, pruritus, angioedema, edema of the face, lips, throat and tongue or difficulty breathing.Bowel Dysfunction Bladder Dysfunction.	40 mg Chewable Tablet 67 mg/ml Paediatric Drops		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
252.	Beacon Pharmaceuticals Ltd. Kathali,Bhaluka, Mymensingh	Emicizumab 30mg/1ml vial	Emicizumab INN 30mg/1ml	Antihemophilic Agent	It a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	**Contra-indication: None** **Side-effect:** Most common adverse reactions (incidence ≥10%) are injection site reactions, headache, and arthralgia	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
253.	Beacon Pharmaceuticals Ltd.	Emicizumab 60mg/0.4ml vial	Emicizumab INN 60mg/0.4ml	Antihemophilic Agent	It a bispecific factor IXa- and factor X-directed antibody indicated for	**Contra-indication: None** **Side-effect:** Most common adverse reactions	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Kathali,Bhaluka, Mymensingh				routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	(incidence ≥10%) are injection site reactions, headache, and arthralgia				
254.	Beacon Pharmaceuticals Ltd. Kathali,Bhaluka, Mymensingh	Emicizumab 105mg/0.7ml vial	Emicizumab INN 105mg/0.7ml	Antihemophilic Agent	It a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	**Contra-indication: None** **Side-effect:** Most common adverse reactions (incidence ≥10%) are injection site reactions, headache, and arthralgia	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
255.	Beacon Pharmaceuticals Ltd. Kathali,Bhaluka, Mymensingh	Emicizumab 150mg/1ml vial	Emicizumab INN 150mg/1ml	Antihemophilic Agent	It a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	**Contra-indication: None** **Side-effect:** Most common adverse reactions (incidence ≥10%) are injection site reactions, headache, and arthralgia	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
256.	a) Acme Laboratories Ltd., Dhamrai, Dhaka b) Delta Pharma	Baricitinib 2 mg film coated Tablets	Baricitinib INN 2 mg	Antiheumatic Drugs	Baricitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an	**Contra-indications**: None Side-effects: Upper respiratory tract infections, Nausea, herpes simplex and herpex zoster.	New	USFDA (2018) BNF-76 Page: 1071	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Ltd.				inadequate response to one or more TNF antagonist therapies.	**Warning and Precautions:** • Serious Infections: Avoid use of Baricitinib in patients with active, serious infection, including localized infections. If a serious infection develops, interrupt Baricitinib therapy until the infection is controlled. Do not give Baricitinib to patients with active tuberculosis. • Thrombosis & Gastrointestinal perforations: Use with caution in patients who may be at increased risk. • Laboratory Assessment: Recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids. • Vaccinations: Avoid use of Baricitinib with live vaccines.				
257.	Delta Pharma Ltd.	Baricitinib 4 mg Film Coated Tablet	Baricitinib INN 4 mg	Antiheumatic Drugs	Baricitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.	**Contra-indications:** None Side-effects: Upper respiratory tract infections, Nausea, herpes simplex and herpex zoster. **Warning and Precautions:** Serious Infections: Avoid use of Baricitinib in patients with active, serious infection, including localized infections. If a serious infection develops, interrupt Baricitinib therapy until the infection is controlled. Do not give Baricitinib to patients with active tuberculosis. Thrombosis & Gastrointestinal perforations: Use with caution in patients who may be at increased risk. Laboratory Assessment: Recommended due to potential changes in lymphocytes, neutrophils,	New	BNF-76 Page: 1071	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						hemoglobin, liver enzymes and lipids.Vaccinations: Avoid use of Baricitinib with live vaccines.				
258.	Opsonin Pharma Limited, Rupatoli, Barisal	Phenylephrine Hydrochloride 1 gm + Promethazine Hydrochloride 125 mg/100 ml Syrup	Phenylephrine Hydrochloride USP 1 gm + Promethazine Hydrochloride USP 125 mg	Antihistamine	upper respiratory Symptoms, including nasal congestion, associated with allergy or the common cold.	**Contraindication:** Contraindicated for Children under 2 years of age. Promethazine is contraindicated for use in the treatment of lower respiratory tract symptoms, Including asthma. Phenylephrine is contraindicated in patients with hypertension or with peripheral vascular insufficiency Promethazine: CNS Depression, Drowsiness, Sedation, **Side-effects:** somnolence, blurred vision, dizziness; confusion, disorientation, and Tinnitus, incoordination, fatigue, euphoria, nervousness, diplopia, insomnia, tremors, convulsive seizures, excitation. Phenylephrine: Restlessness, anxiety, nervousness and dizziness, Hypertension, Precordial pain, respiratory distress, tremor, and weakness.	Promethazine 25 and Syrup; Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride + Triprolidine Hydrochloride Syrup	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
259.	Opsonin Pharma Limited, Rupatoli, Barisal.	Diphenhydramine Hydrochloride 38mg + Ibuprofen 200 mg Tablet	Diphenhydramine Hydrochloride USP 38 mg + Ibuprofen DC 85 Ph. Grade 235.3 mg contains Ibuprofen BP 200 mg	Antihistamine + NSAIDS	Pain reliever Nighttime sleep-aid and	**Contraindication:** Aspirin allergy, immediately before or after cardiac surgery. **Side-effects:** Upset stomach, nausea, Vomiting, headache, diarrhea, constipation, dizziness or drowsiness may occur. This medication may raise your blood pressure.	Diphenhydrami ne 50mg Tablet, Ibuprofen 200mg, 300mg & 400mg Tablet; 100mg/5ml Suspension		প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
260.	a) Pharmasia	Amlodipine 5 mg +	Amlodipine BP 5	Antihypertensive	Indicated for -	**Contraindication:** Hypotension, vasculitis,	New		প্রয়োজনীয়	প্রয়োজন নেই

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Limited Gazipur b) Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Telmisartan 40 mg + Hydrochlorothiazide 12.5 mg tablet	mg + Telmisartan BP 40 mg + Hydrochlorothiazide BP 12.5 mg		Essential Hyper tension High blood pressure	facial flush, respiratory distress, gum hypertrophy, eczema, rash, itchiness, hives, erythema, solar sensitiveness. **Side-effects:** Swelling of ankles or feet, Difficulty in breathing, Dizziness, Increased heartbeat, redness of face, neck, arms and chest, difficulty or painful urination.			রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	বিধায় আবেদন নামঞ্জুর করা হল।
261.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Methyldopa 125mg Film Coated Tablet	Methyldopa USP 125mg	Antihypertensive	Hypertension **Warnings:** It is important to recognize that a positive Coombs test, hemolytic anemia, and liver disorders may occur with methyldopa therapy. The rare occurrences of hemolytic anemia or liver disorders could lead to potentially fatal complications unless properly recognized and managed. Read this section carefully to understand these reactions.	**Contraindication:** It is contraindicated in patients: • with active hepatic disease, such as acute hepatitis and active cirrhosis • with liver disorders previously associated with methyldopa therapy • with hypersensitivity to any component of these products. • on therapy with monoamine oxidase (MAO) inhibitors. **Side effects:** Sedation, usually transient, may occur during the initial period of therapy or whenever the dose is increased. Headache, asthenia, or weakness may be noted as early and transient symptoms. However, significant adverse effects due to ALDOMET have been infrequent and this agent usually is well tolerated. The following adverse reactions have been reported and, within each category, are listed in order of decreasing severity. Cardiovascular: Aggravation of angina pectoris, congestive heart failure, prolonged carotid sinus hypersensitivity, orthostatic hypotension (decrease daily dosage), edema or weight gain, bradycardia. Digestive: Pancreatitis, colitis, vomiting, diarrhea, sialadenitis, sore or “black” tongue, nausea, constipation, distension, flatus, dryness	250mg and 500mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						of mouth. Endocrine: Hyperprolactinemia. Hematologic: Bone marrow depression, leukopenia, granulocytopenia, thrombocytopenia, hemolytic anemia; positive tests for antinuclear antibody, LE cells, and rheumatoid factor, positive Coombs test. Hepatic: Liver disorders including hepatitis, jaundice, abnormal liver function tests Hypersensitivity: Myocarditis, pericarditis, vasculitis, lupus-like syndrome, drug-related fever, and eosinophilia. Nervous System/Psychiatric: Parkinsonism, Bell's palsy, decreased mental acuity, involuntary choreoathetotic movements, symptomsof cerebrovascular insufficiency, psychic disturbances including nightmares and reversible mild psychoses or depression, headache, sedation, asthenia or weakness, dizziness, lightheadedness, paresthesias. Metabolic: Rise in BUN. Musculoskeletal: Arthralgia, with or without joint swelling; myalgia. Respiratory: Nasal stuffiness. Skin: Toxic epidermal necrolysis, rash. Urogenital: Amenorrhea, breast enlargement, gynecomastia, lactation, impotence, decreased libido.				
262.	Opsonin Pharma Limited, Rupatoli, Barisal	Efonidipine Hydrochloride Ethanolate 40 mg Tablet	Efonidipine Hydrochloride Ethanolate INN 40 mg	Antihypertensive	Essential hypertension, Parenchymal hypertension & Angina	**Contraindication:** Those patients show hypersensitivity to Efonidipine or any of the excipients of the drug is contra-indicated. **Side-effects:** The common side effects are hot flushes, facial flushing and headache. Frequent urination, pedal edema, increased triglycerides occurs in less than 0.1%.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
263.	Opsonin Pharma Limited,	Efonidipine Hydrochloride Ethanolate 20 mg Tablet	Efonidipine Hydrochloride	Antihypertensive	Essential hypertension, Parenchymal hypertension	**Contraindication:** Those patients show hypersensitivity to Efonidipine or any of the	New		প্রয়োজনীয় রেফারেন্স নেই	প্রয়োজনীয় রেফারেন্স নেই

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Rupatoli, Barisal		Ethanolate INN 20 mg		& Angina	excipients of the drug is contra-indicated. **Side-effects:** The common side effects are hot flushes, facial flushing and headache. Frequent urination, pedal edema, increased triglycerides occurs in less than 0.1%.			বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	বিধায় আবেদন নামঞ্জুর করা হল।
264.	Opsonin Pharma Limited, Rupatoli, Barisal.	Bisoprolol fumarate 2.5 mg + Cilnidipine 5 mg Tablet	Bisoprolol fumarate USP 2.5 mg + Cilnidipine INN 5 mg	Antihypertensive	Hypertension	The Combination of Bisoprolol fumarate and Cilnidipine is not recommended for use if you have a history of allergy to Cilnidipine or any other component of this medicine.The Combination of Bisoprolol fumarate and Cilnidipine is not also recommended for use in patients having heart conditions like heart attack, rhythm disorders, angina, narrowing of blood vessels etc.The Combination of Bisoprolol fumarate and Cilnidipine shows side effects like Sleepiness, Headache, Ankle swelling, Flushing (sense of warmth in the face, ears, neck and trunk), Slow heart rate, Tiredness, Palpitations, Nausea, Edema (swelling), Constipation, Cold extremities.	Bisoprolol 2.5 , 5, 10 mg tablet & Cilnidipine 5, 10 mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
265.	Opsonin Pharma Limited, Rupatoli, Barisal.	Cilnidipine 10 mg + Olmesartan Medoxomil 20 mg Tablet	Cilnidipine INN 10 mg + Olmesartan Medoxomil BP 20 mg	Antihypertensive	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	**Contraindication:** Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis. **Side-effects:** Dizziness, Flushing, Headache, Hypotension, Palpitations, Dark urine, Abdominal pain, weakness, Rashes, Dry mouth, Excessive thirst	Cilnidipine 5 & 10 mg, Omesartan 10,20 & 40 mg		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
266.	Opsonin Pharma Limited, Rupatoli, Barisal.	Cilnidipine 5 mg + Olmesartan Medoxomil 20 mg Tablet	Cilnidipine INN 5 mg + Olmesartan Medoxomil BP 20 mg	Antihypertensive	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	**Contraindication:** Cardiogenic shock; recent MI or acute unstable angina; severe aortic stenosis. **Side-effects:** Dizziness, Flushing, Headache, Hypotension, Palpitations, Dark urine, Abdominal pain, weakness, Rashes, Dry	Cilnidipine 5 & 10 mg, Olmesartan 10,20 & 40 mg tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						mouth, Excessive thirst				
267.	Opsonin Pharma Limited, Rupatoli, Barisal.	Benidipine Hydrochloride 4 mg Tablet	Benidipine Hydrochloride INN 4 mg	Antihypertensive	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	**Contraindication:** Hypersensitivity to Benidipine is a contraindication. In addition, Benidipine should not be used in the following conditions: Allergic to any of its ingredients, Lactation & Pregnancy. **Side-effects:** Palpitation, flash, headache, rash, itch, photosensitivity, gynecomastia etc.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
268.	Opsonin Pharma Limited, Rupatoli, Barisal.	Benidipine Hydrochloride 8 mg Tablet	Benidipine Hydrochloride INN 8 mg	Antihypertensive	Hypertension, CKD with hypertension patients, Renal parenchymal hypertension, Diabetic neuropathy and angina pectoris.	Hypersensitivity to Benidipine is a contraindication. In addition, Benidipine should not be used in the following conditions: Allergic to any of its ingredients, Lactation & Pregnancy. **Side-effects:** Palpitation, flash, headache, rash, itch, photosensitivity, gynecomastia etc.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
269.	EVEREST Pharmaceuticals Ltd. Kanchpur BSCIC, Soanragon, Narayanagnj BANGLADESH	Diazoxide 50 mg Tablet	Diazoxide BP 50 mg	Antihypoglycemic	Chronic intractable hypoglycaemia	**Contraindication:** In the treatment of hypoglycaemia, Diazoxide is contraindicated in all cases which are amenable to surgery or other specific therapy. Hypersensitivity to any component of the preparation or other thiazides. **Side effects:** Taste disturbance; abdominal pain; anaemia; anorexia (prolonged use); bleeding; constipation; decreased libido; dermatitis; diarrhoea; dizziness; dyspnoea; eosinophilia; extrapyramidal effects; galactorrhoea; headache; heart failure; hyperglycaemia; hyperosmolar non-ketotic coma; hypertrichosis; hyperuricaemia (prolonged use); hypotension; ileus; lacrimation; leucopenia; lichenoid eruption; musculoskeletal pain; nausea; pancreatitis; pruritus; pulmonary hypertension; raised serum creatinine; raised serum urea; reversible nephritic syndrome; sodium and fluid retention; thrombocytopenia; tinnitus; transient cataracts;	New	BNF 76 Page no: 708	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						visual disturbances; vomiting				
270.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Tafenoquine 300mg Tablet	Tafenoquine Succinate INN 376.00 mg eq. toTafenoquine 300 mg	Antimalarial	An antimalarial indicated for the radical cure (prevention of relapse) of Plasmodium vivax malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute P. vivax infection.	**Contraindication:** G6PD deficiency or unknown G6PD status. Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown. Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of Tafenoquine. **Side-effects:** Commonadverse reactions (≥5%) were dizziness, nausea, vomiting, headache, and decreased hemoglobin.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
271.	Beacon Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh	Fremanezumab –vfrm 225mg/1.5mL pre-filled syringe	Fremanezumab –vfrm INN 225mg/1.5ml	Antimigrane	It is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults	**Contra-indication:** Fremanezumab is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients **Side-effect:** The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
272.	Drug International Ltd 252, Tongi I/A Tongi, Gazipur	Aflibercept INN 40mg/ml Solution for injection	Aflibercept INN 40mg/ml	Antineovascularisation Drugs	Aflibercept is indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR) In Patients with DME.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to any ingredient of the product. Aflibercept is contraindicated in patients with ocular or periocular infections & active intraocular inflammation **Side effects:** The most common adverse reactions (≥5%) reported in patients receivingAflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
273.	Navana Pharmaceuticals Limited	Lorcaserin hydrochloride 20 mg Extended Release Tablet	Lorcaserin Hydrochloride INN 20 mg	Anti-obesity	It is a serotonin 2C receptor agonist indicated as an adjunct to a reduced-calorie	**Contraindication:** Pregnancy and hypersensitivity.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					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 27kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes) **Limitations of Use**: The safety and efficacy of coadministration with other products for weight loss have not been established The effect of Lorcaserin on cardiovascular morbidity and mortality has not been established	**Side effects:** 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.			যেতে পারে।	
274.	NIPRO JMI Pharma Ltd.	Lorcaserin Hydrochloride 10mg Tablet	Lorcaserin Hydrochloride Hemihydrate INN 10.4 mg Eq. to Anhydrous Lorcaserin Hydrochloride 10.0 mg	Anti-Obesity	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	**Contraindication:** Pregnancy **Side effects:** • Coordination problems, uncontrolled muscle spasms or muscle twitching (overactive reflexes) • Restlessness • Racing or fast heart beat, high or low blood pressure • Sweating or fever • Nausea, vomiting, or diarrhea • Muscle rigidity (stiff muscles)	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes) **Limitations of Use**: The safety and efficacy of coadministration with other products for weight loss have not been established (1) • The effect of BELVIQ on cardiovascular morbidity and mortality has not been established					
275.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Undenatured Type II Collagen 40mg Capsule	Undenatured Type II Collagen INN 40mg	Anti-ostioarthritis	The indications include: Supports joint health, flexibility and mobility Osteoarthritis Rheumatoid arthritis (RA) Pain associated with joint pain after surgery, pain after injury, and back and neck pain.	**Contraindication :** Hypersensitivity to or any of the ingredients. Patients receiving live virus immunization. **Side-effects:** Nausea, heartburn, diarrhea, constipation, skin reactions & headache.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
276.	Ziska Pharmaceuticals Ltd.	Triflusal 300 mg capsule	Trifusal BP 300 mg	Antiplatelet agent	Triflusal is primarily indicated in conditions like Prevention of thrombosis, Thromboembolism.	**Contraindications**: Trifusal is contra-indicated in patients with: • hypersensitivity to Trifusal or other salicylates • active peptic ulcer or antecedents of complicated peptic ulcer; • any active bleeding. **Side effects:** The symptomatic adverse reactions produced by Triflusal are more or less tolerable and if they become severe, they can be treated symptomatically, these include GI disturbance.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
277.	Beacon	Amisulpride50mg Tablet	AmisulprideBP	antipsychotic	It is indicated for the	**Contra-indication:**	New	BNF-76	অনুমোদন করা	অনুমোদন করা

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceuticals Ltd. Kathali, Bhaluka, Mymensingh		50mg		treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.	CNSdepression.comatosestates. phaeochromocytoma.prolactin-dependenttumours **Side-effect:**Anxiety.breastpain. hypersalivation.musclerigidity.nausea.oculogyriccrisis.trismus.vomiting		Page-390	যেতে পারে।	হল।
278.	Opsonin Pharma Limited, Rupatoli, Barisal.	Rabeprazole Sodium 20 mg/Vial IV Injection	Rabeprazole Sodium INN 20 mg IV	Antiulcerant	Sequential-therapy (step-up) from oral rabeprazole, e.g. a patient previously on oral rabeprazole who is temporarily unable to take oral medication for any reason, Healing of erosive or ulcerative gastro-esophageal reflux disease; Maintenance of healing of erosive or ulcerative gastro-esophageal reflux disease; Benign gastric ulcer; Healing of duodenal ulcer; Treatment of 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:** Dry mouth, nausea and vomiting, constipation, flatulence, abdominal pain, diarrhea, hypersensitivity reactions (including rash, urticaria, angioedema, bronchospasm, anaphylaxis), peripheral oedema, depression, dizziness, drowsiness, headache, insomnia, fever, blurred vision, photosensitivity, pruritus, severe skin reactions (including Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous eruption), sweating, malaise anorexia, weight gain.	10mg & 20 mg Tablet & Capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
279.	Opsonin Pharma Limited, Rupatoli, Barisal.	Dexrabeprazole 5 mg tablet	Dexrabeprazole INN 5 mg	Antiulcerant	Gastro-esophageal reflux disease, Healing of gastric ulcer, Healing of duodenal ulcer, Ulcerative Colitis.	**Contraindication:** Dexrabeprazole is contraindicated in patients with known hypersensitivity to Dexrabeprazole, or to any component of the formulation. **Side-effects:** Gastrointestinal: Nausea,	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						vomiting, stomach pain, diarrhea and gas.				
280.	Opsonin Pharma Limited, Rupatoli, Barisal.	Dexrabeprazole 10 mg tablet	Dexrabeprazole INN 10 mg	Antiulcerant	Gastro-esophageal reflux disease, Healing of gastric ulcer, Healing of duodenal ulcer, Ulcerative Colitis.	**Contraindication:** Dexrabeprazole is contraindicated in patients with known hypersensitivity to Dexrabeprazole, or to any component of the formulation. **Side-effects:** Gastrointestinal: Nausea, vomiting, stomach pain, diarrhea and gas.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
281.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Ilaprazole 10mg enteric coated Tablet	Ilaprazole INN 10mg	Antiulcerant	Indicated for the treatment of- Dyspepsia Peptic ulcer disease (PUD) Gastroesophageal reflux disease (GERD) Duodenal ulcer	**Contraindication:** Ilaprazole should not be prescribed to individuals who are allergic to other PPIs. **Side-effects:** Nausea, Abdominal pain, Constipation, Diarrhoea, Flatulence.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
282.	Beximco Pharmaceuticals Ltd., Tongi	Lamivudine 30.00 mg + Nevirapine 50.00 mg + Zidovudine 60.00 mg oral dispersible Tablet	Lamivudine USP 30.00mg + Nevirapine USP 50.00mg + Zidovudine USP 60.00 mg	Antiviral	It is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected children weighing less than 25 kg. This fixed combination replaces the three components (lamivudine, nevirapine and zidovudine) used separately in similar dosages.	It is contraindicated in patient with Severe hepatic impairment (Child-Pugh C or ALT or AST values >5 times the upper limit of normal, history with severe rash accompanied by liver toxicity due to nevirapine and patient with abnormally low neutrophil counts (less than 0.75 x 109 /litre) or abnormally low haemoglobin level (less than 7.5 g/decilitre or 4.7 mmol/litre). **Side Effects:** The most common side effects of this medication are epidermal necrolysis, serious hepatitis/hepatic failure, and drug reaction with eosinophilia and systemic symptoms, characterised by rash with constitutional symptoms such as fever, arthralgia, myalgia and lymphadenopathy, plus visceral involvement, such as hepatitis, eosinophilia, renal dysfunction and some frequent side effects are headache, nausea, diarrhoea, abdominal pain.	Lamivudine 150 mg + Nevirapine 200 mg + Zidovudine 300mg tablet	USFDA (Tentatative approval)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
283.	Beximco	Tenofovir Disoproxil	Tenofovir	Antiviral	It is indicated for the	The combination is contraindicated in patients	Emtricitabine	USFDA	অনুমোদন করা	অনুমোদন করা

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceuticals Ltd., Tongi	Fumarate 300.00 mg + Emtricitabine 200.00 mg + Efavirenz 600.00 mg Tablet	Disoproxil Fumarate USP 300.00 mg + Emtricitabine USP 200.00 mg + Efavirenz USP 600.00 mg		treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over with virologic suppression to HIV-1 RNA levels of < 50 copies/ml on their current combination antiretroviral therapy for more than three months.	with previously demonstrated hypersensitivity to any of the components of the product. Tenofovir DF and efavirenz have not been studied in patients younger than 3 years of age or weighing less than 13 kg (28.7 lbs). The combination is not recommended for pediatric administration. Adverse effects commonly associated with efavirenz use include impaired concentration, anorexia, abdominal pain, anxiety, and pruritus. Pancreatitis has been reported, although a causal relationship with efavirenz has not been established.	200 mg + Tenofovir Disoproxil Fumarat 300mg tablet		যেতে পারে।	হল।
284.	Beximco Pharmaceuticals Ltd., Tongi	Lamivudine 300 mg Tablet	Lamivudine 300 mg	Antiviral	Lamivudine is indicated as part of antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infected adults and children.	It is contraindicated in patients with previous hypersensitivity reaction to lamivudine. It may causes some serious side effect like stomach pain, shallow breathing, muscle pain, weakness, feeling cold or dizzy and some common side effects like cough, diarrhea, fatigue, headache etc.	100mg & 150mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
285.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Caffeine 10mg/ml injection	Caffeine anhydrous USP 10mg + Citric Acid Monohydrate (API Precursor) 5.00mg/ml	Bronchial smooth muscle relaxant,CNS stimulant	It is indicated for the short term treatment of apnea of prematurity in infants between 28 and <33 weeks gestational age.	**Contraindication:** (caffeine citrate) is contraindicated in patients who have demonstrated hypersensitivity to any of its components. **Side-effects:** central nervous system stimulation (i.e., irritability, restlessness, jitteriness), cardiovascular effects (i.e., tachycardia, increased left ventricular output, and increased stroke volume),gastrointestinal effects (i.e., increased gastricaspirate, gastrointestinal intolerance), alterations in serum glucose (hypoglycemia and hyperglycemia) and renal effects (increased urine flow rate,increased creatinine clearance,	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						and increased sodium and calcium excretion).				
286.	Opsonin Pharma Limited, Rupatoli, Barisal.	Digoxin 0.5 mg /2 ml injection	Digoxin USP 0.5 mg/2 ml	Cardiovascular	It is a cardiac glycoside indicated for: Treatment of mild to moderate heart failure in adults. Increasing myocardial contractility in pediatric patients with heart failure. Control of resting ventricular rate in adults with chronic atrial fibrillation.	**Contraindication:** Digoxin is contraindicated in patients with ventricular fibrillation or in patients with a known hypersensitivity to digoxin. A hypersensitivity reaction to other digitalis preparations usually constitutes a contraindication to digoxin. **Side-effects:** These are principally associated with over dosage but may occur from temporary high serum concentration due to rapid absorption. They include anorexia.	0.25 mg Tablet & 60 ml Solution	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
287.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Loteprednol Etabonate 10 mg/ml sterile Ophthalmic suspension	Loteprednol Etabonate INN 10 mg/ml	Corticosteroid	It is a corticosteroid indicated for the treatment of post-operative inflammation and pain following occular surgery.	**Contraindications:** It 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. **Side Effects:** The most common adverse drug reactions were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.	0.5% Eye Drops 0.5% Eye Ointments	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
288.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Fluticasone Furoate 100mcg + Vilanterol 25 mcg Powder for Inhaler	Fluticasone Furoate INN 100mcg + Vilanterol Trifenatate INN 400mcg eq. to Vilanterol 25 mcg	Corticosteroid	Long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Reducing exacerbations in whom additional treatment of airflow obstruction is desired	**Contraindications:** With severe hypersensitivity to milk proteins. Who have demonstrated hypersensitivity to fluticasone furoate,, vilanterol or any of the excipients **Side Effects:**Increased risk of pneumonia in COPD Increased risk for decrease in bone mineral density Increase the risk of asthma-related death	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
289.	Incepta	Fluticasone Furoate 200	Fluticasone	Corticosteroid	Long-term, once-daily,	**Contraindications:** With severe	New	USFDA	অনুমোদন করা	অনুমোদন করা

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	mcg + Vilanterol 25 mcg Powder for Inhaler	Furoate INN 200mcg + Vilanterol Trifenatate INN 400 mcg eq. to Vilanterol 25 mcg		maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Reducing exacerbations in whom additional treatment of airflow obstruction is desired	hypersensitivity to milk proteins. Who have demonstrated hypersensitivity to fluticasone furoate,, vilanterol or any of the excipients **Side Effects:** Increased risk of pneumonia in COPD Increased risk for decrease in bone mineral density Increase the risk of asthma-related death.			যেতে পারে।	হল।
290.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Fluticasone Furoate 100mcg + Umeclidinium 62.5 mcg + Vilanterol 25 mcgPowder for Inhaler	Fluticasone Furoate INN 100 mcg + Umeclidinium Bromide INN 74.2 mcg eq. to Umeclidinium 62.5 mcg + Vilanterol Trifenate INN 40 mcg eq. to vilanterol 25 mcg	Corticosteroid	Long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Reducing exacerbations in whom additional treatment of airflow obstruction is desired.	**Contraindications:** With severe hypersensitivity to milk proteins. Who have demonstrated hypersensitivity to fluticasone furoate,umeclidinium, vilanterol or any of the excipients **Side Effects:** Candida albicans infection Increased risk of pneumonia in COPD Immunosuppression Hypercorticism and adrenal suppression Paradoxical bronchospasm Cardiovascular effects Reduction in bone mineral density Worsening of narrow-angle glaucoma Worsening of urinary retention.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
291.	Ziska Pharmaceuticals Ltd.	Dexamethasone 1 mg/g Oral Paste	Dexamethasone BP 1.0 mg/g	Corticosteroid	Intractable stomatitis or glossitis associated with erosion and ulceration	**Contraindication:** Hypersensitivity to Dexamethasone Oral Paste is a contraindication. In addition, Dexamethasone Oral Paste should not be used if the individual has the following conditions: Allergic to it in case of eye drops Glaucoma or diabetes **Side effects:** The most commonly reported side-effects of Dexamethasone Oral Paste are anaphylaxis, bradycardia, acne, allergic dermatitis, hyperglycemia, and fluid retention.	0.5 mg Tablet 0.01% Eye Drop		ঔষধটি External Preparetion। "রেজিষ্টার চিকিৎসকের ব্যবস্থাপত্র অনুযায়ী ব্যবহার করতে হবে", এই শর্তে পদটি অনুমোদন করা	ঔষধটি External Preparetion। "রেজিষ্টার চিকিৎসকের ব্যবস্থাপত্র অনুযায়ী ব্যবহার করতে হবে", এই শর্তে পদটি অনুমোদন করা

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
									যেতে পারে।	হল।
292.	Ziska Pharmaceuticals Ltd.	Clobetasol Propionate 0.05% + Salicylic Acid 6% ointment	Clobetasol Propionate BP 0.05% +Salicylic Acid BP 6%	Corticosteroid & keratolytic	Soltop Ointment is prescribed for dry, scaly and resistant Psoriasis, Hyperkeratotic Dermatoses, Recalcitrant Eczema, and Ichthyosis. Clobetasol, an analog of Prednisolone, has a high degree of Glucocorticoid activity and a slight degree of mineralocorticoid activity. Topical Salicylic Acid is used to clear and prevent pimples and skin blemishes in people who have acne.	**Contraindication/Warnings**:The ointment is not meant for children less than 12 years if age. This drug is contraindicated in patients who are under treatment for Ulcerative conditions, Rosacea, Pruritus, and acute infections. Also, the usage of the drug should be discontinued if hypersensitivity to any of its ingredients is noted. **Side effects:** • Perioral Dermatitis • Striae especially in flexures • Dermal and epidermal atrophy especially on the face • Steroid Purpura • Prolonged usage of the ointment in excessive amount can lead to sufficient systemic levels to Adrenal Suppression, Cushing's Syndrome, Diabetes and Hypertension.	Clobetasol Propionate BP 0.05% + Salicylic Acid BP 3% Ointment		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
293.	Opsonin Pharma Limited, Rupatoli, Barisal.	Cysteamine 440 mg/ 100 ml sterile Eye Drops	Cysteamine INN 0.44%	Cystine-depleting agent	Cystine-depleting agent indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis	**Contraindication:** None **Side-effects:** Clinical data reveled the most frequently reported ocular adverse reactions occurring in ≥10% of patients were sensitivity to light, redness, and eye pain/irritation, headache and visual field defects.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
294.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Dextrose Anhydrous 4.00gm + Potassium Chloride 0.150gm + Sodium Chloride 0.180gm +/100ml IV infusion	Dextrose Anhydrous USP 4.00gm + Potassium Chloride BP 0.150gm + Sodium Chloride BP 0.180gm /100ml	Electrolytes	The Potassium Chloride, Sodium Chloride and Glucose intravenous infusion is indicated for • Electrolyte imbalance • Replenishing fluid losses • as a energy source • Restoration and maintenance of sodium, potassiumand chloride ions in body fluids. •It may be used as a vehicle of drug delivery (where	**Contraindication:** The level of sodium and potassium in the Potassium Chloride, Sodium Chloride and Glucose is relatively low. Nevertheless it is contraindicated • In patients who has known hypersensitivity to the product • In patients suffering from conditionin which the administration of either sodium chloride or potassium chloride alone is contraindicated • In patien with hypernatraemia, hyperchloraemia and/or hyperkalaemia that are not related to the concentrationeffect associated to a volume depletion, severe renal insufficiency, uncompensated cardiac failure, Addison's disease	Dextrose 5gm + 225mg Sodium Chloride/100ml, Dextrose 5gm + 450mg Sodium Chloride/100ml,	BNF-76 Page: 1007 [Glucose 4.00gm + Potassium Chloride 0.150gm + Sodium Chloride	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					intravenous delivery is appropriate and the drug is compatible with this solution.	and patients whi ha had a head trauma within 24 hours. This solution is also contraindicated in patients with uncompensated diabetes, other known glucose intolerances, hyperglycemia and hyperlactataemia		0.180gm /100ml]		
295.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Dextrose Anhydrous 4.00gm + Potassium Chloride 0.300gm + Sodium Chloride 0.180gm +/100ml IV infusion	Dextrose Anhydrous USP 4.00gm + Potassium Chloride BP 0.300gm + Sodium Chloride BP 0.180gm /100ml	Electrolytes	The Potassium Chloride, Sodium Chloride and Glucose intravenous infusion is indicated for • Electrolyte imbalance • Replenishing fluid losses • as a energy source • Restoration and maintenance of sodium, potassiumand chloride ions in body fluids. •It may be used as a vehicle of drug delivery (where intravenous delivery is appropriate and the drug is compatible with this solution.	**Contraindication:** The level of sodium and potassium in the Potassium Chloride, Sodium Chloride and Glucose is relatively low. Nevertheless it is contraindicated • In patients who has known hypersensitivity to the product • In patients suffering from conditionin which the administration of either sodium chloride or potassium chloride alone is contraindicated • In patien with hypernatraemia, hyperchloraemia and/or hyperkalaemia that are not related to the concentrationeffect associated to a volume depletion, severe renal insufficiency, uncompensated cardiac failure, Addison's disease and patients whi ha had a head trauma within 24 hours. This solution is also contraindicated in patients with uncompensated diabetes, other known glucose intolerances, hyperglycemia and hyperlactataemia	Dextrose 5gm + 225mg Sodium Chloride/100ml, Dextrose 5gm + 450mg Sodium Chloride/100ml,	BNF-76 Page: 1007 [Glucose 4.00gm + Potassium Chloride 0.300gm + Sodium Chloride 0.180gm /100ml]	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
296.	a) Beacon Pharmaceuticals Ltd. Kathali, Bhauka, Mymensingh b) Incepta Pharmaceuticals Ltd.; Zirabo,	Paracetamol 1.67gm + Phenylephrine Hydrochloride 0.033gm + Guaifenesin 0.67gm/100 ml Syrup	Paracetamol BP 1.67gm + Phenylephrine Hydrochloride USP 0.033gm + Guaifenesin USP 0.67gm/100 ml	Expectorant	Short term relief of the symptoms of colds, chills and influenza, including mild to moderate pain, fever, nasal congestion, with an expectorant effect on a chesty cough. Theraflu Cold and Cough is only indicated in adults.	**Contraindicaion:** Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 Heart disease, hypertension Diabetes Hyperthyroidism Closed angle glaucoma Phaeochromocytoma Patients who are taking or have taken monoamine oxidase inhibitors (MAOIs) within the last two weeks (see section 4.5) Patients taking tricyclic antidepressants . Patients taking beta-blocking	New	MHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Savar, Dhaka					drugs. Patients taking other sympathomimetic drugs such as decongestants, appetite suppressants and amphetamine-like psychostimulants				
297.	Navana Pharmaceuticals Limited	Honey 1.11gm + Glycerol 0.75ml + Liquid Suagar 2.2ml/5ml Syrup	Honey BP 1.11gm + Glycerol BP 0.75ml + Liquid Suagar BP 2.2ml/5ml	Expectorant	For the relief of coughs and sore throats.	**Contraindication:** Hypersensitivity to any of the active components. **Side effect:** Immune system disorder: hypersensitivity reactions, including anaphylaxis.	New	MHRA (Tixylix Honey, Lemon & Glycerol Oral Solution)	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
298.	Opsonin Pharma Limited, Rupatoli, Barisal.	Butamirate Citrate 4 mg + Guaifenesin 100 mg/5 ml Syrup	Butamirate Citrate BP 4 mg + Guaifenesin BP 100 mg/5 ml	Expectorant	Symptomatic treatment of cough of various origin	**Contraindication:** Hypersensitivity to butamirate citrate or to any of the ingredients. **Side-effects:** Butamirate is usually well tolerated. The most common side effects include:Central Nervous System (CNS) dizziness (1%).Digestive system: Nausea, diarrhea, Allergic Reaction: Skin rash and itching (in rare cases)	Butamirate citrate 50 mg Tablet, 150 mg/100 ml syrup & Dextromethorphan Hydrobromide 300 mg + Guaifenesin 4 gm + Menthol 300 mg/100 ml syrup.		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
299.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Balsalazide Disodium 1100 mg Tablet	Balsalazide Disodium USP 1100 mg	Gastrointestinal Agent	Indicated for treatment of Mildly to moderately active ulcerative colitis in male patients 18 years of age and older.	**Contraindication:** Balsalazide Disodium tablets are contraindicated in patients with hypersensitivity to salicylates, aminosalicylates, or their metabolites or to any of the components of Balsalazide disodium tablets.. **Side-effects:** The most common adverse reactions occurring in at least 2% of male patients and at a rate greater than placebo in the	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						clinical study were anemia, diarrhea, pharyngolaryngeal pain, urinary tract infection, arthralgia, insomnia, and musculoskeletal pain.				
300.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur	Methylnaltrexone Bromide 150mg Tablet	Methylnaltrexone Bromide INN 150mg	Gastrointestinal Agent	Methylnaltrexone Bromide is an opioid antagonist. Methylnaltrexone Bromide tablets are indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Limitations of Use: Use beyond four months has not been studied in the advanced illness population.	**Contra-indication:** It is contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation. **Adverse Reactions:** The most common adverse reactions are: OIC in adult patients with chronic non-cancer pain (6.1) • RELISTOR tablets (≥ 2%): abdominal pain, diarrhea, headache, abdominal distention, vomiting, hyperhidrosis, anxiety, muscle spasms, rhinorrhea, and chills.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
301.	SOMATEC Pharmaceuticals Ltd.	Elagolix 150 mg Tablet	Elagolix INN 150 mg	Gonadotropin-releasing hormone (GnRH) antagonist	Indicated for the management of moderate to severe pain associated with endometriosis.	**Contra-indication:** Pregnancy, Known osteoporosis, Severe hepatic impairment, Strong organic anion transporting polypeptide (OATP) 1B1 inhibitors **Side effect:** Most common adverse reactions (>5%) in clinical trials included hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions and mood changes.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
302.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	Drospirenone 0.25mg + Estradiol 0.5mg film coated Tablet	Drospirenone USP 0.250mg + Estradiol Hemihydrate USP 0.517mg (eqv. to 0.5mg of Estradiol)	Hormone	It is an estrogen/progestin indicated in women with an intact uterus for the treatment of: moderate to severe vasomotor symptoms due to menopause.	**Contraindication:** Undiagnosed abnormal genital bleeding, Known, suspected, or history of cancer of the breast, Known or suspected estrogen-dependent neoplasia, Active DVT, PE, or a history of these conditions, Active arterial thromboembolic disease (for example,	Drospirenone 0.5mg + Estradiol 1 mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					moderate to severe vulvar and vaginal atrophy symptoms due to menopause.	stroke and MI), or history of these conditions, Renal impairment, Known liver impairment or disease, Adrenal insufficiency, Known or suspected pregnancy **Side Effects**: The most common adverse reactions that occurred in at least 1 percent of users in clinical trials with Angeliq are gastrointestinal and abdominal pain, female genital tract bleeding, breast pain and discomfort, and headache.				
303.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Cyclosporin 0.9mg/ml Ophthalmic Solution	Cyclosporin USP 0.9 mg/ml	Immuno-suppresant	Cyclosporin ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).	**Contraindications:** None **Side Effects:** The most common adverse reactions following the use cyclosporine ophthalmic solution 0.09% wasinstillation site pain (22%) and conjunctival hyperemia (6%).	10mg, 25mg Capsule & 0.05% Eye Drops	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
304.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Salicylic Acid BP 12.0% w/w; Lactic Acid USP 4.0% Gel	Salicylic Acid 12.00 gm + Lactic Acid 4.00 gm/100gm	Keratolytic	Indicated for topical treatment of warts, verrucas, corns and calluses.	**Contraindication:** Not to be used on or near the face, intertriginous or anogenital regions, or by diabetics or individuals with impaired peripheral blood circulation. Not to be used on moles or on any other skin lesions for which the gel is not indicated. Not to be used in cases of sensitivity to any of the ingredients. **Side-effects:** While the gel is working you may feel a slight tingling sensation and / or some mild tenderness at the treated area. This is usually temporary, and in rare cases may appear as a temporary blemish on the skin.	Salicylic Acid 16.74 gm + Lactic Acid 16.74 gm/100 ml Solution	MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
305.	Pharmasia Limited Gojariapara,	Sodium Picosulfate 5mg/5ml Oral Solution	Sodium Picosulfate BP 5mg/5ml	Laxative	- Short term relief of constipation. - For the management of	**Contraindication:** Ileus or intestinal obstruction. Severe painful or feverish acute abdominal conditions potentially associated	New	MHRA BNF-76	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Bhawal Mirzapur, Gazipur Sadar, Gazipur				constipation of any etiology.	with nausea & vomiting. Acute inflammatory bowel diseases. Severe dehydration. Known hypersensitivity to Sodium Picosulfate or any other component of the product. Rare hereditary conditions that may be incompatible with an excipient of the product. **Side Effects:** Nervous system disorders, Uncommon: Dizziness Not known: Syncope, Gastrointestinal Disorders, Very Common: Diarrhea, Common: Abdominal Discomfort, Abdominal pain, cramps, Uncommon: Nausea, vomiting.		Page: 64		
306.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Sodium Picosulfate 7.5mg/ml Pediatric Drop	Sodium Picosulfate BP 7.5mg/ ml	Laxative	- Short term relief of constipation. - For the management of constipation of any etiology.	**Contraindication:** Ileus or intestinal obstruction. Severe painful or feverish acute abdominal conditions potentially associated with nausea & vomiting. Acute inflammatory bowel diseases. Severe dehydration. Known hypersensitivity to Sodium Picosulfate or any other component of the product. Rare hereditary conditions that may be incompatible with an excipient of the product. **Side Effects:** Nervous system disorders, Uncommon: Dizziness Not known: Syncope, Gastrointestinal Disorders, Very Common: Diarrhea, Common: Abdominal Discomfort, Abdominal pain, cramps, Uncommon: Nausea, vomiting.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
307.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Sodium Picosulfate 10 mg Tablet	Sodium Picosulfate BP 10 mg	Laxative	Short term relief of constipation. - For the management of constipation of any etiology.	**Contraindication:** Ileus or intestinal obstruction. Severe painful or feverish acute abdominal conditions potentially associated with nausea & vomiting. Acute inflammatory bowel diseases. Severe dehydration. Known hypersensitivity to Sodium Picosulfate or any other component of the product. Rare hereditary conditions that may be incompatible with an excipient of the product. **Side Effects:** Nervous system disorders,	New	USFDA (OTC)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						Uncommon: Dizziness, Not known: Syncope, Gastrointestinal Disorders, Very Common: Diarrhea, Common: Abdominal Discomfort, Abdominal pain, cramps, Uncommon: Nausea,				
308.	SOMATEC Pharmaceuticals Ltd.	Plecanatide INN 3mg tablet	Plecanatide INN	Laxative Drugs	Indicated in adults for treatment of chronic idiopathic constipation	**Contra-indication:** Patients less than 6 years of age due to the risk of serious dehydration. Patients with known or suspected mechanical gastrointestinal obstruction **Side effect:** Most common adverse reaction (≥2%) is diarrhea	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
309.	Opsonin Pharma Limited, Rupatoli, Barisal.	Sodium Chloride 300 mg Tablet	Sodium Chloride BP 300 mg	Minerals	It is indicated for Dehydration, Excessive sweating, Water and electrolyte imbalance, Preventing and correcting low levels of sodium in the body.	**Contraindication:** Sensitivity to Sodium chloride, Hypernatraemia, high blood pressure, Kidney failure etc. **Side-effects:** Hypernatremia (high levels of sodium), fluid retention, high blood pressure, heart failure, kidney damage, electrolyte abnormalities, and others.	Sodium Chloride 0.9% solution	BNF-76 (Page:1009)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
310.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Memantine Hydrochloride 14mg Extended-Release + Donepezil Hydrochloride 10mg Capsule	Memantine Hydrochloride USP14 mg + Donepezil Hydrochloride USP 10mg	Moderate to severe dementia in alzhaimers disease	It is indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on: • memantine hydrochloride (10 mg twice daily or 28 mg extended-release once daily) and donepezil hydrochloride 10 mg or • memantine hydrochloride (5 mg twice daily or 14 mg extended-release once daily) and donepezil hydrochloride 10 mg.	**Contraindications:** Contraindicated in patients with known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation. **Adverse reactions**: The most common adverse reactions occurring at a frequency of at least 5% and greater than placebo with memantine hydrochloride extended-release 28 mg/day were headache, diarrhea, and dizziness. The most common adverse reactions occurring at a frequency of at least 5% in patients receiving donepezil and at twice or more the placebo rate, include diarrhea, anorexia,	Donepezil Hydrochloride 5mg, 10mg Tablet & Memantine Hydrochloride 5mg, 10mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						vomiting, nausea, and ecchymosis.				
311.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Memantine Hydrochloride 28mg Extended-Release + Donepezil Hydrochloride 10mg Capsule	Memantine Hydrochloride USP 28mg + Donepezil Hydrochloride USP 10mg	Moderate to severe dementia in alzhaimers disease	It is indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on: • memantine hydrochloride (10 mg twice daily or 28 mg extended-release once daily) and donepezil hydrochloride 10 mg or •memantine hydrochloride (5 mg twice daily or 14 mg extended-release once daily) and donepezil hydrochloride 10 mg.	**Contraindications:** Contraindicated in patients with known hypersensitivity to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives, or to any excipients used in the formulation. **Adverse reactions**: • The most common adverse reactions occurring at a frequency of at least 5% and greater than placebo with memantine hydrochloride extended-release 28 mg/day were headache, diarrhea, and dizziness. • The most common adverse reactions occurring at a frequency of at least 5% in patients receiving donepezil and at twice or more the placebo rate, include diarrhea, anorexia, vomiting, nausea, and ecchymosis.	Donepezil Hydrochloride 5mg, 10mg Tablet & Memantine Hydrochloride 5mg, 10mg Tablet	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
312.	a) NIPRO JMI Pharma Ltd. b) SOMATEC Pharmaceuticals Ltd.	Erdosteine 175mg/5ml Powder For Suspenion	Erdosteine INN 175mg/5ml	Mucolytic	As mucolytic agent for symptomatic treatment of cough, AECB and COPD for children and for patients unable to take the medicine as solid dosage form.	**Contraindications:** It is contraindicated to patients who have hypersensitivity to Erdosteine. It sould not be used in patients with creatinine clearance <25ml/min, or with severe liver failure. **Side effects:** • Less than one in 1,000 patients may complain about gastrointestinal side effects. • Other effects reported, however very rare, are: headache, difficulty of breathing, taste disturbances, nausea, vomiting, diarrhea,	300mg Capsule		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						epigastric pain, urticaria, erythema, eczema. Compliance with the instructions contained in the leaflet that reduces the risk of side effects.				
313.	Acme Laboratories Ltd., Dhamrai, Dhaka	Flibanserin 100 mg Tablet	Flibanserin INN 100 mg	Multifunctional serotonin agonist and antagonist (MSAA)	Flibanserin is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to:• A co-existing medical or psychiatric condition,• Problems within the relationship, or The effects of a medication or other drug substance. **Limitation of Use:** Flibanserin is not indicated for the treatment of HSDD in postmenopausal women or men. It is also not indicated to enhance sexual performance.	**Contraindication:** Flibanserin is contraindicated in use of alcohol, moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors and hepatic impairment. **Side effects:** Most common adverse reactions (incidence ≥2%) are dizziness, somnolence, nausea, fatigue, insomnia and dry mouth.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
314.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	L–Lysine 2.0gm + Vitamin A + Vitamin A 40,000 IU & vitamin D3 8000 IU + Vitamin A Palmitate 35.300mg Equivalent to	L-Lysine HCl USP 2.499gm (eqv. to 2gm of L-Lysine) + Vitamin A + D_3	Multivitamin	It is indicated for dietary supplement for children of growing age. It contains, Vitamin B1, B2, B6 which are necessary for the normal	**Contraindication:** Hypersensitivity to any of the active ingredients.	(Folic Acid 250mcg + L-Lysine 50 mg + Nicotinamide		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
		60,000 IU of Vitamin A + Vitamin E 200 IU + Thiamine 40 mg + Riboflavin 20 mg + Pyridoxine 20 mg + Vitamin C 600mg + Nicotinamide 400mg + Dex Panthenol 200mg/100ml Syrup	Type 100/20 Dried Vitamin D Ph. Grade 0.400ml (eqv. to 40000 IU of Vitamin A & 8000 IU Vitamin D_3) + Vitamin A Palmitate BP 35.300mg (eqv. to 60000 IU of Vitamin A) + Vitamin E Acetate Oily BP 400mg (eqv. to 200 IU of Vitamin E, as DL Alpha Tocopherol 50% Acetate) + Vitamin B_1 BP 50.840mg (eqv. to 40mg Thiamine as Thiamine Hydrochloride) + Vitamin B_2 BP 25.420mg (eqv. to 20mg Riboflavin as Riboflavin Sodium 5-Phosphate) + Vitamin B_6 BP 24.300mg (eqv. to 20mg		processes in protein, fat and carbohydrate metabolism. The presence of Vitamin C helps to maintain healthy teeth and gums. The fat soluble Vitamin and D3 ensure the maintenance of proper level of calcium in the body fluids. The latter ensures healthy growth of bones and teeth. Vitamin E is required for proper cell function. Nicotinamide is essential for healthy skin and nervous system. L-lysine improves health and growth.		2.5 mg + Vitamin A 1500 IU + Vitamin B1 250 mcg + Vitamin B12 2 mcg + Vitamin B2 250 mcg + Vitamin B6 250 mcg + Vitamin C 50 mg + Vitamin D3 100 IU + Vitamin E 10 IU) Tablet			

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			Pyrodoxine as Pyrodoxine Hydrochloride) + Vitamin C BP 600mg + Nicotinamide BP 400mg + Dex Panthenol BP 200mg/100ml							
315.	Opsonin Pharma Limited, Rupatoli, Barisal.	Vitamin (A+D3) Water Miscible Type 100/20 10 mg (equivalent to Vitamin A 1000 IU & Vitamin D3 200 IU) + Ascorbic Acid 15 mg + dl-Alpha Tocopheryl Acetate 5 mg (equivalent to Vitamin E 5 IU) + Pyridoxine Hydrochloride 500 mcg + Thiamine Hydrochloride 500 mcg + Riboflavin Sodium Phosphate 500 mcg + Nicotinamide 6 mg + Cyanocobalamin 0.9 mcg + Calcium Pantothenate 2.174 mg + L-Lysine 100mg/ 5ml Syrup	Vitamin (A+D3) Water Miscible Type 100/20 BP 10 mg (eq. to Vitamin A 1000 IU & Vitamin D3 200 IU) + Ascorbic Acid BP 15 mg + dl-Alpha Tocopheryl Acetate USP 5 mg (equivalent to Vitamin E 5 IU) + Pyridoxine Hydrochloride BP 500 mcg + Thiamine Hydrochloride BP 500 mcg + Riboflavin Sodium Phosphate BP 500 mcg + Nicotinamide BP 6 mg + Cyanocobalamin	Multivitamins	Promotes muscle growth, weight gain and calcium retention; Helps to enhance body height and weight gain; Ensures good eye sight; Necessary for the normal process in protein, fat carbohydrate metabolism; For RBC formation and correct functioning of nervous system; For proper food assimilation and cell functioning;	**Contraindication:** The products are contraindicated in patients with a known hypersensitivity to any of the ingredients of the products. **Side-effects:** Generally well tolerated.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
			BP 0.9 mcg + Calcium Pantothenate BP 2.174 mg + L-Lysine USP 100mg/ 5ml							
316.	Opsonin Pharma Limited, Rupatoli, Barisal.	Aspirin 81 mg + Omeprazole 40 mg tablet	Aspirin BP 81 mg + Omeprazole BP 40 mg	NSAIDS + PPI	For secondary prevention of cardiovascular and cerebrovascular events and to reduce the risk of developing aspirin associated gastric ulcers.	**Contraindication:** The Combination of Aspirin and Omeprazole is not recommended for use if any patient have a history of allergy to Aspirin or Omeprazole or any other component of this medicine. **Side-effects:** The Combination of Aspirin and Omeprazole shows side effects like nausea, diarrhea, gastritis, gastric polyps, and non-cardiac chest pain.	Aspirin 75, 100, 150 & 300 mg Tablet & Omeprazole 10, 20 & 40 mg Capsule	USFDA (Discontinued)	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
317.	Opsonin Pharma Limited, Rupatoli, Barisal.	Ibuprofen 150 mg + Paracetamol 500 mg Tablet	Ibuprofen BP 150 mg + Paracetamol BP 500 mg	NSAIDS + Analgesic	For the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever.	**Contraindication:** This product is contraindicated in-Known hypersensitivity to Paracetamol or Ibuprofen or any other excipients, Hypersensitivity reactions associated with Acetylsalicylic acid or any other NSAIDs, Existing gastrointestinal Ulceration/Perforation or bleeding, Defect in coagulation, Renal failure. **Side-effects:** Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected patients should not drive or operate machinery.	Paracetamol 500, 625 Tablet; Paracetamol 60, 125, 250, 500 Suppository; Syrup; Suspension. Ibuprofen 200 & 400 Tablet, Suspension. Paracetamol 325 mg + Tramadol 37.5 mg Tablet		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
318.	Opsonin Pharma Limited, Rupatoli, Barisal.	Aspirin 250 mg + Caffeine 65 mg + Paracetamol 250 mg Tablet	Aspirin BP 250 mg + Caffeine BP 65 mg + Paracetamol USP 250 mg	NSAIDS + CNS stimulant + Analgesic	Mild to moderate pain including headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, symptomatic relief of sprains, strains, rheumatic	**Contraindication:** Do not take in case of allergic to aspirin, paracetamol, caffeine, or any of the other ingredients listed in this leaflet, have or have ever had a stomach ulcer, perforation or bleeding, suffer from haemophilia or from gout. Patients may experience any of these effects	Aspirin 75 & 300 mg; Paracetamol 500, 625 Tablet; Paracetamol 60, 125, 250,	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					pain, nerve pain of the lower back or legs.	then STOP taking this medicine immediately and contact your doctor or pharmacist: Stomach ulceration or perforation: Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black stools. **Side-effects:** Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features. Breathing problems.	500 Suppository; Syrup; Suspension. Paracetamol 325 mg + Tramadol 37.5 mg Tablet; Caffeine 65 mg.			
319.	Opsonin Pharma Limited, Rupatoli, Barisal.	Aspirin 325 mg + Omeprazole 40 mg Tablet	Aspirin BP 325 mg + Omeprazole BP 40 mg	NSAIDS +PPI	For secondary prevention of cardiovascular and cerebrovascular events and to reduce the risk of developing aspirin associated gastric ulcers.	The Combination of Aspirin and Omeprazole is not recommended for use if any patient have a history of allergy to Aspirin or Omeprazole or any other component of this medicine. **Side-effects:** The Combination of Aspirin and Omeprazole shows side effects like nausea, diarrhea, gastritis, gastric polyps, and non-cardiac chest pain.	Aspirin 75, 100, 150 & 300 mg Tablet & Omeprazole 10, 20 & 40 mg Capsule	USFDA (Discontinued)	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
320.	Opsonin Pharma Limited, Rupatoli, Barisal.	Bromfenac 90 mg + Moxifloxacin 500 mg/100 ml Sterile Eye Drops	Bromfenac Sodium Sesquihydrate INN 0.09 gm + Moxifloxacin Hydrochloride BP 0.5 gm	NSAIDS+ Antibiotics	Coexisting Ocular Infection and Inflammation	**Contraindication:** Moxifloxacin is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication. No contraindication was found by Bromfenac. **Side-effects:** The most commonly reported adverse experiences of bromfenac after cataract surgery include: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye pruritus, eye redness, headache, and iritis. These events were reported in 2-7% of patients. The most frequently reported ocular adverse events by Moxifloxacin were conjunctivitis, decreased visual acuity, dry eye, keratitis,	Moxifloxacin 0.5% and 400 mg Tablet, Bromfenac 0.09%		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients.				
321.	Opsonin Pharma Limited, Rupatoli, Barisal.	Ibuprofen 200 mg + Paracetamol 500 mg Tablet	Ibuprofen BP 200 mg + Paracetamol BP 500 mg	NSAIDS+Analgesic	For the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever.	**Contraindication:** This product is contraindicated in-Known hypersensitivity to Paracetamol or Ibuprofen or any other excipients, Hypersensitivity reactions associated with Acetylsalicylic acid or any other NSAIDs, Existing gastrointestinal Ulceration/Perforation or bleeding, Defect in coagulation, Renal failure. **Side-effects:** Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected patients should not drive or operate machinery.	Paracetamol 500, 625 Tablet; Paracetamol 60, 125, 250, 500 Suppository; Syrup; Suspension. Ibuprofen 200 & 400 Tablet, Suspension. Paracetamol 325 mg + Tramadol 37.5 mg Tablet	MHRA	প্রয়োজন নেই বিধায় পদটির আবেদন না মঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় পদটির আবেদন না মঞ্জুর করা হল।
322.	Pharmasia Limited ,Gazipur	Sodium Zirconium Cyclosilicate 5.0gm/Sachet Power for oral suspension	Sodium Zirconium Cyclosilicate INN 5.0gm/Sachet	Potassium Binder	Indicated for Hyperkalemia	**Contraindication:** Hypersensitivity to the active substance. **Side-effects:** Mild to moderate edema.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
323.	Pharmasia Limited, Gazipur	Sodium Zirconium Cyclosilicate 10.0gm/Sachet Power for oral Suspension	Sodium Zirconium Cyclosilicate INN 10.0gm/Sachet	Potassium Binder	Indicated for - Hyperkalemia	**Contraindication:** Hypersensitivity to the active substance. **Side-effects:** Mild to moderate edema.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
324.	M/s Beacon Pharmaceuticals Ltd.,	Prucalopride 1mg Tablet	Prucalopride Succinate INN 1.321mg eqv. to	Prokinetic agent	It is indicated for symptomatic treatment of chronic constipation in	**CONTRA-INDICATIONS:** Crohn's disease . intestinal obstruction. intestinal perforation . toxic megacolon .ulcerative colitis	New	BNF-76 Page-60	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Kathali,Bhauka, Mymensingh		Prucalopride 1mg		adults in whom laxatives fail to provide adequate relief	**Side-effect:** Appetite decreased . diarrhoea . dizziness. fatigue . gastrointestinal discomfort . gastrointestinal disorders . headache . nausea . vomiting				
325.	M/s Beacon Pharmaceuticals Ltd., Kathali,Bhauka, Mymensingh	Prucalopride 2mg Tablet	Prucalopride Succinate INN 2.642mg eqv. to Prucalopride 2mg	Prokinetic agent	It is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief	**CONTRA-INDICATIONS:** Crohn's disease . intestinal obstruction. intestinal perforation . toxic megacolon .ulcerative colitis **Side-effect**: Appetite decreased . diarrhoea . dizziness . fatigue . gastrointestinal discomfort . gastrointestinal disorders . headache . nausea . vomiting	New	BNF-76 Page-60	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
326.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	(Sodium Picosulfate 10.00mg+ Magnesium Oxide 3.50gm + Anhydrous Citric Acid 12.0gm)/160ml Bottle	(Sodium Picosulfate BP 10.00mg+ Magnesium Oxide BP 3.50gm + Anhydrous Citric Acid BP 12.0gm)/160 ml	Purgative Laxatives	Indicated for - Cleansing of the colon as a preparation for colonoscopy in adults.	**Contraindication:** Sodium picosulfate, magnesium oxide and anhydrous citric acid for oral solution is contraindicated in the following conditions: • Patients with severely reduced renal function (creatinine clearance less than 30 mL/minute) which may result in accumulation of magnesium. • Gastrointestinal obstruction or ileus. • Bowel perforation • Toxic colitis or toxic megacolon • Gastric retention • An allergy to any of the ingredients in sodium picosulfate, magnesium oxide and anhydrous citric acid for oral solution **Side-effects:** Most common adverse reactions (>1%) are nausea, headache and vomiting (abdominal bloating, distension, pain/cramping, and watery diarrhea not requiring an intervention were not collected).	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
327.	Incepta Pharmaceuticals	Lusutrombopag 3mg Tablet	Lusutrombopag INN 3mg	Thrombopoietic Agents	Lusutrombopag is indicated for the treatment of	**Contraindications:** None. **Side Effects:** 3%): headache≥The most	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
	Ltd.; Zirabo, Savar, Dhaka.				thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.	common adverse reaction.				
328.	UniMed & UniHealth Manufacturers Ltd. B.K Bari,	Avatrombopag 20mg Tablet	Avatrombopag INN 20mg	Thrombopoietin receptor agonist	It is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.	**Contra-indication:** None. **Adverse Reactions:** Most common adverse reactions (≥ 3%) are: pyrexia, abdominal pain, nausea, headache, fatigue, and edema peripheral.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
329.	Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Potassium Citrate USP 3.0gm/Sachet Granules for Oral Solution	Potassium Citrate USP 3g Granules/Sachet for Oral Solution	Urinary Alkalinizer	Indicated for the treatment of-Symptomatic relief of mild urinary tract infections (cystitis).	**Contraindication:** The product is intended for short term treatment. Patients should seek doctors' advice if symptoms persist after 48 hours treatment. This product should only be used with caution in patients with cardiac disease. This product contains a source of phenylalanine. **Side-effects:** Potassium salts may give rise to gastric irritation, the effects of which may be minimized by diluting sachet contents well with water. Doses may also be given with or after eal.	540 mg & 1080mg Tablet Citric Acid Monohydrate 5 gm + Potassium Citrate 30 gm/100 ml Oral Solution		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
330.	a) Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka b) Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar, Gazipur	Fesoterodine Fumarate 4mg Extended Release Tablet	Fesoterodine Fumarate INN 4 mg	Urinary Antispasmodic	It is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency.	**Contraindication:** It is contraindicated in patients with urinary retention, gastric retentionor uncontrolled narrow-angle glaucoma. **Side-effects:** Dry mouth, constipation.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
331.	a)Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka b) Pharmasia Limited Gojariapara, Bhawal Mirzapur, Gazipur Sadar,	Fesoterodine Fumarate 8 mg Extended Release Tablet	Fesoterodine Fumarate INN 8 mg	Urinary Antispasmodic	It is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency.	**Contraindication:** It is contraindicated in patients with urinary retention, gastric retentionor uncontrolled narrow-angle glaucoma. **Side-effects:** Dry mouth, constipation.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
332.	Incepta Vaccine Ltd.	Human Immunoglobulin-G 50mg/1 ml in 50 ml IV administration	Human immunoglobulin-G (Human Normal Immunoglobulin) BP 50mg/1 ml	Vaccine, Anti-sera & Immunoglobulin	It is indicated for : A-/Hypogammaglobulinemia. The treatment of Primary Immunodeficiency (PI). Combination therapy with antibiotics in severe bacterial and viral infections. Idiopathic Thrombocytopenic Purpra (in the case where other medicinal products are not effective of patients show apparent hemorrhage of patients need temporary control of hemostasis such as surgeon treatment or childbirth etc.) Guillain-Barre Syndrome	**Contraindications**: • Human Normal Immunoglobulin for intravenous administration is contraindicated in patients who have had a history of anaphylactic or severe systemic hypersensitivity reactions to the administration of human immune globulin. • This product is also contraindicated in IgA deficient patients with antibodied to IgA and a history of hypersensitivity. **Side effects :** More common Chills, Cough,Fast, pounding or irregular heartbeat or pulse,Fever, Noisy breathing, Tightness in the chest, Troubled breathing • Unusual tiredness or weakness. Less common • Bluish coloring of the lips or nail beds • Burning sensation in the head	New	MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					(subacute febric polyneuritics.) Kawasaki Syndrome (to prevent disease of coronary artery complication.)	• Faintness or lightheadedness				
333.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka.	Dihydroergotamine mesylate 4mg/ml Nasal Spray	Dihydroergotamine Mesylate USP 4mg/ml	Vasoconstrictor, Anyimigraine	Dihydroergotamine mesylate Nasal Spray is indicated for the acute treatment of migraine headaches with or without aura..	**Contraindications:** There have been a few reports of serious adverse events associated with the coadministration of dihydroergotamine and potent CYP 3A4 inhibitors, such as protease inhibitors and macrolide antibiotics, resulting in vasospasm that led to cerebral ischemia and/or ischemia of the extremities. The use of potent CYP 3A4 inhibitors (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, troleandomycin, ketoconazole, itraconazole) with dihydroergotamine is, therefore contraindicated (dihydroergotamine mesylate, USP) Nasal Spray should not be given to patients with ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia) or to patients who have clinical symptoms or findings consistent with coronary artery vasospasm including Prinzmetal's variant angina. Because (dihydroergotamine mesylate, USP) Nasal Spray may increase blood pressure, it should not be given to patients with uncontrolled hypertension (dihydroergotamine mesylate, USP) Nasal Spray, 5-HT1 agonists (e.g., sumatriptan), ergotamine- containing or ergot-type medications or methysergide should not be used within 24 hours of each other.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						(dihydroergotamine mesylate, USP) Nasal Spray should not be administered to patients with hemiplegic or basilar migraine. In addition to those conditions mentioned above, (dihydroergotamine mesylate, USP) Nasal Spray is also contraindicated in patients with known peripheral arterial disease, sepsis, following vascular surgery, and severely impaired hepatic or renal functi (dihydroergotamine mesylate, USP) Nasal Spray may cause fetal harm when administered to a pregnant woman. Dihydroergotamine possesses oxytocic properties and, therefore, should not be administered during pregnancy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.. **Side Effects:** Serious cardiac events, including some that have been fatal, have occurred following use of the parenteral form of dihydroergotamine mesylate (D.H.E. 45® Injection), but are extremely rare. Events reported have included coronary artery vasospasm, transient myocardial ischemia, myocardial infarction, ventricular tachycardia, and ventricular fibrillation. Fibrotic complications have been reported in association with long term use of injectable dihydroergotamine mesylate.				
334.	Drug International Ltd 252, Tongi I/A Tongi, Gazipur	Calcium Folinate BP 200mg/20ml	Calcium Folinate BP 200mg/20ml Solution for injection	Vitamin	Calcium Folinate is indicated in advanced colorectal cancer, neutralising the immediate toxic effects of folic acid	**Contraindication:** Calcium Folinate is contraindicated in patients with hypersensitivity to calcium folinate or any of the excipients.It is also contraindicated in the treatment of pernicious anaemia or other	15mg Tablet 50mg/5ml Injection	MHRA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
					antagonists, e.g. Methotrexate. It is also indicated in the treatment of megaloblastic anaemias due to sprue, nutritional deficiency, pregnancy, infancy, liver disease and malabsorption syndrome. It is also used in combination with 5-fluorouracil in cytotoxic therapy.	megaloblastic anaemias and other anaemia's due to B_{12} is deficiency **Side effects:** The most common side effects are –itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat, Fits and fainting. Fever has been observed after administration of calcium folinate as solution for injection.	100mg/10ml Injection			
335.	SOMATEC Pharmaceuticals Ltd.	L-Methylfolate Calcium 7.5 mg Tablet	L-Methylfolate Calcium	Vitamin	-Dietary supplement of Folate -Dietary management of major depressive disorder	**Contra-indication:** For patients with known hypersensitivity to any of the components contained in the product. **Side effect:** Only allergic reactions have been reported following the use of oral L-methylfolate in fow cases	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
336.	UniMed & UniHealth Manufacturers Ltd. B.K Bari, Gazipur	Cholecalciferol (Vitamin D3)10000 IU/ml Oral Drops	Cholecalciferol (Vitamin D3) USP 1gm/100ml	Vitamin	It is indicated for the treatment of Vitamin D deficiency	**Side effect:** Laryngeal edema	1000IU, 20,000 IU, 40,000 IU Capsule 25 mcg/5 ml Syrup 5 mg/ml Injection 7.5 mg/ml Injection	BNF-76 Page-1052	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
337.	Opsonin Pharma Limited, Rupatoli, Barisal	Calcium Carbonate 5 gm + Magnesium 1.5 gm+ Vitamin D_3 4000 IU Zinc 40 mg/100 ml suspension	Calcium Carbonate USP 5 gm + Magnesium BP 1.5 gm+ Vitamin D_3 BP 4000 IU Zinc USP 40 mg	Vitamin + Minerals	Strong bones & Dietary supplement	**Contraindication:** Hypersensitivity of this drug is contraindicated. In addition, Suspension should not be used if you have the following conditions: Allergic reactions, Extreme loss of body water, High amount of calcium in the blood, High calcium levels, Incomplete or infrequent bowel	Calcium Carbonate 500 mg +Vitamin D3 200 IU Tablet, Boron 250 mg + Calcium 600		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

SI	Name of the Manufacturer	Name of the Drug	Generic Name	Therapeutic Class	Indication	Contra-indication & Side-effect	Status (New Molecule/ Existing)	USFDA/BNF/ MHRA Reference	টেকনিক্যাল সাব-কমিটির মতামত	সভার সিদ্ধান্ত
						movements, Increased activity of the parathyroid gland, Kidney disease, Kidney stone, Sarcoidosis, Tumor that dissolves bone **Side effects:** Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away. Abdominal pain, Constipation, Headache, Loss of appetite, Nausea, Vomiting, Stomach ache, Feeling of sickness, Excessive thirst, Muscle weakness	mg + Copper 1 mg + Magnesium 40 mg + Manganese 1.8 mg + Vitamin D3 200 IU + Zinc 7 mg.			
338.	Opsonin Pharma Limited, Rupatoli, Barisal.	Boron 0.75 mg + Calcium (Algae Source) 180 mg + Magnesium 87.5 mg + Vitamin C 12.5 mg + Vitamin D3 400 IU + Vitamin K2 25 mcg Capsule	Boron Ph. Gr 0.75 mg + Calcium (Algae Source) USP 180 mg + Magnesium BP 87.5 mg + Vitamin C BP 12.5 mg + Vitamin D3 BP 400 IU + Vitamin K2 Ph. Gr 25 mcg	Vitamin + Minerals	Calcium deficiency, low bone density, osteoclast mediated bone resorption.	Increased activity of Parathyroid gland, Hypercalcemia, Constipation, kidney stone, Extreme loss of body water are such condition in which Calcium intake is contraindicated. **Side-effects:** The common side effects are Flatulence, Diarrhoea, Constipation, and Allergic reactions etc. Hypercalcemia due to prolong use has rarely been reported.	New		প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।

Annex-I: List of Products for Import (Human)

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
1.	**Manufacture:** Ursapharma Arzneimittel GmbH, IndustriestraBe 35 66129 Saarbrucken, Germany . **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000	Proparakaine-POS 0.5% Eye Drop (10ml bottle)	Proxymetacaine Hydrochloride Ph. Eu. 5.0 mg/ml	Anesthetic	For anesthesia of the ocular surface during operations, foreign body removal, suture removal, and tonometry.	**Contraindication:**. Prolonged usage , previous allergic reaction to the drug. **Side Effect:** allergic reaction , periorbital eczema. With prolonged uncontrolled usage, not in accordance with the recommended dosing , corneal damage may occur.	New	CPP-Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
2.	AstraZeneca Silk Road Business Park Macclesfield Cheshire SK10 2NA United Kingdom. **Importer:** (Aquamarine Distributions Limited.)	**Zoladex 3.6mg Depot Pre-filled Syringe**	Goserelin Acetate as 3.60mg Goserelin	Anticancer	Treatment of Prostate Cancer, Breast Cancer, Endometriosis. Endometrial thinning.	**Contraindications:** Hypersensitivity to the active substance, to other LHRH analogues, or to any excipients of this product. Should not be used during pregnancy or lactation. **Side-effects:** **Very Common (≥ 10%):** Psychiatric disorders: Libido decreased. Vasuclar disorders: Hot flush. Skin and subcutaneous tissue disorders: Hyperhidrosis Reproductive system and breat disorders: Erectile dysfunction, vulvovaginal dryness, breast enlargement. **Common (≥ 1% and < 10%):** Metabolism and nutrition disorders: Glucose tolerance impaired. Psychiatric disorders: Mood swings. Nervous system disorders: Paraesthesia., Spinal cord compression, headache. Cardiac disorders: Caardiac failure, myocardial	New	CPP-UK	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						infarction. Vascular disorders: Blood pressure abnormal. Skin and subcutaneous tissue disorder: Rash, Alopecia. Musculoskeletal connective tisse and bone disorder: Bone pain, Arthralgia. Reporductive system and breast disorders: Gynaecomastia. General disorders and administration site conditions: tumour flare. Investigations: Bone density decreased, weight increased. **Uncommon (≥ 0.1% and <1%):** Immune system disorder: Drug hypersensitivity. Muscoloskeletal connective tissue and bone disorder: Arthralgia. Renal and urinary disorders: Ureteric obstruction. Reproductive system and breast disorders: Breast tenderness. Metabolism and nutrition disorders: Hypercalcaemia. **Rare (≥ 0.01% and <0.1%):** Reproductive system and breast disorders: Ovarian cyst, ovarian hyperstimulation syndrome Immune system disorders: Anaphylactic reaction. **Very Rare (> 0.01%):** Neoplasms benign, malignant and unspecified (including cysts and polyps: Pituitary tumor. Endocrine disorders: Pituitary haemorrhage. Psychiatric disorders: Phychotic disorder.				

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
3.	AstraZeneca Silk Road Business Park Macclesfield Cheshire SK10 2NA United Kingdom. **Importer:** (Aquamarine Distributions Limited.)	**ZOLADEX** 10.8mg Depot Pre-filled Syringe	Goserelin Acetate as 10.80mg Goserelin	Anticancer	Treatment of Prostate Cancer, Breast Cancer, Endometriosis. Endometrial thinning.	**Contraindications:** Hypersensitivity to the active substance, to other LHRH analogues, or to any excipients of this product. Should not be used during pregnancy or lactation. **Side-effects:** **Very Common (≥ 10%):** Psychiatric disorders: Libido decreased. Vasuclar disorders: Hot flush. Skin and subcutaneous tissue disorders: Hyperhidrosis Reproductive system and breat disorders: Erectile dysfunction, **Common (≥ 1% and < 10%):** Metabolism and nutrition disorders: Glucose tolerance impaired. Nervous system disorders: Paraesthesia. Cardiac disorders: Caardiac failure, myocardial infarction. Vascular disorders: Blood pressure abnormal. Skin and subcutaneous tissue disorder: Rash. Musculoskeletal connective tisse and bone disorder: Bone pain. Reporductive system and breast disorders: Gynaecomastia. General disorders and administration site conditions: Injection site reaction. Investigations: Bone density decreased, weight increased. Psychiatric disorders: Mood swings. **Uncommon (≥ 0.1% and <1%):**	New	CPP-UK	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Immune system disorder: Drug hypersensitivity. Muscoloskeletal connective tissue and bone disorder: Arthralgia. Renal and urinary disorders: Ureteric obstruction. Reproductive system and breast disorders: Breast tenderness. **Rare (≥ 0.01% and <0.1%):** Immune system disorders: Anaphylactic reaction. **Very Rare (> 0.01%):** Neoplasms benign, malignant and unspecified (including cysts and polyps: Pituitary tumor. Endocrine disorders: Pituitary haemorrhage. Psychiatric disorders: Phychotic disorder.				
4.	Made in Roche Diagnostics GmbH, Mannheim, Germany for F. Hoffmann-La Roche Ltd, Basel, Switzerland **Local agent:** Roche Bangladesh Limited	Tecentriq 1200mg/20ml Vial Concentrate for solution for infusion	Atezolizumab INN 1200mg/20ml Vial	Anticancer	1. Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma after prior chemotherapy or who are considered cisplatin ineligible. 2. Tecentriq is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy	Contraindication: Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. Side effects: Immune-related pneumonitis Immune-related hepatitis Immune-related colitis, Immune-related endocrinopathies, Immune-related meningoencephalitis, Immune-related neuropathies, Immune-related pancreatitis, etc.		EMA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
5.	Made in Excella GmbH & Co.KG, Feucht, Germany, for F. Hoffmann-La Roche Ltd, Basel, Switzerland. **Local agent:**	Alecensa 150 mg Capsule	Alectinib INN 150mg	Anticancer	Alecensa as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase	Contraindication: Alecensa is contraindicated in patients with a known hypersensitivity to alectinib or any of the excipients. Side effects: The most common adverse drug reactions (≥20%) were constipation (36%), edema (34% including peripheral, generalized, eyelid,		EMA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Roche Bangladesh Limited				(ALK)-positive advanced on-small cell lung cancer (NSCLC) Alecensa as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced NSCLC previously treated with Crizotinib.	periorbital); myalgia (31% including myalgia and musculoskeletal pain), nausea (22%), increased bilirubin (21% including increased blood bilirubin, hyperbilirubinemia and increased bilirubin conjugated), anemia (20%, including anemia and hemoglobin decreased), and rash (20%, including rash, rash maculopapular, dermatitis acneiform, erythema, rash generalized, rash papular, rash pruritic and rash macular).				
6.	AstraZeneca Silk Road Business Park Macclesfield Cheshire SK10 2NA United Kingdom. **Importer:** (Aquamarine Distributions Limited.)	Faslodex 250mg/5ml Pre-filled Syringe	Fulvestrant 250mg/5ml	Antiestrogen	Treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in post menopausal women.	Contraindications: Hypersensitivity to the active substance or to any of the excipients. Side-effects: Infections and infestations: Urinary tract infections (common) Blood and lymphatic system disorders: Reduced platelet count (common) Immune system disorders: Hypersensitivity reactions (very common), Anaphylactic reactions (uncommon). Metabolism and nutrition disorders: Anorexia (common). Nervous system disorders: headache (common). Gastrointestinal disorders: Nausea (very common), vomiting, dairrhoea (common). Vascular disorders: Hot flushes (very common), venous thromboembolism (common). Hepatobiliary disorders: Elevated hepatic enzymes (ALT, AST, ALP) (very common), Elevated bilirubin (common), Hepatic failure, hepatits, elevated gamma-GT (uncommon). Skin and subcutaneous tissus		EMA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						disorders: Rash (very common). Musculoskeletal and connective tissue disorders: Joint and musculoskeletal pain (Very common), Back pain (common). Reproductive syetem and breast disorders: vaginal moniliasis, leukorrhea (Uncommon), Vaginal haemorrhage (common). General disorders and administration site conditions: Asthenia, injection site reactions (very common), Neuropathy peripheral, sciatica (common), Injection site haemorrhage, injection site haematoma, neuralgia (uncommon).				
7.	**Manufacture:** Ursapharma Arzneimittel GmbH, IndustriestraBe 35 66129 Saarbrucken, Germany . **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000	POSIFORMIN 2% preservative free Eye Ointment (5g tube)	Bibrocathol Ph. Eu. 20mg/gm	Antiseptic agent	Unspecific, non Infected irritants of the outer eye, chronic inflammation of the lid margin, non infected fresh corneal wounds ,	**Contraindication:**. Hypersensitivity to the active substance or to any of the excipients , contact lenses should not be worn during use of posiformin 2% . **Side Effect:** In very cases hypersensitivity against bibrocathol or one of the ingredients of posiformin 2 % was observed.	New	CPP-Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
8.	**Manufacturer:** River Pharma Srl; Address: Viale Stazione 6, 26863 Orio Litta (LO), Italy **Importer:** Benvue International Ltd. Address: 1512, O R Nizam Road, Chittagong, Bangladesh.	Syalox 300 Plus Tablet	Sodium Hyaluronate INN 300mg	Cartilaginous Defect Repair Agent	1) Degenerative & connective tissue disorders due to impaired hyaluronic acid level in the joints. 2) Follow up therapy of follow up therapy of intra-articular hyaluronic acid (as Sodium Hyluronate) injection.	**Contraindications:** Hyaluronic Acid (HA) is contraindicated in patients with known hypersensitivity to Hyaluronic Acid (HA) or any of its components. **Side Effects:** Hyaluronic Acid (HA) is well tolerated with few side effects like dyspepsia, nausea, abdominal pain etc.	Sodium Hyaluronate 20 mg/2 ml Injection	Italy	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
9.	B.Braun Medical AG Route de Sorge 9 1023 Crissier Switzerland. **Importer:** (ORION INFUSION LTD.)	Gelofusine, Solution for infusion	Succinylated Gelatin INN 40gm + Sodium chloride Ph. Eu. 7.01gm/1000ml	Colloidal plasma volume substitute	* Prophylaxis and Treatment of imminent or manifest relative or absolute hypovolaemia and shock. * Prophylaxis and Treatment hypotension (e.g. during indication of epidural or spinal anaesthesia) * Procedures involving extracorporeal circulation (e.g. heart-lung machine) * acute normovolaemichaemo dilution	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients, Hypervolaemia. Hyperhydration & Acute congestive heart failure. **Side-effects:** **Immune system disorders** Rare: Anaphylactoid reactions (all grade) Very rare: Severe anaphylactoid reactions **Cardiac disorders** Very rare: Tachycardia **Vascular disorders** Very rare: Hypotension **Respiratory, thoracic and mediastinal disorders** Very rare: Respiratory difficulties **Skin and ubcutaneous tissue disorders** Rare: Allergic skin reactions **General disorders and administration site conditions** Uncommon: Mild transient increase of body temperature. Very rare: Fever, chills	4% succinylated gelatin in sodium chloride for IV infusion	Switzerland **(CPP)**	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
10.	**Manufacturer:** Abbott Biologicals B.V., Veerweg 12 , 8121 AA Olst, The Netherlands **UniHealth Ltd.** House No. 46, Sheikh Kamal Saroni, Road No. 16, RangsNasim Square, Dhanmondi	Femoston Conti 1/5mg Film coated Tablet	Estradiol INN 1mg + Dydrogesterone BP 5mg	Hormone	# Menopausal symptoms in women with a uterus whose last menstrual period occured over 12 months previously. # Osteoporosis prophylaxis in women with a uterus whose last menstrual period occured over 12 months previously.	**Contra-indications:** Acute prophyrias p.918. genital or breast cancer, History during pregnancy of idiopathic jaundice, severe pruritus, or pemphigoid gestationis. History of liver tumours, Severe arterial disease, Undiagnosed vaginal bleeding **Side-Effects:** Acne, alopecia, anaphylatoid, reaction, bloating, breast tenderness, change in libido, depression, dizziness, drowsiness, fluid retention, headache, hirsutism, insomnia, jaundice, menstrual disturbances, nausea, premenstrual-like syndrome, pruritus, rash, skin reaction, urticaria, weight change	Estradiol 2 mg Tablet Dydrogesterone 10 mg Tablet	The Netherlands & UK	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
11.	**Manufacturer:** Abbott Biologicals B.V., Veerweg 12 , 8121 AA Olst, The Netherlands **UniHealth Ltd.** House No. 46, Sheikh Kamal Saroni, Road No. 16, RangsNasim Square, Dhanmondi	Femoston 2/10mg Film coated Tablet	Estradiol INN 2mg + Dydrogesterone BP 10mg	Hormone	# Menopausal symptoms in women with a uterus # Osteoporosis prophylaxis in women with a uterus	**Contraindications:** Acute prophyrias p.918. genital or breast cancer, History during pregnancy of idiopathic jaundice, severe pruritus, or pemphigoid gestationis. History of liver tumours, Severe arterial disease, Undiagnosed vaginal bleeding. **Side-Effects:** Acne, alopecia, anaphylatoid, reaction, bloating, breast tenderness, change in libido, depression, dizziness, drowsiness, fluid retention, headache, hirsutism, insomnia, jaundice, menstrual disturbances, nausea, premenstrual-like syndrome, pruritus, rash, skin reaction, urticaria, weight change	Estradiol 2 mg Tablet Dydrogesterone 10 mg Tablet	The Netherlands & UK	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
12.	**Manufacturer:** Abbott Biologicals B.V., Veerweg 12 , 8121 AA Olst, The Netherlands **UniHealth Ltd.** House No. 46, Sheikh Kamal Saroni, Road No. 16, RangsNasim Square, Dhanmondi	Femoston 1/10mg Film coated Tablet	Estradiol INN 1mg + Dydrogesterone BP 10mg	Hormone	# Menopausal symptoms in women with a uterus # Osteoporosis prophylaxis in women with a uterus	**Contraindications:** Acute prophyrias p.918. genital or breast cancer, History during pregnancy of idiopathic jaundice, severe pruritus, or pemphigoid gestationis. History of liver tumours, Severe arterial disease, Undiagnosed vaginal bleeding. **Side-Effects:** Acne, alopecia, anaphylatoid, reaction, bloating, breast tenderness, change in libido, depression, dizziness, drowsiness, fluid retention, headache, hirsutism, insomnia, jaundice, menstrual disturbances, nausea, premenstrual-like syndrome, pruritus, rash, skin reaction, urticaria, weight change	Estradiol 2 mg Tablet Dydrogesterone 10 mg Tablet	The Netherlands & UK	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
13.	Besins Manufacturing Belgium , Groot-Bijaardenstraat 128, 1620 , Drogenbos , Belgium . **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Androgel 16.2mg/gm Gel	Natural Micronized Testosterone USP 16.2mg/gm	Hormone	Androgel is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been	**Contraindication:**. ANDROGEL 16.2mg/g is contraindication suspected prostate cancer or breast carcinoma, hypersensitivity to testosterone. **Side Effect:** the most frequently observed clinical adverse drug reaction observed with ANDROGEL 16.2mg/g used at the recommended dosage were psychiatric disorders and skin reaction at the application site.	Testosterone 1% Gel Testosterone Undecanoate 40 mg Capsule	CPP-Belgium CPP-France	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					confirmed by clinical features and biochemical tests.					
14.	BAG Health Care GmbH, Amtsgerichtsstr 1-5. 35423 Lich, Germany . **Local Agent**: Doctor's Pharma Ltd. , 80/22 Mymenshing Road , Nurjahan Tower (9th Floor) Dhaka-1000	Karma FSH 75 IU/Vial (Solution for Injection)	Follicle Stimulation Hormone (FSH) Ph. Eu. 75 IU/Vial	Hormone	Indicated for Induction of ovulation in patients with polycystic ovarian disease who have an elevated LH/FSH ratio and who have failed to respond to adequate clomiphene citrate therapy.	**Contraindication**: High levels of FSH Indicating primary ovarian failure , uncontrolled thyroid or adrental dysfunction , an organic intracranial lesion such as pituitary tumor, the presence of any cause of infertility other than anovulation as stated in indications unless they are candidates for in vitro fertilization, ovarian cysts or enlargement not due tovarian polycystic ovarian disease, prior hypersensitivity to urofolltrophin, FSH is contra-indication in woman who are pregnant. There are limited human data on the effects of FSH when administered during pregnancy. **Side Effect:** severe pain in your lower stomach, nausea, vomiting , diarrhea, bloating ,feeling short fo breath, swelling in your hands or legs, weight gain, urinating less than usual,.	New	CPP-Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
15.	BAG Health Care GmbH, Amtsgerichtsstr 1-5. 35423 Lich, Germany . **Local Agent**: Doctor's Pharma Ltd. , 80/22 Mymenshing Road , Nurjahan Tower (9th Floor) Dhaka-1000, Bangladesh	Karma FSH 150 IU/Vial (Solution for Injection)	Follicle Stimulation Hormone (FSH) Ph. Eu. 150 IU/Vial	Hormone	Indicated for Induction of ovulation in patients with polycystic ovarian disease who have an elevated LH/FSH ratio and who have failed to respond to adequate clomiphene citrate therapy.	**Contraindication**: High levels of FSH Indicating primary ovarian failure , uncontrolled thyroid or adrental dysfunction , an organic intracranial lesion such as pituitary tumor, the presence of any cause of infertility other than anovulation as stated in indications unless they are candidates for in vitro fertilization, ovarian cysts or enlargement not due tovarian polycystic ovarian disease, prior hypersensitivity to urofolltrophin, FSH is contra-indication in woman who are pregnant. There are limited human data on the effects of FSH when administered during pregnancy. **Side Effect:** severe pain in your lower stomach, nausea, vomiting , diarrhea, bloating ,feeling short fo breath, swelling in your hands or legs, weight gain,	New	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						urinating less than usual				
16.	BAG Health Care GmbH, Amtsgerichtsstr 1-5. 35423 Lich, Germany . **Local Agent**: Doctor's Pharma Ltd., 80/22 Mymenshing Road , Nurjahan Tower (9th Floor) Dhaka-1000, Bangladesh	Karma HMG 75 IU/Vial (Solution for Injection)	Human Menopausal Gonadotropin BP 75IU/Vial	Hormone	Indicated for the induction of ovulation in the amenorrhoeic patient or anovulatory woman with regular or irregular cycles	**Contraindication:** Ovarian digenesis, absence of uterus , Premature menopause tubular occlusion. **Side Effect:** Local reaction at the injection site, fever and arthralgia have been observed in rare cases, in the male , a combined treatment with HMG and may cause gynecomastia.	New	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
17.	BAG Health Care GmbH, Amtsgerichtsstr 1-5. 35423 Lich, Germany . **Local Agent**: Doctor's Pharma Ltd. , 80/22 Mymenshing Road , Nurjahan Tower (9th Floor) Dhaka-1000, Bangladesh	Karma HMG 150 IU/Vial (Solution for Injection)	Human Menopausal Gonadotropin BP 150 IU/Vial	Hormone	Indicated for the induction of ovulation in the amenorrhoeic patient or anovulatory woman with regular or irregular cycles	**Contraindication:** Ovarian digenesis, absence of uterus , Premature menopause tubular occlusion. **Side Effect:** Local reaction at the injection site, fever and arthralgia have been observed in rare cases, in the male , a combined treatment with HMG and may cause gynecomastia. .	New	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
18.	BAG Health Care GmbH, Amtsgerichtsstr 1-5. 35423 Lich, Germany . **Local Agent**: Doctor's Pharma Ltd., 80/22 Mymenshing Road , Nurjahan Tower (9th Floor) Dhaka-1000, Bangladesh	Karma HCG 10000 IU/Vial (Solution for Injection)	Human Gonadotropin (HCG) Ph. Eu. 10000 IU/Vial	Hormone	In the female , HCG is used in the treatment of anovulatoty infertility . where its administration would form part of recognized treatment regimen involving the prior stimulation of follicular maturation and endometrial proliferation.	**Contraindication:** Stimulation of ovulation with HCG may lead to superovulation and the hyperstumulation syndrome. **Side Effect:** In the female, a local reaction at the injection site, fever and arthralgia have been observed in rare cases. In the male, a combined treatment with HCG may cause gynecomastia.	New	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
19.	BAG Health Care GmbH,Amtsgerichtsstr. 1-5, 35423Lich, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh	Alveofact 45mg/ml, (Powder and Solvent for preparation of a suspension)	Total phospholipids 108 mg/Vial	lung surfactant	Alveofact is a natural bactan lung surfactant. This substance reduces the surface tension in the alveoli. In case of surfactant deficiency the alveoli may collapse . Preventive use in premature neonates with a high risk of respiratory distress syndrome.	**Contraindication:** no substance-specific contraindication are know, **Side Effect:** The amount of fluid may cause short-term obstruction of the large airways , brain and pulmonary hemorrhages have been described, hypersensitivity , existing hypersensitivity .		Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
20.	**Manufacture:** Ursapharma Arzneimittel GmbH, IndustriestraBe 35 66129 Saarbrucken, Germany . **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000	VITA-POS Preservative Free Eye Ointment (5g Tube)	Retinol Palmitate Ph. Eu. 250 I.U/gm	Vitamin	Improvement & Protection of the lacrimal film and for the protection of the surface of the eye.	**Contraindication:**. Patients with know hypersensitivity to retinol palmitate. **Side Effct:** No Specific side effect occurs	New	Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
21.	Sanofi-Aventis Deutschland GmbH, Industriepark Höchst,	**Toujeo Solostar**	Insulin Glargine 300U/ml solution for injection	Antidiabetic	Treatment of diabetes mellitus in adults.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients.	Insulin Glargin 100IU/ml Solution For	Germany (**EMA CPP**)	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Brüningstraße D-65926 Frankfurt am Main, Germany. **Importer:** (Sanofi Bangladesh Limited)		(Each pen contains 1.5 ml of solution for injection, equivalent to 450 units.)			**Side-effects:** **Immune system disorders:** Rare: Allergic reactions **Metabolism and nutrition disorders:** Very Common: Hypoglycaemia **Nervous system disorders:** Very Rare: Dysgeusia **Eyes disorders:** Rare: Visual impairment, Retinopathy **Skin and subcutaneous tissue disorders:** Common: Lipohypertro-phy, Uncommon: Lipoatrophy **Musculoskeletal and connective tissue disorders:**Very Rare: Myalgia **General disorders and administration site conditions:** Common: Injection site reactions, Rare: Oedema	Injection Insulin Glargin 300IU/3ml Injection			
22.	**Manufacturer** BoehringerIngelheimPharma GmbH & Co. KG, Germany **Local Agent**: Radiant Export Import Enterprise 474 (5th Floor), Road- 3, Sector-12, Uttara, Dhaka-1230	Glyxambi Film Coated Tablet	Empagliflozin INN 10mg + Linagliptin INN 5mg	Antidiabetic	Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus: to improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Glyxambi do not provide adequate glycaemic control when already being treated with the free combination of empagliflozin and linagliptin.	**Contraindication** Hypersensitivity to empagliflozin or linagliptin or any of the excipients. **Side effect** Common side effects of Glyxambi: Urinary tract infection,Commoncold symptoms Upper respiratory tract infections,Genital yeast infection, Increased urination, Joint pain, Nausea, Runny or Stuffy nose,Diarrhoea,Cough **Adverse Drug reactions** **Infections and infestations** Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections Urinary tract infection (including pyelonephritis and urosepsis) Nasopharyngitis **Immune system disorders:** Hypersensitivity, Angioedema, Urticaria **Metabolism and nutrition disorders:** Hypoglycemia (when used with sulphonylurea or insulin)2 Ketoacidosis	New	EMA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Renal and urinary disorders Increased urination **Respiratory, thoracic &mediastinal disorders** Cough **Skin and subcutaneous tissue disorders** Rash, Pruritus				
23.	**Manufacturer** BoehringerIngelheimPharma GmbH & Co. KG, Germany **Local Agent**: Radiant Export Import Enterprise 474 (5th Floor), Road- 3, Sector-12, Uttara, Dhaka-1230	Glyxambi Film Coated Tablet	Empagliflozin INN 25mg + Linagliptin INN 5mg	Antidiabetic	Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus: to improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Glyxambi do not provide adequate glycaemic control when already being treated with the free combination of empagliflozin and linagliptin●	**Contraindication** Hypersensitivity to empagliflozin or linagliptin or any of the excipients. **Side effect** Common side effects of Glyxambi: Urinary tract infection,Commoncold symptoms Upper respiratory tract infections, Genital yeast infection, Increased urination, Joint pain, Nausea, Runny or Stuffy nose, Diarrhea, Cough **Adverse Drug reactions** **Infections and infestations** Vaginal moniliasis, vulvovaginitis, balanitis and other genital infections Urinary tract infection (including pyelonephritis and urosepsis) Nasopharyngitis **Immune system disorders** Hypersensitivity, Angioedema, Urticaria **Metabolism and nutrition disorders:** Hypoglycaemia (when used with sulphonylurea or insulin) Ketoacidosis **Renal and urinary disorders** Increased urination **Respiratory, thoracic &mediastinal disorders** Cough **Skin and subcutaneous tissue disorders** Rash	New	EMA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						Pruritus, Bullous pemphigoid				
24.	Japan Bio Products Co. Ltd., Japan Local Agent: Renata Ltd.	Laennec Injection (Human-placental extract)	Water soluble substance of a product of enzymatic human placental 112 mg/2ml		Improvement of hepatic function in chronic liver diseases	**Caution for USe:** **1. Careful Administration** LAENNEC should be administrated with care in patients predisposed to allergies. **2. Important Basic Cautions** This product is manufactured from the extract of human placenta delivered full-term in Japan. In order to screen each donor, a complete medical history, interviewing such as a history of travel and serologic testing for viruses, bacteria and infection are performed, after nucleic-acid testing (NAT) to meet with requirements for HBV-DNA, HCV-RNA and HIV-1-RNA is carried out. In addition, it has been confirmed that high-pressure steam sterilization for 20 minutes at 121 °C during the manufacturing process is effective in inactivating various viruses such as HIV etc. Furthermore, although in the product test, the nucleic-acid test meets with requirements for HBV-DNA, HCV-RNA, HIV-1-RNA, HTLV-DNA, and parvovirus B19-DNA, patients should be made aware of the following points during administration: To date, the transmission of infection, such as variant Creutzfeldt-Jakob disease (vCJD), by administration of this product in Japan or other countries has not been reported. However, although safety measures are taken to prevent infection during the manufacturing process, it is theoretically impossible to fully eliminate the risks of infection transmission originating in a human placenta used as raw material. While safety measures during the manufacturing process to prevent infection, as well as confirmation of the necessity of	New	Japan	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						treatment for the disease before administration are carried out, doctors should explain to patients and try to have them understand that when human placenta is used as the raw material of a product, the risk of infection cannot be fully ruled out. **3. Drug Interactions** When this product is directly mixed with a strong base preparation of pH 8.5 or more, attenuation of pharmacological activity has been reported. No co administration with this product resulting in the enhancement or attenuation of the pharmacological effect of this product or concomitant drugs, appearance of adverse reactions, or aggravation of disease has been reported. **Adverse reactions :** Adverse reactions or patients who were suspected to have suffered adverse reactions to this product were reported in a total of 10 (3.7 %) of the 273 patients selected for safety evaluation in the clinical study performed during implementation of reevaluation of the drug efficacy. The most frequently observed adverse reactions were injection site pain in 7 patients (2.6 %), hypersensitivity (such as rash, fever, and itching) in 1 patient (0.4 %), injection site indurations in 1 patient (0.4 %), and gynaecomastia in 1 patient (0.4 %). The causal relationship between gynaecomastia and this product is unknown. No abnormal changes in laboratory values were observed.[1)] • Clinically significant adverse reactions **Shock (incidence unknown): Since this product is a protein/amino acid preparation derived from human tissue, this product may cause a				

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						shock. If any signs of abnormality are observed, the drug should be discontinued immediately, appropriate measures should be taken and the condition should be monitored fully. • Other adverse reactions (in descending order of occurrence)				
25.	**Manufacturer:** Amgen Manufacturing Limited, USA **Local Representative:** Novartis Bangladesh Ltd. AHN Tower 7th Floor 13 C R Dutta Road (old Sonargaon Road) Biponan C/A, Dhaka 1000 Bangladesh	**Aerinex** 70mg/ml Solution for Injection in a Pre-filled Syringe	Erenumab INN 70mg/ml		**Aerinex** is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. **Side Effects:** General disorders and administration site condition, gastrointestinal disorders, musculoskeletal and connective tissue disorders & skin and subcutaneous tissue disorders.		EMA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
26.	**Manufacturer:** Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Dobutamine hydrochloride Hameln 5mg/5ml in 50ml vial. Solution for infusion	Dobutamine Hydrochloride Ph. Eur 250mg/50ml	Cardiac	To treat heart failure (cardiac decomposition) if the heart is not beating strongly enough (depressed contractility),- in heart failure where there is severe low blood pressure	**Contraindication:** - severe heart failure (NYHA III or IV), - predisposition for or documented medical history of clinically significant or chronic arrhythmia, particularly recurrent persistent ventricular tachycardia, - significant disturbance in conduction, - acute pericarditis, myocarditis or endocarditis, - aortic dissection, - aortic aneurysm, - poor sonographic imaging conditions, - inadequately treated / controlled arterial hypertension,	Dobutamine Hydrochloride 280mg/Vial	Germany BNF-76 Page:221	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					(hypotension),- to detect poor blood supply to the heart (cardiac stress testing). Paediatric population	- obstruction of ventricular filling (constrictive pericarditis, pericardial tamponade), - hypovolaemia, - previous experience of hypersensitivity to dobutamine. **Side Effect:** • feel or actually be sick • produce more saliva than usual • produce more tears than usual • suffer from bronchial spasm and increased bronchial secretion • suffer from diarrhoea and stomach cramps • have constricted (pin-point) pupils in your eye • suffer from urinary incontinence (you pass urine when you do not mean to) • suffer from excessive sweating • have a slow pulse • suffer from hypotension (blood pressure that is much lower than usual) • suffer from muscle spasms				
27.	**Manufacturer:** Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Flumazenil-Hameln 0.1mg/ml, 5ml ampoule. Concentrate for solution for infusion.	Flumazenil 0.5mg/5ml Ph. Eu	Antidote for benzodiazepines	Indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in anesthesia and in the intensive care in the following	**Contraindication:**. Hypersensitivity to flumazenil or to any of the excipients. Patients receiving benzodiazepines of control of a potentially life-threatening condition . (e.g control of intracranial pressure or status epilepticus). **Side Effect:** Immune systems disorders Common: Allergic reactions Rare: Severe hypersensitivity reactions (including anaphylaxis) Psychiatric disorders	New	Germany BNF-76 Page:1328	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					situations: In anesthesia- Termination of hypnosedative effects in general anesthesia induced and/or maintained with benzodiazepines in hospitalized patients.- Reversal of benzodiazepine sedation in short-term diagnostic and therapeutic procedures in ambulatory patients and hospitalized patients.- For the reversal of conscious sedation induced with benzodiazepines in children > 1 year of age. In intensive care situations - For the specific reversal of	Common:Anxiety*, emotional lability, insomnia, somnolence Uncommon: Fear Nervous system disorders: Common:Vertigo, headache, agitation*, tremor, dry mouth, hyperventilation, speech disorder, paresthesia Uncommon: Convulsions (in patients suffering epilepsy or severe hepatic insufficiency, mainly after long-term treatment with benzodiazepines or multiple medicinal products abuse, Eye disorders **Common:** Diplopia, strabismus, lacrimation increased Ear and labyrinth disorders Uncommon:Abnormal hearing Cardiac disorders Common:Palpitations* Uncommon:Tachycardia or bradycardia, extrasystole				

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					the central effects of benzodiazepines, in order to restore spontaneous respiration.- For diagnosis and treatment of intoxications or overdose with only or mainly benzodiazepines					
28.	**Manufacture:** Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Glyceryl Trinitrate Hameln 1mg/ml in 50ml vial, Ready to use solution	Glyceryl Trinitrate 50mg/50ml	Antianginal	• Unresponsive congestive heart failure, including that secondary to acute myocardial infarction; acute left-sided heart failure and acute myocardial infarction, • Refractory unstable angina pectoris and coronary insufficiency, including Prinzmetal's angina, • Control of hypertensive episodes and/or myocardial ischaemia during and after cardiac surgery, • Induction of controlled hypotension for surgery.	**Contraindication:**. Glyceryl Trinitrate should not be used in the following cases: • Hypersensitivity to the active substance, other nitrates or any of the excipients listed in Section. • Acute circulatory failure (shock, collapse) • Cardiogenic shock (unless a sufficient end-diastolic pressure is maintained by appropriate measures) • Severe anaemia, • Severe cerebral haemorrhage • Head trauma **Side Effect:** Headaches caused by vasodilation occur frequently , especially at the onest of therapy. Flushing, drowsiness, orthostatic hypotension and refex tachycardia are reported occeasionally. Less often states of collapse occur , sometimes accompanied by bradyarrythmias . in rare cases where there is a large	2.6 mg Tablet & 400 mcg/Metered Inhalation 50 mg/10 ml Injection	Germany BNF-76 Page:219	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						drop in blood pressure, symptoms of angina pectoris may be enhanced.				
29.	**Manufacture:** Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Naloxone-hameln 0.4mg/ml in 1ml ampoule Solution for Injection	Naloxone 0.4mg/ml	Opioids Antidote	It may be used for the complete or partial reversal of opioid depression, including mild to severe respiratory depression induced by natural and synthetic opioids, the agonists/antagonists nalbuphine and pentazocine, or dextropropoxyphene. It may also be used for the diagnosis of suspected acute opioid over dosage. Naloxone may be used to counteract respiratory and other CNS depression in the newborn resulting from the administration of analgesics to the mother during	**Contraindication:** Naloxone should not be given to patients who are known to be hypersensitive to the drug, or any of the excipients. **Side Effect:** Immune system disorders Very rare: Allergic reactions (urticaria, rhinitis, dyspnoea, Quincke's oedema), anaphylactic shock Nervous system disorders Common: Dizziness, headache Uncommon: Tremor, sweating Rare: Seizures, tension Cardiac disorders Common: Tachycardia Uncommon: Arrhythmia, bradycardia Very rare: Fibrillation, cardiac arrest Vascular disorders Common: Hypotension, hypertension	400 mcg/ml Injection	Germany BNF-76 Page:1330	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					childbirth					
30.	**Manufacture:** Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Fentanyl Hameln 50mcg/ml in 50ml vials for perfusion pump	Fentanyl Ph. Eu 2.5mg/50ml,	Anesthesia	Short duration analgesia during pre-medication, induction and maintenance of anaesthesia, and in the immediate post-operative period. Opioid analgesic supplement to general and regional anaesthesia. Combination with a neuroleptic as an anaesthetic pre-medication for the induction of anaesthesia, and as an adjunct in the maintenance of general and regional anaesthesia.	**Contraindication:** Known hypersensitivity or intolerance to Fentanyl, other opioid analgesics, or to any of the excipients._As for any opioid analgesic, Fentanyl should not be used in patients susceptible to respiratory depression, use of Fentanyl in patients who have received MAO inhibitors within 14 days is not recommended. Fentanyl may cause muscle rigidity upon IV administration. Therefore, the need for reversal and muscle relaxants contraindicates its use in patients with a history of myasthenia gravis. For Children two years of age or younger Safe conditions for use have not been established. Use in patient after operative interventions in the biliary tract is not recommended. **Side Effect:** Fentanyl Injection may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. Common Side Effects are, An Unusual Sense Of Well Being Sedation , Headaches , Post-Operative Confusion Or Agitation, Neurological Or Airway, Complications Of Anesthesia, Vein Pain O Inflammation, Chills Or Lowered Body Temperature, Visual Disturbance.	100mcg Tablet 100mcg/2 ml Injection	Germany	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
31.	Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road ,	Neostigmine Methyl sulfate Hameln 2.5mg/ml Solution for injection	Neostigmine Ph. Eu 2.5mg/ml	Cholinesterase inhibitor	• Treat abnormally tired and weak muscles (myasthenia gravis).	**Contraindication:** It is contraindicated in patients with hypersensitivity to neostigmine or to any of the excipients in this injection. Neostigmine should not be administered to patients with mechanical obstruction of gastrointestinal or urinary tracts, peritonitis or doubtful bowel viability.	500 mcg/ml Injection	Germany BNF-76 Page: 1091	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.				• Reverse the effects of muscle relaxants. • Improve movement in the small intestine. • Reduce urine retention after surgical procedures.	Neostigmine should not be used in conjunction with depolarizing muscle relaxants such as suxamethonium as neuromuscular blockade may be potentiated. **Side Effect:** • feel or actually be sick • produce more saliva than usual • produce more tears than usual • suffer from bronchial spasm and increased bronchial secretion • suffer from diarrhoea and stomach cramps • have constricted (pin-point) pupils in your eye • suffer from urinary incontinence (you pass urine when you do not mean to) • suffer from excessive sweating • have a slow pulse • suffer from hypotension (blood pressure that is much lower than usual) suffer from muscle spasms				
32.	Siegfried Hameln GmbH Langes Feld 13, 31789 hameln, Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Midazolam Hydrochloride Hameln 1mg/ml in 50ml vial for perfusion pump	Midazolam Hydrochloride Ph. Eu 50mg/50ml	Sedative hypnotic	Midazolam 1mg/ml is a short-acting sleep-inducing drug that is indicated: *In adults* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia: - As a sedative component in combined anaesthesia. • SEDATION IN INTENSIVE CARE UNITS	**Contraindication:** Hypersensitivity to benzodiazepines. Chronic respiratory insufficiency. **Side Effect:** headache, nausea, vomiting, cough, drowsiness, hiccups, "oversedation," or. injection site reactions (pain, swelling, redness, stiffness, blood clots, and tenderness).	7.5mg & 15mg Tablet 1 mg/ml, 15 mg/3 ml Injection	Germany BNF-76 Page: 338	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					In children • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia • SEDATION IN INTENSIVE CARE UNITS					
33.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai-625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka	FLURES injection	Fluorescin injection IP 20% w/v in 3ml	Diagnostic agent, Ophthalmic	Ophthalmic angiography. Angiography in diagnostic examination of the fundus. Evaluation of iris vasculature. Differentiate between viable and non-viable tissue. To asses aqueous flow. Differential diagnosis of malignant tumors. Determination of circulation time and adequacy of the circulation	**Contraindication:** Persons those who are hypersensitivity to any component of this preparations.	India		আমদানি নিমিত্তে রেজিষ্ট্রেশন প্রদানের জন্য প্রয়োজনীয় প্রি-সেলস সার্টিফিকেট দাখিল না করায় পদটির আবেদন নামঞ্জুর করা যেতে পারে। ঔষধটি স্থানীয়ভাবে উৎপাদনের ব্যবস্থা গ্রহনের জন্য বাংলাদেশ ঔষধ শিল্প সমিতিকে পত্র প্রেরণ করতে হবে।	আমদানি নিমিত্তে রেজিষ্ট্রেশন প্রদানের জন্য প্রয়োজনীয় প্রি-সেলস সার্টিফিকেট দাখিল না করায় পদটির আবেদন নামঞ্জুর করা হল। ঔষধটি স্থানীয়ভাবে উৎপাদনের ব্যবস্থা গ্রহনের জন্য বাংলাদেশ ঔষধ শিল্প সমিতিকে পত্র প্রেরণ করতে হবে।

Sl No.	Name of the manufacturer	Name of the product	Generic Name	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
34.	**Manufacturer:** **River Pharma Srl;** Address: Viale Stazione 6, 26863 Orio Litta (LO), Italy **Importer:** Benvue International Ltd. Address: 14/1, Joy Tower, Chatteshawri Road, Chittagong, Bangladesh.	Nevralip 600 Retard Tablet	Alpha Lipoic Acid Ph. Eu. 600 mg	Antioxidant	It is indicated for treatment of neuropathic pain induced by chemotherapy, diabetes, neurological disorders	**Contraindications:** Alpha Lipoic acid (ALA) is contraindicated in patients with known hypersensitivity to Alpha Lipoic acid (ALA) or any of its components. **Side Effects:** Alpha Lipoic acid is well tolerated but is generally rare. Low doses of lipoic acid show no side effects. But higher doses could cause skin rash, nausea or stomach upset, along with nervousness, fatigue and insomnia.	New	Italy	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Annex-J: List of Products for Local Manufacture (Veterinary):

Sl. No.	Name of the Manufacturer	Name of the Product	Generic Name	Therpeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule/Existing)	USFDA, BNF or MHRA Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	সভার সিদ্ধান্ত
01.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	**Amprolium Hydrochloride 50% Solution (Vet)**	Amprolium Hydrochloride USP 50gm/100ml	Anti-Protozoal	It is used as a therapeutic agent against Eimeria infections in poultry, especially E. tenella, E. necatrix, E. acervulina and E. praecox. It is effective against other protozoal infections like Histomoniasis (Blackhead) in poultry and turkeys; against coccidiosis in calves, lambs, kids and pigs; against amoebiasis in various species.	**Contraindication:** Do not use in layers producing eggs for human consumption. **Side effects:** Prolonged high dose treatment may result in delayed growth or poly-neuritis (caused by reversible thiamine deficiency). The development of natural immunity against the different protozoa may be delayed. Use in laying hens may cause egg-drop.	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
02.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Elemental Calcium 60mg+ Elemental Phosphorus 30mg+ Vitamin B12 15mcg+ Vitamin C 10mg+ Vitamin D3100 500IU+ Citric Acid 30mg per gm Powder	Elemental Calcium INN 60mg+ Elemental Phosphorus INN 30mg+ Vitamin B12 BP/Ph. EUR 15mcg+ Vitamin C BP/PH.EUR 10mg+ Vitamin D3100 BP/PH.EUR 500IU+ Citric Acid BP/PH.EUR 30mg	Multivitamin	Combination of Calcium, Phosphate & Vitaminis used for the prevention & treatment of Calcium & Phosphorus deficiency syndrome. e.g. – rickts, osteomalacia, osteoporosis, osteopetrosis, calcium tetany/lactation tetany etc. and cage layer fatigue, thin & soft shelled eggs, abnormal shaped eggs, lower egg production.	**Contraindications:** Combination of Calcium, Phosphate & Vitaminis contraindicated in Birds hypersensitive to any of its components **Side-effect:** It has no side effect at recommended dose.	New		অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
03.	Renata Limited Mirpur, Dhaka	Moxidectin 0.50gm/100ml Pour-on Solution (Vet)	Moxidectin USP 0.50gm/100ml	Ectoparasiticide	Moxidectin kills some of the most common internal and external parasites by selectively binding to a parasite's glutamate-gated chloride ion channels. These channels are vital to the function of invertebrate nerve and muscle cells; when moxidectin binds to the channels, it disrupts neurotransmission, resulting in paralysis and death of the parasite.	**Contraindications :** For external use only. Do not apply to areas of skin with mange scabs, skin lesions, mud or manure. Moxidectin Pour-On is not recommended for use in species other than cattle. This product has been formulated specifically for topical use in cattle and should not be used in other animal species or by other routes of administration as adverse reactions may occur.	New	USFDA	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Annex-K: Products List for Import (Veterinary)

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
1.	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 RIUDOMS (Tarragona) SPAIN **Local Agent:** Haychem (Bangladesh) Ltd. 18,19 BSCIC, Maskanda, Mymensingh	SULFADIM Oral Solution	Sodium Sulfadimethoxine Ph. Eu. 26.75 gm eq. to 25.0 gm Sulfadimethoxine/100ml	Antibiotic	Poultry, broilers and replacement chicks: Treatment of caecal and intestinal coccidiosis, fowl cholera and infectious coryza. Turkeys: Treatment of caecal and intestinal coccidiosis and fowl cholera. Dairy calves, dairy heifers, beef cattle, sheeps and goats: foot rot, shipping fever complex and bacterial pneumonia associated with *Pasterella spp*, calf diphteria . Rabbits : coccidiosis	Contraindication: Do not use in animals with known sulphonamide sensitivity, liver damage, renal insufficiency or dyscrasias. **Side-effect:** Anaphylactic reaction, vomits, and urinary tract disorders may appear. Prolonged treatments (longer than 6 days) may cause acute haemorrhages in some treated birds, basically in hot periods. In such cases, a vitamin K supplement is required.	New	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
2.	**Manufacturer:** **LAVET PHARMACEUTICALS** 14 Ottó utca, Budapest, H-1161 Hungary **Local Agent:** **UNIVET LIMITED** House 1, Road 10/A, Nikunja 1, Khilkhet, Dhaka – 1229, Bangladesh	DIFLOCIN 10% Oral Solution	Difloxacin (as hydrochloride) 100mg/gm	Antibiotic	Treatment of respiratory, intestine and systemic infections caused by Difloxacin sensitive organisms in poultry	**Contradiction:** Not for use in laying poultry when eggs are produced for human consumption. **Side effects:** Diflocin is of low toxicity and side-effects are very rarely encountered. If suspected adverse reactions do occur, treatment should be discontinued. During the toxicological examinations no undesirable effects were detected.	New	Hungary	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
3.	Laboratories Biove, France (Inter Agro BD Limited, Mohakhali, Dhaka)	SODIBIO Injection	Ampicilline Trihydrate Eur.Ph 10 gm, + Colistin (as Sulphate) 25 MIU + Dexamethasone(as acetate) 25gm/100 ml	Antibiotic	Affections due to germs susceptible to Ampicilline and colistin in cattle, sheep, goats and pigs. Ampicilline : Semi-synthetic betalactum with wide spectrum, eliminated under active form by urine and bile, with entero-biliary cycle. Colistin: Polypeptide bacteriostatic and bactericidal agent, effective against Colibacilli, effective against Salmonella, Klobsiella (gram Negative.) . It is eliminated through urine	-Do not used in rabbits. -Animals susceptible to penicillin' risk of allergic reactions	Ampicilline Trihydrate 10gm + Colistin 50 MIU + Dexamethasone 25gm/100 ml Injection	France	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
4.	Laboratories Biove, France (Inter Agro BD Limited, Mohakhali, Dhaka)	TYLOLIDE Powder for Solution	Tylosin (as tartrate) 100000000 IU (100%)	Antibiotic	TYLOLIDE is an oral powder used for treatment of infections due to tylosin sensitive germs disease in calves, pig, turkey and poultry. It is orally administered dissolve in drinking water or milk. It is composed of 100 % of tylosin tartrate granular. In Chickens: For the control of mortality caused by necrotic enteritis (NE) associated with Clostridium perfringens in broiler chickens. An aid in the treatment of chronic respiratory disease (CRD) associated with Mycoplasma gallisepticum in boiler and replacement chickens. For the control of CRD associated with Mycoplasma galliseptium at the time of vaccination or other stress in chickens. For the control of CRD associated with Mycoplasma synoviac in boiler chickens. Turkeys : For the reduction in severity of effects of infectious	None known	Tylosin 20% Powder	France	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					sinusitis associated with Mycoplasma galliseptium. Swine: For the treatment and control of swine dysentery (SD) associate with Brachyspira hyodysenteriae. For the treatment and control of SD associated with Brachyspira hyodysenteriae when followed immediately by Tylolide Type A medicated article in feed.					
5.	EWHAPHARMTEK Corp. South Korea (Novatech BD Limited, Gazipur)	TILCOSIN PLUS (VET) Oral Solution	Tilmicosin Phosphate 150g + Doxycyline Hyclate 100g /Liter	Antibiotic	- For the treatment against the following diseases by susceptible bacteria (*E.coli, Salmonella, Mycoplasma Pasteurella, Staphylococcus, Heamophilus).* Poultry: Chronic Respiratory Disease, Complex Chronic Respiratory Disease, Colibacillosis, Mycoplasmosis, Infectious Coryaza, Streptococcosis, Staphylococcosis.	Contra-indications Not for use in animals from which eggs are produced for human consumption. Do not use in case of hypersensitivity to Tilmicosin or to any of the excipients. Doxycycline: Hypersensitivity to tetracycline or to any of the excipients. Do not administer to animals with severe liver- or kidney insufficiency	Tilmicosin Phosphate 150g /L	South Korea	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
6.	**Manufacturer:** Lexington Enterprises Pte. Ltd. 30 penjuru road , Singapore **Local Agent:** Century Agro Lilmited Union Heights, Level-7, 52/2 west Panthapath Dhaka-1205.	CEC Solution	Enrofloxacin 2.5gm + Ciprofloxacin 6.5gm + Colistin sulphate 0.25gm/ 1000ml	Antibiotic	It is recommended for various poultry disease and infection like- 1. prevents & controls all kinds of bacterial diseases. 2. Improves growth & body weight. 3. It should be used mainly as growth promoter and to control mild infections only. 4. During serious outbreaks potential antibiotics should be used.	**Contradiction:** Hypersensitivity to ciprofloxacin. Administration to animals with a serious impaired hepatic and/or renal function. Concurrent administration of tetracyclines, chloramphenicol, macrolodes and lincosamides. **Side effects:** Hypersensitivity reaction. Administration to juvenile animal can lead to arthropathy.	New	Singapore	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					5. Mycoplasmosis, E-coil, coryza, fow cholera, salmonellosis. 6. It is act against all gram positive and gram negative organisms. 7. Mix infection. 8.For prevention and treatment of chronic Respiratory Disease (CRD) and associated symptoms viz cough, sneezing, nasal discharge, tracheal rales, gasping, unthriftiness etc.					
7.	**Manufacturer:** Lexington Enterprises Pte. Ltd. 30 penjuru road , Singapore. **Local Agent:** Century Agro Lilmited Union Heights, Level-7, 52/2 west Panthapath Dhaka-1205.	LINCOSEP Oral Solution	lincomycin 2.2gm + Spectionomycin 2.2gm/ 100ml	Antibiotic	It is recommended for various poultry diseases and infections like- Effective controlof CRD. E.coli, Salmonella, Klebsiella and proteus. Enteritis. It can be used generally for enteric and control of diarrhea.	**Contradiction:** Hypersensitivity reactions. **Side effects:** Do not use in poultry producing eggs for human consumption. don not use in horses, ruminating animals, guinea pigs and rabbits. do not use in animals known to be hypersensitive to the active ingredients. do not co-administer with penicillins, cephalosporins, quinolones and/or cycloserine. do not administer to animals with seriously impaired impaired renal functions.	Lincomycin Base 22.2 gm + Spectinomycin 44.4 gm/100 gm Water Soluble Powder	Singapore	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
8.	Laboratories Biove, France (Inter Agro BD Limited, Mohakhali, Dhaka)	ACTILIVER I Solution for Injection	Membutone Ph. Eu. 50 mg /ml	Choleretic agent	Membutone increases the excretion of the bile, the gastric and the pancreatic juice into the gut by twice to five fold the normal secretion and stimulates the function of the gastrointestinal tract.It is a Solution for injection used for bovines and pig.	**Contraindications:** Do not use in animals with known hypersensitivity to the active ingredient. Not recommended for use in animals with cardiac disease. Special warnings for each target species: None.	New	France	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
9.	Manufacturers : Biocide biodegradables ZIX, SL, Spain Local agent : Planet pharma Ltd Delta dahlia (7Floor) 36, kamal ataturk avenue, banine.	**ZIX VIROX Liquid**	Hydrogen peroxide 25.0 % + Peracetic acid 5.0 % +Acetic acid 8.0 %	Disinfectant	New generation of bactericidal, antiviral, fungicidal and antiprotozoan products for the treatment of the surface areas of swine, poultry, cattle and sheep.	Contra-indication : Any contraindication have been identified regarding this regarding this product and any reported. there are no limits to the maximum content of the substance in the complete food. Blanking period (lime between doses, if required); not applicable	New	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
10.	Manufacturers : Biocide biodegradables ZIX, SL, Spain Local agent : Planet pharma Ltd Delta dahlia (7Floor) 36, kamal ataturk avenue, banine.	**VIROX Powder**	Potassium Monopersulphate 53.5% + Sulphamic acid 1% + Sodium dodecylbenzene sulphonate 0.8%	Disinfectant	Disinfection of livestock stalls Surfaces, walls, ceilings, etc In the surroundings in the presence of animals. Material, cages, utensils, tools. Cadaver containers. Feeders and drinkers. Water tanks and pipes. Foot washes. Effective against foot rot. Vehicles: Drive-through disinfection. Vehicle wheel washes. Live animal transport. Carcass transporters. Incubators and hatcheries. Disinfection of fertile eggs. Harmless to the embryo. Aquaculture.	Contra-indication : Any contraindication have been identified regarding this regarding this product and any reported. there are no limits to the maximum content of the substance in the complete food. Blanking period (lime between doses, if required); not applicable Side-effect : None	New	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
11.	Manufacturers : Biocide biodegradables ZIX, SL, Spain Local agent : Planet pharma Ltd Delta dahlia (7Floor) 36, kamal ataturk avenue, banine.	**AQUAZIX® PLUS Ag Liquid**	Hydrogen peroxide 50.0 % + Silver 0.038%	Disinfectant	New generation of bactericidal, antiviral, fungicidal and antiprotozoan products for the treatment of the surface areas of swine, poultry, cattle and sheep.	Contra-indication : Any contraindication have been identified regarding this regarding this product and any reported. there are no limits to the maximum content of the substance in the complete food. Blanking period (lime between doses, if required); not applicable Side-effect : None	New	Spain	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
12.	Manufacturer: ADBIOTECH.CO.,LTD 39,Geodudanjil-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea **Local Agent:** Al-Madina Pharmaceuticals Ltd. 1/1, TilarGati, kakil, Sathais,Tongi, Gazipur	AMAZON Soluble powder disinfectant	Triple salt-500g + Malic acid, KVP 5-100g + Citric acid, KVP5 30gm + Tartaric acid, KVP5 20gm/kg	Disinfectant	For sterilization and disinfection about tank (footing), doorway, floor of house, playground, transportation equipment (farm, animal transport, barley, feed, hay, milk transporter etc.) For sterilization and disinfection about virus and bacteria. - Bacteria : Salmonella typhimurium, Brucella ovis. - Virus : ND disease virus, FMD virus, AI disease virus, CFS virus.	**Contraindications:** None reported. **Side effects:** None reported.	New	Republic of Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
13.	**Manufacturer:** ADBIOTECH.CO.,LTD 39,Geodudanjil-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea **Local Agent:** Al-Madina Pharmaceuticals Ltd. 1/1, TilarGati, kakil, Sathais,Tongi, Gazipur.	IGUASU Soluble powder disinfectant	Didecyl dimethyl ammonium chloride- 100gm + Anhydrous Citric Acid, KVP5- 200g + Phosphoric acid, KVP5- 60g + Tartaric acid, KVP5 40g/Liter	Disinfectant	1.For the disinfection and sterilization of bacteria and virus susceptible to this agent. Bacteria: Salmonella typhimuirium, Brucell ovis Virus ND disease virus, FMD virus, AI virus, and CFS virus 2.For sterilization and disinfection about tank(footing), doorway, floor of house, playground, transportation equipment (farm, animal transport, barley, feed, hay, milk transporter etc.)	**Contraindications:** None reported. **Side effects:** None reported. .	New	Republic of Korea	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
14.	**Manufacturer:** Lexington Enterprises Pte. Ltd. 30 penjuru road , Singapore. **Local Agent:** Century Agro Lilmited Union Heights, Level-7, 52/2 west Panthapath Dhaka-1205.	**COUGHNIL**	Bromhexine HCl 80mg + menthol 10mg + Ammonium chloride 2200mg + levocetrizine Dihydrochloride 5mg + Sodium Citrate 1100mg/1000ml	Expectorant	used for all types of cough except for infected sore throat Novel action on MAST cells to prevent release of histamines Additionally builds immunity to fight infection Does not harm CNS nor cause any drowsiness Though the syrup is sweeter, they can as well be used by diabetic patients without fear.It is highly safe, effective and works great on children.Important Note	Contradiction: None Side Effects: Well tolerated	New	Singapore	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
15.	Laboratories Biove, France (Inter Agro BD Limited, Mohakhali, Dhaka)	Bioveine Calcium GMC Injection	Calcium gluconate 25.04 mg plus Magnesium Hypophosphite 52.96 mg/ ml	Minerals	Treatment and prevention of hypocalcemia (milk fever) and/or hypomagnesemia (lactation tetany, transport tetany, grass tetany) in cattle, sheep and goats with metabolic and hepatic disorders observed during milk fever, peripartum paresis, grass tetany or eclampsia	**Contraindications:** Do not use in case of animals suffering from cardiac disorder	Calcium gluconate 28 gm plus Magnesium Hypophosphite 9 gm/ 100 ml (DCC-209)	France	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
16.	**Manufacturer**: M/S ChoongAng Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Importer**: M/S Pharma& Firm 3/2, ityHeartBuilding, 67, NayaPaltan, Dhaka-1000	PoulShot® Flu H9N2+ND Vaccine	Each dose: Avian influenza virus (AIV, H9N2, 01310 strain) ----------≥$10^{9.5}$ EID_{50} Newcastle disease virus (NDV, Lasota strain).----------≥$10^{9.}$ EID_{50} Adjuvant ---------- 70% Inactivator----------≤ 0.2%	Vaccine	For active immunization of chickens as an aid in the control and prevention of avian influenza caused by AIV and Newcastle disease caused by NDV.	**Contraindication:** -None **Side-effect:** Inappetance, coughing, sneezing and decreased egg production may occur. **Withdrawal period** -None	New	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
17.	**Manufacturer**: M/S ChoongAng Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Importer**: M/S Pharma & Firm 3/2, ityHeartBuilding, 67, NayaPaltan, Dhaka-1000	CaniShot® DHPPL	Each dose: CaniShot® DHPP Canine distemper virus (CDV,Onderstepoort strain) ----------30% Canine adenovirus type 2 (CA-2, Manhattan strain).----------10% Canine parvovirus (CPV, 780916-LP strain----------20% Canine para influenza virus (CPIV, D008 strain----20% Stabilizer---------20% aniShot® Lepto Leptospiracanicola-------0.5ml eptospiraicterohaemorrhagiae ----------0.5mlThimerosal----------	Vaccine	As an aid in the control and prevention of CDV, CAV-2, CPV, CPIV, Lepospiracanicola and L. icterohaemorrhagiae in dogs	**Contraindication:** -None **Side-effect:** Inappetance, Lethargy and anaphylaxis may occur. **Withdrawal period** -None	New	Korea	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
18.	**Manufacturer**: M/S ChoongAng Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Importer**: M/S Pharma & Firm 3/2, ityHeartBuilding, 67, NayaPaltan, Dhaka-1000	PoulShot Flu H9N2+ND Vaccine	**Each dose:** Avian inflenza Virus (AIV, H9N2, 013010 Strain)---------- -≥10^8 EID_{50} Newcastle disease virus (NDV, Lasota strain) ----------≥10^8 EID_{50} Adjuvant ----------70% Inactivator----------≤0.2%	Vaccine	For the prevention against low pathogenic avian influenza infection and Newcastle disease.	**Contraindication:** -None **Side-effect:** Inappetance, Lethargy and anaphylaxis may occur. **Withdrawal period** -None	New	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
19.	FATRO S.p.A , Italy (M/s. SP Vet Care Limited, Dhaka)	PM-OLVAC (Poultry Vaccine)	i) Inactive Newcastle disease virus 100 DP50 and ii)Inactivated pasteurella multocida 100 DP50	Vaccine	PM-OLVAC is indicated to prevent mortality, Syndrome and lesions of the Newcastle disease and fowl cholera in chickens and turkeys.	There are no known contra-indications	New	Italy	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
20.	FATRO S.p.A , Italy (M/s. SP Vet Care Limited, Dhaka)	OLVAC A+ B + HG (Poultry Vaccine)	i) Inactivated virus of Newcastle disease: not less than 50 PD 50 ii) Inactivated virus of Infectious bronchitis: not less than 10 7.5 EID 50 iii) Inactivated denovirus EDS 76: not less than 1000 HAU iv) Inactivated H. paragallinarum serotvpe A : not less than 3 x 10 9 CFU v) Inactivated H. paragallinarum serotvpe C : not less than 3 x 10 9 CFU Emulsion for Injection (One dose of Vaccine (0.5ml) contains)	Vaccine	OLVAC A+B+ HG is indicated for active immunization to prevent mortality , clinical signs and lesions of the Newcastle Disease, Infectious bronchitis, Infectious Coryza and Egg Drop Syndrome in poultry.	There are no known contra-indications	New	Italy	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
21.	**Manufacturer :** Laboratorios Hipra S.A., Spain **Local Agent :** (Nasco Agro Product) 307 SK. mujibe road, agrabad chittagong.	HIPRAVIAR CLON/H120 Vaccine 1000 dose/vial 2500 dose/vial	Live Newcastle Disease Virus, Strain Clone CL/79…>/=$10^{6.5}$ EID50 Live Infectious Bronchitis Virus, Strain H120…>/=10^{3} EID50 /dose	Vaccine	To prevent Newcastle Disease and Infectious Bronchitis.	**Contraindications**: None has been described. **Side effects:** None has been described. .	New	Spain	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
22.	**Manufacturer :** Laboratorios Hipra S.A., Spain **Local Agent :** (Nasco Agro Product) 307 SK. mujibe road, agrabad chittagong.	AVISAN MULTI/CO Vaccine 1000 dose/bottle	Inactivated Infectious bronchitis virus, Strain H52…….>/=10^{6} EID50 Inactivated Newcastle disease virus, Strain La Sota……>/=10^{8} EID50 Inactivated EDS-76(Egg drop syndrome) virus, Strain 127.....>/=307.2 HAU Avibacterium paragallinarum serotype A >/=$1.25x10^{9}$ microorganisms Avibacterium paragallinarum serotype B >/=$1.25x10^{9}$ microorganisms Avibacterium paragallinarum serotype C >/=$1.25x10^{9}$ microorganisms/dose(0.5ml)	Vaccine	To prevent Infectious bronchitis, Newcastle disease, Egg drop syndrome-76 and Infectious Coryza Disease.	**Contraindications**: None has been described. **Side effects:** None has been described.	New	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
23.	**Manufacturer :** Laboratorios Hipra S.A., Spain **Local Agent :** (Nasco Agro Product) 307 SK. mujibe road, agrabad chittagong	CORIPRAVAC AH Vaccine 1000 dose/bottle	Avibacterium paragallinarum inactivated serotype A, strain 17756…..8-32 MAT Avibacterium paragallinarum inactivated serotype B, strain 0222…..8-32 MAT Avibacterium paragallinarum inactivated serotype C, strain Modesto…..8-32 MAT /dose(0.5ml)	Vaccine	Active immunization to prevent avian infectious coryza in breeders and layers.	**Contraindications**: None has been described. **Side effects:** None has been described.	New	Spain	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
24.	Merial 29, av. Tony Garner France Advance Animal Since Co. Ltd. 149/A, DIT Extension Road, Motijheel, Dhaka-1000.	Gallimune 208 ND + Flu H9 M.E. emulsion for solution	Virus inactive De La Gripe AVIARE SOUCHE H9N2, TITRE MINIMUM Avant inactivation .....10^8 DIO50 Virus INACTIVE De La MALADIE DE New Castle Souch ULSTER 2C, TITRE MINIMUM Avant inactivation .....10^8 DIO50 Excipient Huilex QSP 0.3ml Inactivated Avian Influenza Virus H9N2 Strain, MINIMUM TITRE before inactivation .....10^8 DIO50 Inactivated NEW CASTLE Disease Virus, ULSTER 2C Strain, MINIMUM TITRE before inactivation .....10^8 DIO50 -Oil Excipient QS 0.3ml	Vaccine	For prevention against Newcastle disease and acian influenza in Poultry	**Contraindication:** * Allow the vaccine to reach room temperature (+ 20^0c) before use * make sure vaccination equipment is clean and sterilized before use* shake well before use * avoide intravenous injection * only healthy bird should be vaccinated* Inject subcutaneously in the lower neck or ntramuscularly into the brest Donot use syringes with natural rubber- based or butyl derived elastomer pistons* In case of accidental injection to man, urgent medical attention is necessary**Side Effects:** Vaccination with this vaccine is safe and satisfacory when as recommended hereby	New	France	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
25.	Merial Select, inc, 1168 airport Parkway, Gainesville, Georgia 30503, USA Advance Animal Since Co. Ltd. 149/A, DIT Extension Road, Motijheel, Dhaka-1000.	TROVAC- AIV H5 Vaccine	AVIAN Influenza- Fowl Pox Vaccine Live, Fowl Pox Vector, H5 Subtype	Vaccine	To prevent Avian influenza (H5) and Fowl Pox in Poultry	Only vaccination healthy bird. Administer subcutaneous injection. Avoid stress condition during & following vaccination. Do not vaccinated 21 days of slaughter.	New	USA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
26.	**Manufacturer:** Artvet 1000 N west st suite 1200 wilmington, DE 19801, USA **Local Agent:** Pharmaraw Bangladesh 16/D, Lake circus kalabagan, Dhanmondi, Dhaka1205.	SANTAB Tablet	Sodium Dichloroisocyanurate 5.0gm	Water Purifier	For high quality safe drinking water to improve performance of farm animals. as well as surfaces and qeuipment in farms sanitabis effective against water brone pathogens including salmonella sp. escherichia coli campylobacter jejuni pseudomonas aeruginosa clostruginosa clostridium sp. shigella sonnei aspergillus sp. candida albicans sanitab also clean nipples and biofilms and preven spread of algae sanitab is also effective as a teat dip	**Contradiction:** Chlorine hypersensitivity. **Side effects:** Do not swallow. remove conatact lenses.	New	USA	মৎস অধিদপ্তরের মতামত গ্রহণ করতে হবে।	মৎস অধিদপ্তরের মতামত গ্রহণ করার সিদ্ধান্ত গৃহীত হয়।
27.	Eagle Vet Tech Co., Ltd. ; 235-34, Chusa-ro, Shinam-myun, Yesan-kun, Chungchongnam-do, Korea **Local Agent:** ACI Ltd., 245 Tejgaon I/A, Dhaka-1208	Superflo 300 Sol.	Florfenicol 300g/L	Antibiotic	For the treatment of Salmonellosis and Colibacillosis of Poultry. Withdrawal Period: 05 days	**Contraindication:** Do not use this product for more than 7days consecutively. **Side Effects:** None	200.00gm/L 300mg/Vial Injection	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
28.	Unibiotech Co., Ltd. 235-22, Chusa-ro, Sinam-myeon, Yesan-Gun, hungcheongnam-do, Korea 340-861 **Local Agent:** ACI Ltd., 245 Tejgaon I/A, Dhaka-1208	Godorel	Gonadorelin 50 mcg/ml	Hormone	Cattle: Ovarian cysts, abnormal estrus of treatment, prevention and estrus synchronization.	**Contraindication:** None **Side Effects**: No toxic effects of Gn-RH were observed at therapeutic doses.	100mcg/Vial Injection	Korea	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
29.	**DELOS IMPEX 96 SRL** Romania **Local Agent**: Safe Bio Product Ltd., Gazipur	BROMEX Oral Solution	Enrofloxacin EP 200mg + Bromhexine HCL EP 15mg/ml	Antibiotic	Treatment of mixed infections caused by the following bacteria susceptible to enrofloxacin: Mycoplasma gallisepticum, Mycoplasma synoviae, Avibacterium paragallinarum, Pasteurella multocida, Escherichia coli.	**Contraindication:** Do not use for prophylaxis. Do not use when resistance/ cross-resistance to (fluoro) quinolones is known to occur in the flock intended for treatment. Do not use in chickens with known hypersensitivity to the active substance or to excipients. **Side Effects:** Not known.	Enrofloxacin 100 mg/ml Oral Solution	Romania	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
30.	Ceva Animal Health Inc. 131 Malcolm Road, Guelph, Ontario N1K 1A8, Canada (ACI Ltd.)	**IMMUCOX 5 Vaccine**	Eimeria Acervulina…at least 151 oocysts + Eimeria Brunetti…at least 40 oocysts + Eimeria Maxima…at least 50 oocysts + Eimeria Necatrix…at least 51 oocysts + Eimeria Tenella…at least 25 oocysts/dose.	Vaccine	Aids in the development of immunity in chicken against clinical signs of coccidiosis.	**Contraindication:** Be sure that no coccidiostat (anticoccidioal) is used in the feed. Even a low level of coccidiostat can reduce or negate the effectiveness of the vaccine. Broad spectrum antibiotics (e.g. tetracyclines, sulfa drugs and nitrofurans) should not be used together with IMMUCOX 5 for the first 16 days after vaccination. **Side Effects:** None	New	Canada	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
31.	Unibiotech Co., Ltd. 235-22, Chusa-ro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea (ACI Ltd.)	**DANOXYL Injection**	Danofloxacin INN ….. 25mg (As Danofloxacin Mesylate….. 31.73mg)/ml	Antibiotic	Treatment of the diseases by bacteria susceptible to danofloxacin like Shipping fever, Pasteurellamultocida, Pasteurellahaemolytica of cattle and E.coli, Salmonella typhimuriam of Calf.	**Contraindication:** Do not use for milking. Do not mix with other drugs. **Side Effects:** Subcutaneous injection in cattle may cause local inflammatory reaction. It may cause joint abnormalities (lacerations, pain, cartilage defect) when it is administered to growing animals Withdrawal Period: 5 days	New	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
32.	Ceva-Phylaxia Veterinary Biologicals Co. Ltd. 1107 Budapest, Szállás u. 5 Hungary (ACI Ltd.)	**NOVAMUNE Vaccine**	Live attenuated IBD virus, strain SYZA26 … min. 2.65 log10 CID_{50}/dose	Vaccine	For the active immunization of future layer chickens in order to reduce mortality, clinical signs, acute lesions of bursa of fabricious and to prevent virus shedding caused by classical and very virulent strains of Infectious bursal disease virus. The onset of immunity is expected from four weeks after vaccination depending on the initial maternally derived antibodies (MDA) level. The duration of immunity is demonstrated until 9 weeks after vaccination.	**Contraindication:** Do not vaccinate chickens from non-vaccinated parent flocks or having no MDA against IBD virus. **Side Effects:** In vaccinated chickens mild to moderate lymphocyte depletion can be observed after the vaccine take, which is maximal at around 7 days after vaccine take. After 7 days, this depletion decreases and is followed by lymphocyte repopulation and regeneration of the bursa of Fabricious.	New	Hungary	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
33.	**Manufacturer:** Intervet Productions S.A; Rue de Lyons, 27460, Igoville, France	EXZOLT	Fluralaner INN 10 mg/ml oral Solution	Systemic Insecticide	Treatment and control of poultry Red Mite (Dermanyssus gallinae) or Northern Fowl Mite (Ornithonyssus sylviarum) infestation in pullets, breeders and layer hens.	**Contraindication:** None **Side-effect:** None Known **Withdrawal Period:** Meat and offal- 14 days Eggs- Zero days.	New	France	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Marketing authorization: Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands **Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.									
34.	Intervet International B.V.; Wim de korverstraat, 5831 AN Boxmeer The Netherlands **Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	INNOVAX ND-IBD	Cell Associated live turkey herpes virus strain HVP360* : $\geq 10^{3.3}$ PFU**/dose * HVP360 is a HVT-based recombinant encoding the NDV F protein and the IBDV VP2 protein. ** Plaque Forming Unit	Vaccine	For active immunization of healthy 18-days-old chickens embryos by the in-ovo route or of one-day-old chickens by the subcutaneous route: - to reduce mortality and clinical signs caused by Newcastle Disease (ND) virus, - prevent mortality and to reduce clinical signs and lesions caused by Infectious Bursal disease (IBD) virus	**Contraindication:** None **Side-effect:** None Known **Withdrawal Period:** Zero Days **Drug Interaction :** Innovax ND-IBD can be administered on the same day, but not mixed with, live Nobilis Newcastle disease vaccines, such as Nobilis ND Clone 30 and Nobilis ND C2. For this associated use, an onset of immunity of 2 weeks has been demonstrated for ND. Innovax-ND-IBD can be administered on the same day, but not mixed with, live Nobilis Infectious Bronchitits Vaccines, such as	New	The Netherlands	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
					-to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus. Onset of immunity against ND is 4 weeks against IBD 2 weeks, and against MD 8 days. Duration of immunity is lifelong.	Nobilis IB Ma5 and Nobilis IB 4-91. Innovax-ND-IBD can be mixed and administered with Nobilis Rismavac in the same solvent. Do not use together with other vaccines containing a HVT strain				
35.	**Manufacturer:** Intervet International GmbH Feldstraβe 1a D-85716 Unterschleiβheim, Germany **Marketing Authorization/ Supplier:** Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands **Local Agent:** Bengal Overseas Ltd.; Paragon House (6th	**COBACTAN LC** Injection Tube (Vet)	Cefquinome 75 mg/8 gm Syringe (as Cefquinome Sulphate)	Antibiotic	For the treatment of clinical mastitis in the lactating dairy cow caused by the following cefquinome sensitive organisms: *Streptococcus uberis*, *Streptococcus dysgalactiae*, *Staphylococcus aureus* and *Escherichia coli*.	**Contraindication:** Not to be administrated to the animals which are known to be hypersensitive to cephalosporin antibiotics and other β-lactam antibiotics. **Side-effect:** In very rare case anaphylactic reactions have been noted in animal after administration of the products. **Withdrawal Period:** Meat and offal :2 days Milk : 84 Hours **Pharmaceutical Form:** Intramammary Ointment (Oily Suspension)	25 mg/ml Injection	Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Floor) 5, Mohakhali C/A, Dhaka-1212.									
36.	**Manufacturer:** Schering Plough Sanate Animel La Grindoliere, Zone Artisanale 49500, Segre, France **Marketing Authorization/ Supplier:** Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands **Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**CEPRAVIN DC Injection (Vet)**	(Cefalonium (as cefalonium dehydrate) BP (Vet) 0.25 gm/syringe)	Antibiotic	The CEPRAVIN DC recommended for routine dry cow therapy to treat existing sub-clinical infections and to prevent new infections which occur during the dry period caused by the following cefalonium sensitive organism: *Corynebacterium bovis, Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcusuberis,Echerichia coli, Klebsiella* spp. and *Arcanobacterium pyognes*.	**Contraindication:** Do not use in Lactating cow. Not intended for use within 54 days of Calving. Not to be administered to animals which are known to be hypersensitive to Cephalosporin antibiotics and other *β*-Lactam antibiotics. **Side-effect:** None Known **Use in Pregnancy and Lactation:** Intended for use during the last trimester of pregnancy once the lactating cow has been dried off. There is no adverse treatment effect on the foetus. Not to be used in cows those are lactating. **Withdrawal Period:** Meat and offal: Zero Days. Milk: 96 hours after calving, if cow calve at least 54 days after treatment, milk for human consumption may be taken after 54 days plus 96 hours after treatment. The absence of antibiotic should be confirmed by testing before its milk is used for human consumption. This is advisable because of variation in the milking cow's ability to excrete	New	Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
						antibiotic from dry cow products. In cows suffering from hypocalcaemia, it may be necessary to discard milk for a longer period.				
37.	Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands **Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis IBmulti+ND+EDS Vaccine**	Inactivated IBV strain M41:Including ≥4.0 $\log_2$ VN units/dose + Inactivated IBV strain 249G : Including ≥4.0 $\log_2$ VN units/dose + Inactivated NDV clone 30: Inducing ≥ 4.0 $\log_2$ HI units per 1/50 dose or containing ≥50 PD_{50} units/dose + Inactivated EDSV strain BC 14 : Inducing ≥ 6.5 $\log_2$ HI units/dose	Vaccine	Vaccination of breeder and layer for protection against the Massachusetts and D207/D274 serotypes of Infectious Bronchitis Virus, Newcastle Disease virus and Egg Drop Syndrome virus.	**Contraindication:** Vaccinate only healthy animals **Side-effect:** A slight transient swelling may be felt at the site of vaccination. **Withdrawal Period:** Zero Days	New	The Netherlands	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
38.	Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands **Local Agent:** Bengal Overseas Ltd.; Paragon House (6th Floor) 5, Mohakhali C/A, Dhaka-1212.	**Nobilis IB Primo QX Vaccine**	Live Infectious Bronchitis Virus strain D388: ≥ $4\log_{10}EID_{50}$ per dose per bird	Vaccine	For the active immunization of chickens from one day old onwards to reduce clinical signs of disease caused by infection with Infectious Bronchitis Virus serotype D388/QX. Onset of immunity: 3 weeks. Duration of immunity: 8 weeks.	**Contraindication:** None **Side-effect:** Vaccination may induce a mild transient respiratory reaction lasting a few days, which may depend on the health and condition of the birds. **Withdrawal Period:** Zero Days	New	The Netherlands	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।
39.	Intervet International B.V. Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands	Nobilis IBmulti+ND **Vaccine**	Inactivated IBV strain M41: Including ≥4.0 $\log_2$ VN units/dose + Inactivated IBV strain D274 :Including ≥4.0 $\log_2$ VN units/dose +	Vaccine	Vaccination of chickens against disease caused by infectious Bronchitis viruses of types covered by the vaccine strains and Newcastle Disease virus.	**Contraindication:** None **Side-effect:** In healthy animals no clinical reactions. Slight swelling at the sight of injection for some weeks after vaccination	New	The Netherlands	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।

নং	প্রস্তুতকারকের নাম ও ঠিকানা	ঔষধের নাম	জেনিরিক নাম	থেরাপিউটিক ক্লাস	নির্দেশনা	Contraindication & Side-effect	Status (New/Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	Local Agent: Bengal Overseas Ltd.; Paragon House (6^{th} Floor) 5, Mohakhali C/A, Dhaka-1212.		Inactivated NDV:Inducing ≥ 4.0 $\log_2$ HI units per 1/50dose or containing ≥50 PD_{50} units/dose			is occasionally observed. **Withdrawal Period: Zero Days**				

Annex-L: Product list for Import (Medical Devices)

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
1.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai- 625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka	Auro octane Ophthalmic Solution	PFCL (Perfluoro-n-octane Liquid) in 5ml	C	AURO OCTANE is used for the treatment of: Retinal detachments/ PVR/ PDR, Giant tears, Ocular trauma, Removal of dislocated lenses and foreign bodies from the vitreous.	**Contraindication:** It cannot be excluded that AURO OCTANE may generate alterations of the retina if present over a long period because of its high gravity. If remnants of AURO OCTANE, in the form of mobile drop stay in front of the retina they may influence the refraction and thus change the visual acuity temporarily. **Warnings:** It should not be injected directly into the vitreous, or injected simultaneously with aspiration of the vitreous, as severe intraocular damage may occur. It must always be injected near-side of the retinal tear to prevent any sub-retinal infiltration.	India Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
2.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai- 625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka-1215.	AUROGEL Plus Ophthalmic Gel	(Sodium Hyaluronate 1.6%w/v) High Cohesive Viscoelastic in 1ml	C	Cataract extraction. Intraocular lens (IOL) implantation. Corneal transplantation surgery. Glaucoma filtering surgery. Retinal attachment surgery.	**Contraindication:** Hypersensitivity against Sodium hyaluronate.	India Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
3.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai- 625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka-1215.	AUROSIL Ophthalmic Solution	Silicone oil Polydimethyl siloxane 1000CST in 10ml	C	Retinal detachment with giant tear, retinal detachment with proliferative vitreo retinopathy (PVR), proliferative diabetic retinopathy (PDR) and traumatic retinal detachment.	**Contraindication:** Pseudophakic patients with silicone intraocular lens (silicone oil can chemically interact and opacify silicone elastomers).	India Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
4.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai- 625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka	AUROVISC Ophthalmic Gel	2ml Syringe gel (Hypromellose ophthalmic solution USP 2% w/v)	C	Aurovisc is indicated as a surgical aid (medical device) during surgical procedures involving the anterior chamber of the eye, including extraction of the lens and insertion of intraocular lenses. It maintains the depth of the anterior chamber during the whole surgical procedure and permits greater operative precision without the risk of damaging the endothelium of the cornea or other intraocular tissues.	**Contraindication:** It is contraindicated in patients with known history of hypersensitivity to its ingredients.	India Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
5.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai- 625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka	AUROBLUE Ophthalmic Solution	Trypan blue solution in 1ml (Trypan blue 0.06% w/v sodium chloride IP 0.85% w/v)	C	Used as a capsule staining agent in cataract surgery.	**Contraindication:** Auroblue is contraindicated when a non hydrated (Dry state) hydrophilic acrylic Intraocular lens (IOL) is planned to implant into eye, because the dye may be absorbed by the IOL and get stained.	India Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
6.	**Manufacturer :** Aurolab no 1 Sivagangai main road veerapanjan, madurai- 625020, India **Local Agent**: IRIS enterprise, 14/A & 31/A, Tejkuni Para, Suit# 12-B, Farmgate, Dhaka	AURO Coat plus Ophthalmic Gel	(Sodium Hyaluronate BP 3% w/v Chondroitin Sulphate Sodium BP 4% w/v) in 1ml	C	Aurocoat plus is indicated as a surgical aid (medical device) during surgical procedures involving the anterior chamber of the eye, including extraction of the lens and insertion of intraocular lenses. It maintains the depth of the anterior chamber during the whole surgical procedure and permits greater operative precision without the risk of damaging the endothelium of the cornea or other intraocular tissues. The visco elasticity of the solution maintains the normal position of vitreous phase and prevents formation of a flat chamber during surgery.	**Contraindication:** It is contraindicated in patients with known history of hypersensitivity to its ingredients.	India		**রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা যেতে পারে।**	**রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা হল।**

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
7.	Manufacturer: Medio-Haus-Medizinprodukte GmbH, Germany Local Agent : GM Healthcare Ltd. 216/44, Mitford Road, Dhaka	Vibex Rapid Riboflavin Ophthalmic Solution	0.1% Riboflavin, Saline, HPMC	C	VibeX Rapid™ is formulated with no dextran thus reducing corneal thinning. It has a diffusion rate of twice that of standard riboflavin. VibeX Rapid™ is topically applied to the cornea after epithelium removal, then UVA light from the KXL® System is applied to activate it for Accelerated Cross-Linking.	**Contraindications:** Corneal thickness, with epithelium, less than 375 µm - Pregnancy - Epithelial healing problems - Refractive keratotomy - Herpetic keratitis (UV can activate herpes) - Rheumatic disorders - Known sensitivity against one of the ingredients - Corneal melting		EC Certificate	রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা যেতে পারে।	রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা হল।
8.	Manufacturer: Medio-Haus-Medizinprodukte GmbH, Germany Local Agent : GM Healthcare Ltd. 216/44, Mitford Road, Dhaka	ParaCel Ophthalmic Solution	0.25% Riboflavin, HPMC, BAC	C	ParaCel™ is Avedro's trans-epithelial riboflavin specifically formulated for direct application on the intact epithelium. Used in conjunction with VibeX Xtra™, ParaCel's higher concentration of riboflavin and proprietary formulation allow for the fastest penetration and diffusion into the corneal stroma. Intact epithelium diminishes the effects of cross-linking when low-powered UVA devices are used. Only Avedro's KXL® System offers 45 mW/cm2 of power for effective, Accelerated Cross-Linking through the intact epithelium using ParaCel.	**Contraindications:** - Corneal thickness, with epithelium, less than 325 µm - Pregnancy, nursing women, children - Epithelial healing problems - Refractive keratotomy - Herpetic keratitis (UV can activate herpes) - Rheumatic disorders - Known sensitivity against one of the ingredients - Corneal melting		EC Certificate	রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা যেতে পারে।	রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা হল।

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
9.	Manufacturer: Medio-Haus-Medizinprodukte GmbH, Germany Local Agent : GM Healthcare Ltd. 216/44, Mitford Road, Dhaka	Vibex Xtra Riboflavin Ophthalmic Solution	0.22% Riboflavin, Saline, Isotonic	C	VibeX Xtra™ is formulated specifically for use during a Lasik Xtra® procedure. VibeX Xtra is applied directly to the stromal bed prior to replacing the flap following excimer laser ablation. Formulated in an isotonic solution, VibeX Xtra diffuses quickly to minimize flap exposure time and deliver the appropriate concentration of riboflavin for cross-linking. Once the flap has been repositioned over the cornea, UVA light from the KXL® System is applied to activate VibeX Xtra to restore biomechanical integrity to the cornea.	**Contraindications:** - Pregnancy - Epithelial healing problems - Refractive keratotomy - Herpetic keratitis (UV can activate herpes) - Rheumatic disorders - Known sensitivity against one of the ingredients - Corneal melting		EC Certificate	**রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা যেতে পারে।**	**রেজিষ্ট্রেশনের জন্য প্রয়োজনীয় ফ্রি সেল সার্টিফিকেট দাখিল এর শর্তে অনুমোদন করা হল।**
10.	Ursapharm Arzneimittel GmbH, IndustriestraBe 35 66129 Saarbrucken , Germany. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka	HYLO-DUAL Eye Drops (Preservative free)	Sodium Hyaluronate 0.05% + Ectoin 2%	C	Allergy Related Dry Eye, provides protection against environmental allergens and relief for itching and burning eyes.	**Contraindication:** Hypersensitivity to any of its Ingredients. **Side Effect:** In Rare Cases Excessive Tear May Occur	Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
11.	Ursapharm Arzneimittel GmbH, IndustriestraBe 35 66129 Saarbrucken , Germany. **Local Agent**: Zas Corporation, 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka	Hylo-Care (Preservative free eye drops)	Sodium Hyaluronate 0.1% + Dexpanthenol 2%	C	Severe dry eye, healing in a damaged or injured cornea especially after eye surgery or because of dry eyes.	**Contraindication:** Hypersensitivity to any of its Ingredients. **Side Effect:** In Rare Cases Excessive Tear May Occur	Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
12.	Meran Tip Urunleri Teknoloji san. Ve Tic .ltd. Istanbul Turkey. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka	Capsule Dye Ophthalmic Solution 1ml PFS Vial	Trypan Blue Ophthalmic Solution 0.06%	C	Vital stain to selectively color dead tissues or cells blue in ophthalmic surgery.	**Contraindication:** Hydrophilic acrylic intraocular lens (IOL) is planned to be inserted into the eye because the dye may be absorbed by the IOL and stain the IOL**.** **Side Effect**: N/A	Turkey Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
13.	Meran Tip Urunleri Teknoloji san. Ve Tic .ltd. Istanbul Turkey. **Local Agent**: Zas Corporation , 80/22 Mymenshing Road , Nurjahan Tower (3rd Floor) Dhaka	Membrane Dye Ophthalmic Solution	Trypan Blue Ophthalmic Solution 1.5%	C	Vital stain to selectively color dead tissues or cells blue in ophthalmic surgery	**Contraindication:** Hydrophilic acrylic intraocular lens (IOL) is planned to be inserted into the eye because the dye may be absorbed by the IOL and stain the IOL**.** **Side Effect**: N/A	Turkey Germany	EC Certificate	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
14.	**Quantium Medical S.L.U., Spain** **Distributor: Fresenius Kabi AG, Germany** **Local Agent**: Radiant Export Import Enterprise Lubdhok, 4th Floor,474 P, Road No-3,Sector-12,Uttara, Dhaka 1230	CONOX – Depth of Anesthesia Monitor	Anesthesia Monitor	B	The CONOX is a non-Invasive depth of anesthesia monitor for assessing and analgesic effect of patients undergoing general anesthesia or sedation in adult population It is also designed to help the anesthesiologist assess patient brain activity and to rapidly detect how certain drugs are affecting the patient. The Conox monitor shows the values without interpreting data (i.e. any interpretation of the data must be performed by a trained professional). The main index, qCON, is obtained from the electroencephalogram (EEG) recording with a superficial sensor placed on the patient's forehead and analysed by a digital processor. The final value serves as a guide to the experts to determine the effect of certain anaesthetics on the patient during anaesthesia.	**Contraindication:** Patients with a history of psychiatric or neurological disease, drug abuse or medication known to affect the central nervous system. • There are no studies published yet on children under anesthesia. • The sensor should not be placed on injured skin. **Side Effect:** Skin wounds due to allergy, irritability, all kind skin problems.	Spain	EC	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
15.	**By Shenzhen Med-link Electronics Tech Co.Ltd., China For Quantium Medical S.L.U., Spain Distributor: Fresenius Kabi**	Conox Sensor	Sensor for transmitting EEG signals	B	A sensor placed on the patient's forehead transmits EEG signals to the analogue-digital converter (ADC); the ADC amplifies and digitizes these signals. The monitor software filters the ADC data, rejects artefacts, and processes	**Contraindication:** Patients with a history of psychiatric or neurological disease, drug abuse or medication known to affect the central nervous system. • There are no studies published yet on children under anesthesia. • The sensor should not be placed on injured skin.	Spain	EC	অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

Sl No	Name of the Manufacturer & Importer	Brand Name	Name of the Medical Device	Class	Uses	Contra-indication & Side-effect	FSC/CPP	EC Certificate	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির সভার সিদ্ধান্ত
	AG, Germany **Local Agent**: Radiant Export Import Enterprise Lubdhok, 4th Floor,474 P, Road No-3,Sector-12,Uttara, Dhaka 1230				it using digital signal processing techniques. EEG signals are processed to extract its complex characteristics to provide recognition of the changes of pattern in time during the acquisition.	**Side Effect:** Skin wounds due to allergy, irritability, all kind skin problems.				