

**NEW DRUGS APPROVAL LIST FROM SND DIVISION
(FROM 01/01/2023 TO 31/12/2023)**

S.No.	Drug	Indication	Date of Approval
1	Loperamide Hydrochloride Orally Disintegrating Tablets 2mg (Additional Dosage Form)	Indicated for the Symptomatic treatment of acute diarrhea in adults	03-01-2023
2	Brivaracetam injection 50mg/5mL (10mg/mL) (Additional Dosage Form)	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy	03-01-2023
3	Nitisinone Capsules 2mg /5mg /10mg /20mg (Additional strength)	Nitisinone Capsules is indicated for the treatment of adult and paediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine	09-01-2023
4	Chlorhexidine Gluconate 2% w/v Wet Wipes (Additional Dosage Form)	Chlorhexidine Gluconate Wet Wipes are disposable antibacterial towels that provide rinse-free bathing for patients at hospitals protecting them from nosocomial infection, the product is intended to use on all exposed skin	09-01-2023
5	Amantadine Extended Release Tablets 129 mg and 193 mg (Additional Dosage Form)	For the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients	09-01-2023
6	Meropenem Injection IP 125 mg (Additional Strength)	Meropenem injection is indicated in children for treatment of the following infections caused by single or multiple bacteria sensitive to Meropenem: Pneumonia and Nosocomial Pneumonia, Urinary Tract Infections, Intra-abdominal Infections, Skin and Skin Structure infections, Meningitis, Septicaemia. Meropenem has been proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infection	09-01-2023
7	Tofacitinib Extended Release Tablets 11mg/22mg (Additional Dosage Form and strength)	A. Indication for Tofacitinib Extended Release Tablet 11mg: · Rheumatoid Arthritis: Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers. · Psoriatic Arthritis: Indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers. · Ulcerative Colitis: Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or intolerance to one or more TNF blockers. B. Indication for Tofacitinib Extended Release Tablets 22mg: · Ulcerative Colitis: Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or intolerance to one or more TNF blockers	09-01-2023

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8	Dabrafenib Capsules 50mg and 75mg (Additional indication)	Dabrafenib is indicated, in combination with trametinib, for the treatment of adult and paediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Limitation of use: · Dabrafenib is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. · Babrafenib is not indicated for treatment of patients with wild-type BRAF solid tumors	10-01-2023
9	Trametinib tablets 0.5mg and 2 mg (Additional indication)	Trametinib is indicated, in combination with dabrafenib, for the treatment of adult and paediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.” Limitation of use: Trametinib is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition	10-01-2023
10	Vitamin E Capsule USP 400 mg (Hard Gelatin Capsules / additional dosage form)	For the Prevention and treatment of Vitamin E Deficiency	13-01-2023
11	Mercaptopurine Powder for Oral Suspension 10mg/mL (Additional Dosage Form)	Treatment of Acute Lymphoblastic Leukaemia (ALL)	24-01-2023
12	Lenvatinib capsules 12mg/18mg/24mg (Additional Strength)	Lenvatinib is indicated: 1. The treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). 2. The first line treatment of patients with unresectable hepatocellular carcinoma (HCC). 3. In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior antiangiogenic therapy	09-03-2023
13	Gabapentin Extended Release Tablets 300mg and 600mg (Additional Indication)	Indicated for the management of postherpetic neuralgia.	23.03.2023
14	Pretomanid tablets 200mg (Additional Indication)	Indicated as part of a combination regimen with Bedaquiline and Linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB).	23.03.2023
15	Chlorine-based disinfectant liquid 6.850 % w/w (Klercide sporicidal Active Chlorine)	For disinfection of floors, walls and other hard surface, various pathogens like bacteria, virus etc including corona virus.	17.04.2023

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16	Pretomanid tablets 200mg (Additional Indication)	Pretomanid is indicated, as part of a combination regimen with bedaquiline and linezolid, for treatment of MDR-TB or RR-TB in patients ≥ 14 years of age who have no previous exposure (defined as >1 month) to bedaquiline, pretomanide, or linezolid, with moxifloxacin in the absence of baseline resistance to fluoroquinolones or without moxifloxacin if resistance to fluoroquinolones is presents (pre-XDR-TB).	19.04.2023
17	Hydrogen Peroxide disinfectant liquid 4.28% w/w (Klerricide sporicidal Enhanced Peroxide)	For disinfection of floors, walls and other hard surface against various pathogens like bacteria, virus etc including corona virus.	17.04.2023
18	Cholecalciferol Aqueous injection 6,00,000 IU/2ml (Additional Strength)	Indicated for the treatment of Vitamin D3 deficiency	17.04.2023
19	Delamanid Dispersible Tablets 25mg (Additional Dosage Form)	“Delamanid Dispersible Tablets 25 mg for the indication that “for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adults, adolescents, children and infants with a body weight of at least 10 kg when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability”	18.04.2023
20	Dolutegravir Oral Film 5mg and 10mg (Additional Dosage Form)	Indicated combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adult, adolescents and children of at least 4 weeks of age or older and weighing at lease 3kg.	21.04.2023
21	Cyclophosphamide Capsules 25mg/50mg	Cyclophosphamide is indicated for treatment of: Malignant Diseases: <ul style="list-style-type: none"> • Malignant lymphomas (Stages III and IV of the Ann Arbor staging system), Hodgkin’s disease, lymphocytic lymphoma (nodular or diffuse), mixed-cell type lymphoma, histiocytic lymphoma, Burkitt’s lymphoma, • Multiple myeloma, • Leukemias: chronic lymphocytic leukemia, chronic granulocytic leukemia (it is usually ineffective in acute blastic crisis), acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia (cyclophosphamide given during remission is effective in prolonging its duration) • Mycosis fungoides (advanced disease) • Neuroblastoma (disseminated disease) • Adenocarcinoma of the ovary • Retinoblastoma • Carcinoma of the breast 	04.05.2023
22	Esomeprazole Dual-Release Gastro-Resistant Tablets 80mg (Additional Dosage Form)	Indicated for the treatment of moderate to severe refractory gastro-esophageal reflux disease (GERD) for 4 weeks only.	17.05.2023

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23	Cefixime Oral Suspension IP 200mg/5ml (Additional strength)	For the treatment of enteric (typhoid) fever	30.05.2023
24	Perampanel Oral Suspension 0.5mg/ml (Additional Dosage Form)	It is indicated adjunctive therapy for the treatment of :- <ul style="list-style-type: none"> • Partial-onset Seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older. • Primary Generalized Tonic-Clonic Seizures in patients with epilepsy 12 years of age and older. 	30.05.2023
25	Icosapent Ethyl Capsules 500mg and 1000mg (Additional strength)	Used as an adjunct therapy for severe hypertriglyceridemia a (TG levels > 500mg/dl) and to reduce the risk of cardiovascular events in certain patients with elevated triglycerides.	06.06.2023
26	Amisulpride Injection 5mg/2ml (Additional Dosage Form)	<ul style="list-style-type: none"> • Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class. • Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis. 	06.06.2023
27	Testosterone Topical gel 1.62% w/w (Metered-Pump Packed, containing 1.62% w/w Testosterone) (Also expressed as 16.2mg/gm of Testosterone) (Additional Dosage Form)	Indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by the clinical features and biochemical tests.	12.06.2023
28	Tofacitinib Ointment 2% w/w (Additional Dosage Form)	For the treatment of mild to moderate atopic dermatitis (AD) in patients 18 years & above having flare up of disease.	16.06.2023
29	Brivaracetam Sustained Release Tablets 50mg/100mg/150mg (Additional strength)	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.	26.06.2023
30	Gabapentin Extended Release Tablets 300mg and 600mg (Additional Indication)	For the treatment of neuropathic pain.	28-07-2023
31	Benzydamine Hydrochloride Mouthwash 0.15% w/v (Additional Dosage Form)	Benzydamine Mouthwash is a locally acting analgesic and anti-inflammatory treatment for the relief of painful inflammatory conditions of the mouth and throat including: <ul style="list-style-type: none"> • Traumatic Conditions: Pharyngitis following tonsillectomy or the use of a naso-gastric tube; • Inflammatory Conditions: Pharyngitis, aphthous ulcers and oral ulceration due to radiation therapy; • Dentistry: For use after dental operations. 	28-07-2023
32	Darolutamide 300mg Film Coated Tablets (Additional Indication)	Darolutamide is indicated for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.	28-07-2023
33	Tofacitinib Oral Solution 1 mg/ml (Additional Dosage Form)	For the treatment of juvenile idiopathic arthritis (PcJIA) in patients 2 years of age and older.	25.08.2023

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34	Icosapent Ethyl Capsule 1g (Additional Indication)	As ab adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) • Established cardiovascular disease or • Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease. • As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of Icosapent ethyl on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.	14.09.2023
35	Dydrogesterone Extended Release Tablets 20mg (Additional Dosage Form)	Indicated in cases where progesterone supplement is needed.	03.11.2023
36	Tacrolimus Lipid Suspension for enema 4 mg/vial and Diluent for Tacrolimus lipid suspension for enema (Additional Dosage Form)	For achieving remission in adult patients with mild to moderately active left-sided/distal ulcerative colitis including proctosigmoiditis/proctitis refractory to mesalamine treatment.	02.011.2023
37	Solifenacin succinate Oral solution 1mg/ml (Additional Dosage Form)	For Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.	03.11.2023
38	Olaparib film coated tablets 100mg / 150mg (Additional Indication)	In combination with Abiraterone and Prednisone or Prednisolone is indicated for the treatment of adult patients with metastatic castration-resistant prostate cancer.	17.11.2023
39	Methadone Hydrochloride oral Solution IP 1mg/ml (Additional Dosage Form)	1. For the management of chronic refractory moderate to severe pain. 2. For the treatment of opioid dependence and for maintenance treatment for opioid dependence.	30.11.2023
40	Lenalidomide Capsules 10mg (Additional Indication)	“Lenalidomide as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation “	01.12.2023
41	Enzalutamide Oral solution 32mg/ml (Additional Dosage Form)	1. In the treatment of adult men with metastatic castration resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. 2. For the treatment of adults with metastatic castration resistant prostate cancer (mCRPC) whose disease has progressed on or after Docetaxel therapy.	04.12.2023