

LIST OF NEW DRUG APPROVED FROM 01-01-2016 to TILL DATE BY NEW DRUGS DIVISION

S.No	Name Of Drug	Indication	Date of issue
1	Nintedanib soft Gelatin Capsule 100/150mg (Nintedanib ethanesulfonate)	For the treatment of Idiopathic Pulmonary Fibrosis (IPF).	11.03.16
2	Cisatracurium Besylate Bulk & 2mg/ml injection	As an adjunct to general anaesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery.	14.03.16
3	Fomepizole Bulk & Fomepizole Injection 1.5gm/Ampoule	As an antidote for Ethylene glycol or Methanol used poisoning or for use in suspected Ethylene glycol or Methanol ingestion, either alone or in combination with hemodialysis.	14.03.16
4	Tofacitinib Tablets 5 mg(Tofacitinib Citrate)	“For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)”.	01.04.16
5	Nintedanib Soft Gelatin Capsule 100/150mg (Nintedanib ethanesulfonate)	"In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumor histology after line chemotherapy".	01.04.16
6	Ceftaroline Fosamil Injection 600 mg/Vial	"For the treatment of adult (\geq 18 years of age patients with community-acquired pneumonia".	09.05.2016
7	Panobinostat Hard Gelatin Capsules 10mg/15mg/20mg (Panobinostat lactate)	"In combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma, who have received at least 1 prior therapy"	27.05.2016

8	Bepotastine Besilate Bulk & Bepotastine Besilate 1.5 %w/v Ophthalmic solution	"For the treatment of itching associated with allergic conjunctivitis"	08.06.16
9	Ibutilide Bulk & Ibutilide Fumarate Injection 0.1mg/ml	"For the rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm. Patient with atrial arrhythmias of longer duration are less likely to respond to Ibutilide Fumarate Injection. The effectiveness of Ibutilide has not been determined in patients with arrhythmias of more than 90 days in duration".	10.06.16
10	Acotiamide Hydrochloride Bulk & Tablet 100mg	"For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia".	06.07.2016
11	Sacubutril+ Valsartan film coated tablets 50mg/100 mg/200mg	"To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction".	14.07.2016
12	Lurasidone Hydrochloride Bulk & Lurasidone Hydrochloride Tablets 40mg/80mg	"For the treatment of Patients with Schizophrenia"	18.07.16
13	Fenticonazole Nitrate Vaginal Capsule 600 mg	"For the treatment of vulvovaginal candidiasis"	10.08.2016
14	Palbociclib Capsules 75mg/100mg/125 mg	"Palbociclib is a kinase inhibitor indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease".	11.08.2016
15	Midodrine Hydrochloride 2.5 mg Tablet	"For the treatment of symptomatic orthostatic hypotension"	02.09.2016

16	Phospholipids Fraction from Bovine Lung (surfactant) 50 mg/vial	"Preventive use in premature neonates with a high risk of respiratory Distress Syndrome"	12.09.2016
17	Dolutegravir 50 mg Tablet & Bulk (Dolutegravir Sodium)	"Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults weighing more than 40 kg"	07.11.2016
18	Alcaftadine Eye Drops 0.25% w/v & Bulk	"For the prevention of itching associated with allergic conjunctivitis in patients between the age group 10 to 60 years"	21.11.2016
19	Bepotastine Besilate Bulk		23.11.2016
20	Lenvatinib 4mg/10mg Hard Gelatin Capsules (Lenvatinib Mesylate)	"For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer"	02.12.2016
21	Perampanel 2mg/4mg/6mg/8mg/10mg/12mg Tablets	"The adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older"	02.12.2016
22	Azilsartan Medoxomil Bulk & 40mg/80mg Tablets	"Indicated for the treatment of hypertension in adults patients, either alone or in combination with other antihypertensive agents"	09.12.2016