

Updating website as on 01-01-2022 to 31-07-2022

S. No	Drug Name	Composition	Indication	Date of Approval
1	Ivermectin Tablets 12 mg (Additional Strength)	Each uncoated tablet contains: Ivermectin IP.....12 mg Excipients.....QS	Treatment of intestinal helminths and suppression of microfilaraemia especially with bancrofti infections	03-01-2022
2	Enzalutamide Tablets 160mg (Additional Dosage form & Strength)	Each film coated tablets contains : Enzalutamide160mg	• The treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. • The treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy "WARNING: To be sold by retail on the prescription of Oncologist only"	
3	Tofacitinib Tablets 10 mg (Additional Strength)	Each tablet contains Tofacitinib Citrate 16.16mg equivalent to Tofacitinib 10mg	1. 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). 2. For the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to Methotrexate or other non-biologic disease	11-01-2022

			modifying antirheumatic drugs (DMARDs). The firm should conduct Phase IV study in rheumatoid arthritis and psoriatic arthritis with statistically significant number of patients. Accordingly, firm should submit Phase IV CT protocol within 3 months after approval and study should be completed within 2 years from the approval of the study "WARNING: To be sold by retail on the prescription of a Rheumatologist or Specialist in Internal Medicine only"	
4	Methotrexate Injection 1000mg/10ml (Additional Strength)	Each ml contains: Methotrexate100mg	1. Acute lymphocytic leukaemias (ALL): in combination with other cytotoxic medicinal products. 2. Non-Hodgkin's lymphomas: in combination with other cytotoxic medicinal products in adult patients with Non-Hodgkin's lymphomas of intermediate and high degree of malignancy & in combination with other cytotoxic medicinal products in paediatric patients. 3. Head and neck cancer: as palliative monotherapy in patients with metastatic or recurrent disease. 4. Breast cancer: in combination with other cytotoxic medicinal products in patients for adjuvant treatment after tumour resection or mastectomy and for palliative treatment in advanced disease. 5. Choriocarcinoma and similar trophoblastic diseases: as monotherapy in patients with good prognosis (low risk) & in combination with other cytotoxic medicinal products in	11-01-2022

			patients with poor prognosis (high risk). 6. Osteosarcoma: in combination with other cytotoxic medicinal products for adjuvant and neoadjuvant therapy. 7. Cancer of the bladder: in combination with other cytotoxic medicinal products. "WARNING: To be sold by retail on the prescription of Oncologist only"	
5	Ibrutinib Capsules 140 mg (Additional Indication)	Each Hard Gelatin Capsules Contains: Ibrutinib.....140 mg	For the treatment of patients with Marginal Zone Lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20 based therapy "WARNING: To be sold by retail on the prescription of Oncologist only"	21-01-2022
6	Ibrutinib Capsules 140 mg (Additional Indication)	Each Hard Gelatin Capsules Contains: Ibrutinib.....140 mg	For the treatment of patients with chronic Graft Versus Host Disease (cGVHD) who have received at least one line of systemic therapy "WARNING: To be sold by retail on the prescription of Oncologist only"	21-01-2022
7	Lincomycin Hydrochloride Sustained Release Tablet 1000 mg (Additional Dosage Form)	Each film coated Sustained Release tablets contains: Lincomycin Hydrochloride eq to Lincomycin..... 1000mg	Indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patient or for whom penicillin is inappropriate The firm should submit safety data of the product to CDSCO every two months for the next one year "WARNING: To be sold by retail on the prescription of Medical specialist only"	21-01-2022

8	Clobazam oral suspension 5mg/5mL & 10mg/5mL (Additional Strength)	Each 5ml contains: Clobazam I.P.....5mg/10mg Approved colours used	1. Acute and chronic anxiety states. 2. As an adjunctive therapy in patients with refractory epilepsy. "WARNING: To be sold by retail on the prescription of Neurologist/Psychiatrist only"	02-02-2022
9	Rosuvastatin Sprinkle Capsules 10 mg, 20 mg and 40 mg (Additional Dosage Form)	Each capsule contains: Rosuvastatin calcium equivalent to Rosuvastatin 10 mg / 20 mg / 40 mg Excipients q.s.	- As an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. - As an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (Type III Hypolipoproteinemia). - As adjunctive therapy to other lipid lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDLC, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia.	28-02-2022
10	Minocycline Hydrochloride Topical Gel 4% (Additional Dosage Form & Additional Indication)	Each gram of gel contains: 40 mg of Minocycline equivalent to 43 mg of Minocycline Hydrochloride Ph. Eur.	Indicated for the topical treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older The firm should conduct Phase IV Clinical trial	28-02-2022
11	Lenalidomide Capsules 5mg/10mg/15mg (Additional Indication)	Each hard gelatin capsule contains: Lenalidomide..... 5mg/10mg/15mg	- Follicular Lymphoma: Lenalidomide in combination with a Rituximab product, is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL). - Marginal Zone Lymphoma: Lenalidomide	02-03-2022

			in combination with a Rituximab product, is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL) "WARNING: To be sold by retail on the prescription of oncologist only"	
12	Thymosin Alpha-1 for injection 1.6 mg (Additional Indication)	Each Vial Contains: Thymosin Alpha 1 for Injection... 1.6 mg Excipients...q. s.	As add-on therapy for the treatment of moderate to severe Covid patients requiring ventilator support (NIV as well as Mechanical ventilation) The firm should conduct active PMS study for which protocol should be submitted for further review by the committee "WARNING: To be sold by retail on the prescription of Medical specialists only"	02-03-2022
13	Glutathione for Injection 600 mg / vial (Additional Indication)	Each Vial Contains: Glutathione BP..... 600 mg Excipients... q. s.	As an add-on to the standard of care in moderate COVID-19 patients "WARNING: To be sold by retail on the prescription of Medical specialists only"	11-03-2022
14	Levosalbutamol tartrate Inhalation Aerosol (Levosalbutamol) 45mcg/actuation)	Each actuation delivers (ex-actuator): Levosalbutamol Tartrate 59 mcg equivalent to Levosalbutamol...45mcg Ethanol anhydrous Ph Eur4.7% w/w Excipients – Oleic Acid USP NF Norflorane Ph.	Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease	14-03-2022

		Eur.(Propellant HFA 134a).....q.s		
15	Trametinib 0.5 mg and 2 mg tablets (Additional Indication)	Each film coated tablet contains: Trametinib dimethyl sulfoxide equivalent to Trametinib..... 0.5mg/2mg	Trametinib is indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an appropriate test and involvement of lymph node(s), following complete resection “WARNING: To be sold by retail on the prescription of Oncologist only”	17-03-2022
16	Trametinib 0.5 mg and 2 mg tablets (Additional Indication)	Each film coated tablet contains: Trametinib dimethyl sulfoxide equivalent to Trametinib..... 0.5mg/2mg	Trametinib is indicated, in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAFV600E mutation and with no satisfactory locoregional treatment Options “WARNING: To be sold by retail on the prescription of Oncologist only”	17-03-2022
17	Dabrafenib Capsules 50mg and 75mg (Additional Indication)	Each hard gelatin capsule contains: Dabrafenib Mesylate equivalent to Dabrafenib 50mg/75mg	Dabrafenib in combination with trametinib for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an appropriate test, and involvement of lymph node(s), following complete resection “WARNING: To be sold by retail on the prescription of Oncologist only”	17-03-2022
18	Dabrafenib Capsules 50mg and 75mg	Each hard gelatin capsule contains: Dabrafenib	Dabrafenib in combination with trametinib for the treatment of patients with	17-03-2022

	(Additional Indication)	Mesylate equivalent to Dabrafenib50mg/75mg	locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAFV600E mutation and with no satisfactory locoregional treatment options “WARNING: To be sold by retail on the prescription of Oncologist only”	
19	Tacrolimus Hard Gelatin Capsules 0.75mg (Additional Strength)	Each Hard Gelatin Capsules contains: Tacrolimus Monohydrate equivalent to Tacrolimus ... 0.75mg	For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants "WARNING: To be sold by retail on the prescription of a Nephrologist only"	05-04-2022
20	Estriol Cream BP 1mg/gm (Additional Dosage Form)	Each gram contains: Estriol BP.....1mg Chlorhexidine Hydrochloride BP (as preservative)0.1 mg	For vaginal symptoms due to Estrogen deficiency in menopause	11-04-2022
21	Betahistine dihydrochloride Orodispersible film 8mg/16mg/24mg (Additional Strength)	Each Orodispersible Contains: Betahistine dihydrochloride ...8mg/16mg/24mg	indicated in the treatment of Menier's syndrome, characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss	12-04-2022
22	Linezolid Sustained Release Tablets 1200 mg (Additional Dosage Form & Strength)	Each film coated sustained release tablet contains: Linezolid IP1200mg	For the treatment of complicated/uncomplicated skin & skin structure infection, community acquired pneumonia & osteomyelitis in adults You are required to conduct PMS study in adequate number of patients. Accordingly, submit protocol to this office within six months of launch of product in Indian market	12-04-2022

23	Empagliflozin Tablets 10/25mg (Additional Indication)	Each Film coated tablets contains: Empagliflozin 10/25mg	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure subject to condition that the drug should be prescribed only to the patients with eGFR more than 30ml/min/1.73m ²	05-05-2022
24	Tofacitinib Extended Release Tablets 11mg (Additional Strength)	Each film-coated extended release tablets contains: Tofacitinib Citrate equivalent to Tofacitinib.....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 The firm should conduct the Active PMS Study. Accordingly, the firm should submit Active PMS Study protocol within 03 months after approval of the product "WARNING: To be sold by retail on the prescription of a Rheumatologist, Gastroenterologist, Hepatologist or Specialist in Internal Medicine only"	09-05-2022
25	Clozapine Extended Release Capsules 12.5mg/25mg/50 mg/100mg/200mg (Additional Dosage Form)	Each Extended Release Capsules contains: Clozapine 12.5mg/25mg/50mg /100mg/200mg	Indicated in the management of schizophrenic patients "WARNING: To be sold by retail on the prescription of Psychiatrist only"	09-05-2022

26	Magnesium Sulphate Intravenous Infusion 4% w/v (Additional Strength)	Each 100 ml contains: Magnesium Sulphate Heptahydrate.....4g (equivalent to 32.5 mEq of Magnesium) Excipients.....qs Water for injection..... qs to 100ml	Indicated for the prevention and control of seizures in pre-eclampsia and eclampsia, respectively "WARNING: To be sold by retail on the prescription of a Gynecologist only"	11-05-2022
27	Sacubitril + Valsartan Tablet (Additional Indication)	Each Film Coated Tablet Contains: 1. Sacubitril + Valsartan.....50mg (24mg+26mg) (as sodium salt complex) 2. Sacubitril + Valsartan.....100mg (49mg+51mg) (as sodium salt complex) 3. Sacubitril + Valsartan.....200mg (97mg+103mg) (as sodium salt complex)	To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with Left Ventricular Ejection Fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat	11-05-2022
28	Metformin Hydrochloride Sustained Release Tablets 500/850/1000mg (Additional Indication)	Each Sustained Release Tablets contains: Metformin Hydrochloride ...500/850/1000mg	• Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with Impaired Glucose Tolerance and/or Impaired Fasting Glucose, and/or increased HbA1C who are: o At high risk for developing overt type 2 diabetes mellitus and o Still progressing towards type-2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months. • Treatment with metformin SR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk. • Lifestyle modifications should be continued when metformin is initiated, unless the patient is unable to do so because of medical reasons.	17-05-2022
29	Vardenafil Oral Jelly 20mg/5g	Each sachet (5g) contains: Vardenafil	For the treatment of erectile dysfunction	17-05-2022

	Sachet (Pineapple Flavour) (Additional Dosage Form)	Hydrochloride Trihydrate equivalent to Vardenafil.....20mg	"WARNING: To be sold by retail on the prescription of a Urologist/Endocrinologist/Psychiatrist/Cardiologist only"	
30	Sodium Dichloroisocyanurate / Sodium Troclosen / NaDCC Tablets 0.5 gm, 2.5 gm and 5.0 gm (Additional Strength & Indication)	Each uncoated effervescent disinfectant Tablets contains: Sodium Dichloroisocyanurate / Sodium Troclosen / NaDCC0.5 gm/ 2.5 gm/ 5.0gm Excipients:.....qs	Cleaning , Cleaning of work surfaces, Cleaning of Hospital Surfaces	17-05-2022
31	Levothyroxine Sodium Tablets 125mcg/137mcg/ 150mcg (Additional Strength)	Each uncoated tablet contains: Thyroxine Sodium Eq. to anhydrous Thyroxine sodium125mcg/137mcg/150mcg	For the treatment of hypothyroidism	18-05-2022
32	Thyroxine Sodium Tablets 62.5mcg (Additional Strength)	Each uncoated tablet contains: Thyroxine Sodium Eq. to anhydrous Thyroxine sodium62.5mcg	For the treatment of hypothyroidism	18-05-2022
33	Ropivacaine Solution for Infusion 2 mg/ml (250ml) in Administration System (Additional Dosage Form)	1ml solution for infusion contains ropivacaine hydrochloride monohydrate, equivalent to 2 mg ropivacaine hydrochloride. 1 dispensing device (Ropivacaine 2 mg/ml Solution for Infusion in Administration System) contains 250ml ropivacaine hydrochloride monohydrate solution for infusion, equivalent to	For acute, postoperative pain management in adults. It is used to maintain a continuous peripheral nerve block via a continuous infusion and for continuous wound infiltration "WARNING: To be sold by retail on the prescription of Anesthesiologist only"	18-05-2022

		500mg ropivacaine hydrochloride		
34	Liposomal Amphotericin B Injection 50 mg/vial (Lyophilized) (Additional Indication)	Each vial contains: Amphotericin B.....50 mg (intercalated into Liposomal Membrane)	• Febrile Neutropenia in cancer patients. • For the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy. • For the treatment of visceral leishmaniasis The Firm should conduct active post marketing surveillance studies in at least 250 patients. Accordingly, you should submit the protocol for approval. The data of safety monitoring shall be submitted on monthly basis	02-06-2022
35	Pantoprazole Powder for Oral Suspension (Sodium Bicarbonate as Buffer) 40mg per sachet (Additional Dosage Form)	Each sachet contains: Pantoprazole sodium IP Equivalent to Pantoprazole.....40mg (sodium Bicarbonate as buffer)	For the treatment of gastric ulcer, duodenal ulcer, Zollinger Ellison Syndrome and Gastro-Esophageal reflux disease	14-06-2022
36	Dexamethasone Intravitreal Implant 0.7mg (Additional Indication)	Each Intravitreal Implant contains: Dexamethasone.....0.7mg (in solid polymer drug delivery system)	For the treatment of diabetic macular edema The firm should conduct active post marketing surveillance study in 500 patients with follow up period of six months. The protocol for active post marketing surveillance study should be submitted to CDSCO within three months of approval of the drug	15-06-2022

			"WARNING: To be sold by retail on the prescription of Ophthalmologist only"	
37	Carbetocin injection 100 mcg/ml (Pre Filled Syringes)	Each ml of solution for injection in vial contains: Carbetocin.....100mcg Excipients.....q.s. Water for injections.....q.s. to 1.0ml	Prevention of postpartum haemorrhage due to uterine atony Firm should submit the Phase IV clinical trial protocol within 3 months of approval of the product "WARNING: To be sold by retail on the prescription of a Gynecologist and obstetrician only"	17-06-2022
38	Colchicine Tablets USP 0.6mg (Additional Strength)	Each tablets contains: Colchicine.....0.6mg	For treatment and prophylaxis of acute gout. It is also indicated for the treatment of familial Mediterranean fever	17-06-2022
39	Gabapentin Oral solution 250mg/5ml (Additional Dosage Form)	Each Oral solution contains: Gabapentin2 50mg/5ml	For the treatment of neuropathic pain and as adjunctive therapy in the treatment of partial seizures with or without secondary generalization in adults	27-06-2022
	Cisatracurium Besylate Injection 20mg/10ml (Additional Indication)	Each ml contains: Cisatracurium Besylate USP Equivalent to Cisatracurium.....2 mg Benzyl Alcohol IP 0.09% (As Preservative) Water for Injection IP.....qs	Indicated for in-patients as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation in the ICU The firm should conduct Phase IV clinical trial for the indication to provide skeletal muscle relaxation during mechanical ventilation in the ICU. Accordingly, you should submit the Phase IV clinical trial within 3 months after approval for further review "WARNING: To be sold by retail on the prescription of Specialist only"	25-07-2022
	Fosfomycin Sodium for	Each vial contains: Fosfomycin Sodium	For the treatment of uncomplicated urinary tract	26-07-2022

	Injection 4 gm (Powder for solution for infusion) (Additional Dosage Form)	EP equivalent to Fosfomycin.....4gm Excipients.....q.s	infections (acute cystitis) in women due to susceptible strains of E. Coli and Enterococcus faecalis	
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