

Annexure A

Approval

LIST OF APPROVED DRUG

LIST OF NEW DRUG APPROVED FROM 01-01-2017 to TILL DATE BY NEW DRUGS DIVISION

S.No	Name of drug	Indication	Date of issue
1	Hydrocortisone Aceponate 0.584mg/ml Cutaneous Spray Solution (Vet.)	For symptomatic treatment of inflammatory and pruritic dermatosis in dogs.	06.01.17
2	Dexlansoprazole Delayed Release Capsule 30/60mg & Bulk	For the treatment of i) Healing of all grades of erosive esophagitis (EE). ii) Maintaining healing of EE and relief of heartburn. iii) Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).	16.01.17
3	Carfilzomib Sterile Lyophilized Powder for Injection 60mg/vial (50ml vial)	Relapsed or refractory multiple myeloma <ul style="list-style-type: none">• Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.• Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	17.01.17
4	Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma	18.01.17

		with BRAF V600E mutation as detected by an appropriate test.	
5	Trametinib 0.5mg/2mg Tablets (Trametinib Dimethyl Sulfoxide)	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.	18.01.17
6	Alectinib 150mg Capsules (Alectinib Hydrochloride)	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.	23.01.17
7	Eliglustat 84mg Capsules (Eliglustat Tartrate or Hemitartrate Salt)	For the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an appropriate test.	31.01.17
8	Pasireotide long-acting release 20/40/60mg powder for suspension for injection (Additional Indication) (Pasireotide pamoate)	For the treatment of patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option.	14.02.2017
9	Etonogestrel 68 mg implant	For use by women to prevent pregnancy.	15.02.2017
10	Bepotastine Besilate 1.5 %w/v Ophthalmic solution	For the treatment of itching associated with allergic conjunctivitis	22.02.2017
11	Dienogest 2mg Tablets	For the management of Pelvic pain associated with Endometriosis	09.03.2017
12	Eprinomectin 0.5% for beef and dairy cattle (vet.)	It is indicated for the treatment and control of gastrointestinal roundworm (including inhibited Ostertagia ostertagi), lungworm, grubs, sucking and biting lice, chloriopic and sarcoptic-mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle.	14.03.2017
13	Bepotastine Besilate 10 mg Tablets	For the treatment of allergic rhinitis	27.03.2017
14	Prucalopride 1mg/2mg Tablet & Bulk (Prucalopride Succinate)	For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief	13.04.2017
15	Teriflunomide 14 mg tablets	For the treatment of patients with relapsing form of multiple sclerosis	13.04.2017
16	Pomalidomide 1mg/2mg/3mg/4mg Capsules & Bulk	In combination with dexamethasone, for patient with multiple myeloma who have received at least two prior therapies including lenalidomide and a	01.05.2017

		proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	
17	Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet	For the treatment of adult patients with -chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection. -Without cirrhosis or with compensated cirrhosis -With decompensated with chronic for use in combination with Ribavirin.	04.05.2017
18	Velpatasvir Bulk		04.05.2017
19	Osimertinib 40 mg/80 mg Film coated Tablets (Osimertinib Mesylate)	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy	29.05.2017
20	Argatroban Hydrate Bulk & Injection 250 mg/2.5 ml	1) For prophylaxis or treatment of thrombosis in adult patients with Heparin induced thrombocytopenia (HIT). 2) As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)	30.05.2017
21	Fluralaner chewable tablets 112.5 mg/250 mg/500mg/1000mg/1400 mg	For the treatment of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile <i>Ixodes</i> <i>ricinus</i> , <i>Ixodes hexagonus</i> , <i>Ixodes scapularis</i> , <i>Ixodes</i> <i>holocyclus</i> , <i>Dermacentor reticulatus</i> , <i>Dermacentor</i> <i>variabilis</i> and <i>Rhipicephalus sanguineus</i>) and flea (<i>Ctenocephalides felis</i> and <i>Ctenocephalides</i> <i>canis</i>) killing activity for 12 weeks. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. the onset of effect is within 8 hours of attachment for fleas (<i>C. felis</i>) and 12 hours of attachment for ticks (<i>I. ricinus</i>) The product effectively controls environmental flea population in area to which treated dogs have access.	30.5.2017

		The product can be used as part of an treatment strategy for the control of Flea Allergy Dermatitis (FAD)	
22	Fluticasone Furoate (100 mcg) and Vilanterol Trifenatate (25 mcg) powder for inhalation	Indicated for the maintenance treatment of the airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/ or emphysema and to reduce exacerbation of COPD in patients with an exacerbation history.	29.06.2017
23	Mirabegron Prolonged Release Tablet 25 mg /50 mg	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	12.07.2017
24	Delamanid 50 mg tablet	For the use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability	02.08.2017
25	Mirabegron Prolonged Release Tablet 25 mg /50 mg & Bulk	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	18.08.2017
26	Efonidipine Hydrochloride Ethanolate Bulk & Tablets 10 mg/20mg/40mg	Indicated for the management of <ul style="list-style-type: none"> • Hypertension • Renal parenchymal hypertension • Angina 	28.08.2017
27	Brivaracetam Film Coated Tablets 50mg/75mg/100mg	As adjunctive therapy in the treatment of partial -onset seizures in patients 16 years of age and older with epilepsy	07.09.2017
28	Treosulfan Bulk & injection 5g/vial	For the conditioning treatment prior to haematopoietic stem-cell transplantation	26.09.2017
29	Ribociclib 200 mg Film coated Tablets	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post menopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer	27.09.2017
30	Dienogest Bulk & 2mg Tablet	For the management of Pelvic pain associated with Endometriosis	28.09.2017
31	Apremilast bulk & film coated tablets 10 mg/20 mg/30 mg	for treatment of patients with moderate to severe plaque psoriasis who are candidate for phototherapy or systemic therapy	13.10.2017
32	Arbekacin bulk & Injection 200mg/4ml	Treatment of following infections caused by Methicillin resistant Staphylococcus aureus	20.10.2017

		(MRSA)", sepsis pneumonia	
33	Benestermeycin Intra-mammary suspension (vet.)	For the treatment of subclinical mastitis at drying off, and the prevention of new bacterial infections of the udder during the dry period in dairy cows, caused by bacteria susceptible to penicillin and framycetin	03.11.2017
34	Midostaurin 25 mg Capsules	<ul style="list-style-type: none"> • In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive. • For the treatment of adult patients with advanced systemic mastocytosis (Advanced SM) 	09.11.2017
35	Tenofovir Fumarate bulk capsules & Alafenamide 25 mg capsules	For the treatment of chronic Hepatitis B virus infection in adults with compensated liver disease	10.11.2017

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 (≥ 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/100mg/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

LIST OF APPROVED DRUG FROM 01-01-2015 to 31-01-2015

S.No	Name Of Drug	Indication	Date of issue
1	Sofosbuvir Tablet 400 mg	"In combination with other medicinal products for the treatment of chronic Hepatitis C (CHC) in adults".	13.01.2015
2	Bedaquiline Tablet 100 mg	"In adults (\geq 18 years), as part of Combination therapy of pulmonary tuberculosis due to multi-drug resistant Mycobacterium tuberculosis when an effective treatment regimen cannot Otherwise be provided".	14.01.2015
3	Lixisenatide pre-filled solution for injection 10 μ g/20 μ g	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in patients who are not controlled on existing therapy:	15.01.2015

		<p>In combination with the following oral antibiotics:</p> <p>-Metformin, a sulphonyl urea, or a combination of these agents.</p> <p>In combination with a basal insulin: alone, in combination with metformin, or in combination with sulphonyl urea.</p>	
4	Dapagliflozin Tablet 5mg/10mg	<p>“In adult aged 18 years and older with Type-II diabetic mellitus to improve glycemic control: As mono-therapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance.</p> <p>As add-on combination therapy in combination therapy in combination with other glucose- lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycemic control”</p>	25.02.2015
5	Pasireotide solution for injection 0.3mg/0.6mg/0.9mg	<p>“For the treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been Curative”</p>	18.03.2015
6	Emphagliflozin Tablet 10mg/25mg	<p>“As an adjunct to diet and exercise to improve glycemic Control in adults with Type 2 diabetes Mellitus.”</p>	07.05.2015
7	Gadobutrol solution for injection	<p>"In adult, adolescence and children aged 2 years and older for:</p>	07.05.2015

		<p>1. contrast enhancement in cranial and spinal magnetic resonance imaging (MRI).</p> <p>2. Contrast enhancement MRI of other body regions: liver kidneys.</p> <p>3. Contrast enhancement in Magnetic Resonance Angiography (CE-MRA)</p> <p>4. For MRI of the breast to assess the presence and extent of malignant breast</p>	
8	Teneligliptin Tablet 20mg	For the treatment of Type 2 Diabetes Mellitus as a Monotherapy adjunct to diet and Exercise	18.05.2015
9	Ceritinib 150 mg Hard Gelatin Capsules	"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"	13.01.2015
10	Vilazodone Hydrochloride 20mg/40mg and Bulk	"For the treatment of Major depressive disorders in adults"	19.08.15
11	Gemigliptin 50mg tablets	"As an adjunct to the diet & exercise to improve to improve glycemic control in adults with type-2 diabetes mellitus, as an monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone"	21.08.15
12	Atosiban Acetate Injection 6.75mg/0.9ml and Bulk	<p>"Indicated to delay imminent pre-term birth in pregnant adult women with:</p> <p>-regular uterine contractions of at least 30 Seconds duration at the rate of ≥ 4 per 30 minutes</p> <p>-a cervical dilation of 1 to 3 cm (0-3</p>	16.09.15

		for nulliparas) and effacement of $\geq 50\%$ - a gestational age from 24 until 33 Completed weeks a normal foetal heart rate"	
13	Ibrutinib Hard gelatin Capsule 140mg	"For the treatment of adult patients with:- -mantle cell lymphoma (MCL) who have received at least one prior therapy. -Chronic Lymphocytic leukemia (CLL) who have received at least one prior therapy. - Chronic lymphocytic leukemia with 17p deletion"	07.10.2015
14	Ledipasvir (90mg)+ Sofosbuvir (400mg) Tablet	" For the treatment of chronic hepatitis C (CHC) Genotype 1 infection in adults"	08.12.2015
15	Ledipasvir Bulk		08.12.2015
16	Daclatasvir Dihydrochloride bulk & Tablet 30mg/60mg	"For use with Sofosbuvir for the treatment of patient with chronic hepatitis C virus (HCV) genotype 3 infection"	14.12.2015
17	Enzalutamide 40 mg soft Capsule	"For the treatment of adults with metastatic castration resistant prostate cancer whose disease has progressed on or after Docetaxel therapy	18. 12 .2015

Start date: 09/02/2015

End date: 01/12/2066

ANNEXURE B

F. No: 7-5/2017/DCG(I)/MISC(099)
Directorate General of Health Services
Office of Drug Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated:- 24 NOV 2017

To,
All State/UT Drugs Controllers

Subject: Amendment in the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R 1337(E) dated 27.10.2017 regarding validity of licence & provision for joint inspection of manufacturing premises for grant of licence for manufacture for sale of Drugs and Cosmetics & verification of compliance –Reg.

Sir,

Ministry of Health and Family Welfare, Government of India has amended the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R.1337 (E) dated 27.10.2017 providing that manufacturing licence for drugs and cosmetics and approval of drugs/cosmetics testing laboratories shall remain valid if the licensee deposits licence retention fee before the expiry of period of every succeeding five years from the date of issue, unless, it is suspended or cancelled by the licensing authority.

The amendment also provides that before grant of licence in Form 25 or Form 25A or Form 25B or Form 25F or Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA to manufacture for sale or for distribution of Drugs or in Form 32 or Form 32A or Form 33 for manufacture of Cosmetics, the State Licensing Authority shall cause the manufacturing premises to be inspected jointly by the Central and State Drugs Inspectors. Further, the premises licensed shall be inspected jointly to verify the compliance with the conditions of licence and the provisions of the Act and the Rules not less than once in three years or as needed as per risk based approach.

Copy of the notification is enclosed herewith for your information and necessary action.

In this regard, for effective and uniform implementation of the provisions of joint inspection of manufacturing premises, detailed guidelines would be prepared in consultation with the State Drugs Controllers and other stakeholders.

However, in the meantime to ensure smooth processing of applications for grant of manufacturing licenses following modalities may be followed.

- i. Applications for the grant of manufacturing licenses complete in all respect as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945 should be submitted by the manufacturers to the respective State Licensing Authority.
- ii. The State Licensing Authority should fix a date for joint inspection of the manufacturing premises, in coordination with the respective Zonal/Sub-Zonal offices of CDSCO at least seven days prior to the date of inspection.

- iii. In case drugs inspector of CDSCO Zonal/Sub-Zonal offices is not available on any specific date, drugs inspector from CDSCO (HQ) will be deputed for the joint inspection.
- iv. Proper coordination between the State Licensing Authorities, CDSCO HQ and Zonal/Sub-Zonal offices should be ensured for timely inspection and processing of the applications.
- v. In case of deficiency in the application in respect of any inspection, the joint inspection team may verify such documents during the inspection and record details of the same in the inspection report.

Your cooperation and valuable feedback or suggestions in this regard will be highly appreciated for further improvement in the implementation of the new rules.

Yours faithfully



24-11-17

Dr. G. N. Singh
Drugs Controller General (India)

Copy to : All Zonal/Sub-Zonal Offices, CDSCO.

e.c. PPS to DGHS

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ANNEXURE C


File No. X-11026/163/2017-BD
Directorate General of Health Services
Ministry of Health and Family Welfare
Central Drugs Standard Control organization
Office of Drugs Controller General (India)
(Biological Division)

27 NOV 2017
Dated: _____

To,
All State/UT Drugs Controllers

It has been reported that the sample of Snake Venom Antiserum I.P., Lyophilized, (Equine Origin) Batch No. A05315062, Mfg. Date: May 2015, Expiry date: April 2019, manufactured by M/s Bharat Serums & Vaccines, Ltd., Ambernath - 421 501, was declared as Not of Standard Quality by CDL, Kasauli with respect to potency test, vide test report no. CDL/2017/GA16 dated 11.10.2017.

In this regard, all the State/UT Drugs Controllers, CDSCO Zonal or Sub-Zonal officers are requested to direct the inspectorate staff under their control to keep strict vigil on the movement of said product (Batch no. A05315062) in the market.


(Dr. G. N. Singh)
Drugs Controller General (India)

Copy for necessary action to:
1. CDSCO Zonal or Sub-Zonal Offices

ANNEXURE D

List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, For the Month of October, 2017

Sl. No.	Name of Drugs/medical device/cosmetics	Batch No./Date of Manufacture/Date of Expiry/Manufactured By	Reason for failure	Drawn By	From
1.	Oxytocin Injection I.P. 1 ml	B. No.: OX-1616, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Systochem Laboratories Ltd, B-75, Roop Nagar, Indl Area, Loni – 201 102(U.P)	Description & Particulate Matter	CDSCO, South Zone, Chennai	CDL, Kolkata
2.	Serratiopeptidase Tablets I.P. 10 mg	B. No.: N1604042, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. Talent Healthcare, 66-67, Sector 6A, SIDCUL, IIE, Haridwar 249 403, (Uttarakhand)	Disintegration & Assay	CDSCO, South Zone, Chennai	CDL, Kolkata
3.	Carbimazole Tablets I.P. 5 mg	B. No.: T-12112, Mfg dt: 08/2016, Exp dt: 07/2018, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar 143 001	Description, Identification & Assay	CDSCO, South Zone, Chennai	CDL, Kolkata
4.	Erythromycin Stearate Tablets I.P. 250 mg	B. No.: ES-1602, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. Minopharm Laboratories Pvt. Ltd., Hyderabad 500 073, Works: Opp. I.D.A, Pernamitta - 523002	Dissolution	CDSCO, South Zone, Chennai	CDL, Kolkata
5.	ELPRIL 2.5 (Enalapril Maleate Tablets I.P.)	B. No.: AP6109, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Affy Parenterals, Village: Gullerwala, P.O. Baddi, Solan 173 205 (H.P.)	Uniformity of Content, Dissolution & Assay	CDSCO, East Zone, Kolkata	CDL, Kolkata
6.	ELPRIL 5 (Enalapril Maleate Tablets I.P.)	B. No.: AP7042, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Affy Parenterals, Village: Gullerwala, P.O. Baddi, Solan 173 205 (H.P.)	Uniformity of Content, Dissolution & Assay	CDSCO, East Zone, Kolkata	CDL, Kolkata
7.	Oxymac (Oxytocin Injection I.P.)	B. No.: OT-16010, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Macin Remedies India Ltd, B-21, Ind. Focal Point, Moga-	Description & Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata

		142001			
8.	Levocetirizine Tablets I.P. 5 mg	B. No.: 9700717, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Karnataka Antibiotics & Pharmaceuticals Limited, Plot No. 14, II Phase, Peenyar, Bangalore 560 068	Related Substances	CDSCO, East Zone, Kolkata	CDL, Kolkata
9.	Amikacin Sulphate Injection I.P. 250mg/ml	B. No.: P7171, Mfg dt: 04/2017, Exp dt: 03/2019, Mfd by: M/s. Bharat Parenterals Ltd., Vill. Hariupra, Ta. Savli, Dist- Vadodara - 391520, Gujarat.	Description & Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata
10.	L-BEX-OD (Alpha Lipoic Acid, Pyridoxine Hydrochloride Methylcobalamin, Folic Acid & Vitamin D ₃ Tablets)	B. No.: LBBDT16003, Mfg dt: 08/2016, Exp dt: 01/2018, Mfd by: M/s. Ravian Life Science Pvt. Ltd., Plot No. 34, Sector-8A, IIE, SIDCUL, Haridwar-249403	Disintegration	CDSCO, East Zone, Kolkata	CDL, Kolkata
11.	Anodex (Dexamethasone Sodium Phosphate Injection I.P. 4mg/ml)	B. No.: FN-231, Mfg dt: 11/2016, Exp dt: 10/2018, Mfd by: M/s. COAX Bioremedies Pvt. Ltd., 83, Sec-28, Industrial Area, Delhi Road, Hisar 125 044	Description, Particulate Matter	CDSCO, East Zone, Kolkata	CDL, Kolkata
12.	Tramicort 40 mg/ml (Triamcinolone Acetonide Injection I.P. 1 ml)	B. No.: VI7074, Mfg dt: 05/2017, Exp dt: 04/2019, Mfd by: M/s. Scott-Edil Pharmacia Limited, 56, E.P.I.P, Phase - I, Jharmajri 173 205	Extractable Volume	CDSCO, Head Quarter, New Delhi	CDL, Kolkata
13.	Becomax Forte (B-Complex with Vitamin C Capsules)	B. No.: HL0099, Mfg dt: 12/2016, Exp dt: 05/2018, Mfd by: M/s. Hindustan Laboratories, Plot No. 5-9, Survey No. 38/2, Aliyali Village, Palghar (W), Dist. Palghar-401404	Assay of Folic Acid	CDSCO, Head Quarter, New Delhi	CDL, Kolkata
14.	Prednisolone Tablets I.P	B. No.: AT17077, Mfg dt: 05/2017, Exp dt: 04/2020. Mfd by: M/s. Arbro Pharmaceuticals Pvt Ltd, 6/14, Kirti Nagar, Industrial	Related Substances	CDSCO, Head Quarter, New Delhi	CDL, Kolkata

		Area, New Delhi-110015			
15.	Gentamicin Injection I.P. 2 ml	B. No.: 5000816, Mfg dt: 05/2016, Exp dt: 04/2018, Mfd by: M/s. Karnataka Antibiotics & Pharmaceuticals Limited , Plot No 14, II Phase, Peenyar, Bangalore-560058	Description, Particulate Matter	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
16.	Amikacin Sulphate Injection I.P. 500 mg - 2 ml	B. No.: 7901616, Mfg dt: 05/2016, Exp dt: 04/2018, Mfd by: M/s. Karnataka Antibiotics & Pharmaceuticals Limited , Plot No 14, II Phase, Peenyar, Bangalore-560058	Description, Particulate Matter	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
17.	Ajanta Brand Rolled Bandages (Non Sterilized) 20 x 14 Superfine	B. No.: B.420, Mfg dt: 05/2017, Exp dt: 04/2020, Mfd by: M/s. Ajanta Surgical Industries, Kanth (Moradabad, U.P).	Threads/dm (Warp/Weft), Wt. in gm/m ² , Length, Foreign Matter, Fluorescence	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
18.	Dexamethasone Sodium Phosphate Injection I.P 2ml	B. No.: HLI612H, Mfg dt: 08/2016, Exp dt: 07/2018, Mfd by: M/s. Himalaya Mediteck Private Ltd., Plot No. 35 & 36, Pharmacy, Selaqui, Industrial Area, Dehradun - 248197	Description, Particulate Matter & Bacterial Endotoxins	CDSCO, North Zone, Ghaziabad	CDL, Kolkata
19.	Dysmeril – Spas (Mefenamic Acid & Dicyclomine HCl Tablets)	B. No.: JBT-2843, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. J. B. Remedies Pvt. Ltd., 11 th Mile Stone, Roorkee Road, KH. No. 298, Vill. Kurdi, Manglaur, Roorkee, Haridwar - 247 667 (U.K.).	Disintegration	CDSCO, Hyderabad Zone	CDL, Kolkata
20.	CEZOTUM ^(R) 1g (Cefoperazone & Sulbactam for Injection) & Sterile Water for Injection I.P.	B. No.: UP16034, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Unimark Remedies Ltd., At Plot No. 23, EPIP, Phase - II, Thana Baddi -173205, Dist- Solan (H.P.) B. No.: WB6L10, Mfg dt: 12/2016,	Particulate Matter & Clarity of Solution	CDSCO, Hyderabad Zone	CDL, Kolkata

		Exp dt: 11/2019, Mfd by: M/s. Auraya Healthcare, Plot No. 80E, E.P.I.P. Phase I, Jharmajri, Baddi, H.P. India			
21.	Blue Valley Shaving Cream	B. No.: B-27, Mfg dt: 07/2017, Exp dt: 06/2020, Mfd by: M/s. Shree Sudarshan Cosmetics DSIDC Indl. Complex Narela, Delhi- 110040	Total Microbial Count	Drugs Control Department N.C.T. Delhi	RDTL, Chandigarh
22.	Cefadroxil Oral Suspension IP	B. No.: CLS1701, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Modern Laboratories 45-47, Sector D- 2, Sanwer Road Indore (M.P)- 452015.	Assay of Cefadroxil calculated as Anhydrous Cefadroxil	CDSCO, Sub-Zone, Jammu	RDTL, Chandigarh
23.	Diclofenac Potassium, Paracetamol and Serratiopeptidase Tablets (RECOV- SR TABLETS)	B. No.:T-170746 , Mfg dt: 07/2017 Exp dt: 06/2019 Mfd by: M/s. Medirose Drugs & Pharmaceuticals 51, Industrial Area, Phase-III, Sansarpur Terrace, Distt. Kangra, Pin-176501 (H.P)	Disintegration	CDSCO, Sub-Zone, Baddi	RDTL, Chandigarh
24.	Iron, Folic Acid Tablets IP (SAMFER SMALL TABLETS)	B. No.: TX-12052 , Mfg dt: 06/2017 , Exp dt: 05/2019, Mfd by: M/s. Legen Healthcare, Plot No. 20, Sector-5, Parwanoo, Distt. Solan (H.P)-173220	Identification of Folic Acid	CDSCO, Sub-Zone, Baddi	RDTL, Chandigarh
25.	Cefixime and lactic Acid Bacillus Dispersible Tablets (THEOXIME –LB TABLETS)	B. No.: THG160043, Mfg dt: 09/2016 Exp dt: 08/2018 Mfd by: M/s. Theon Pharmaceuticals Ltd., Vill. Saini Majra, Tehsil Nalagarh, Dist. Solan H.P.-174101	Assay of Lactic Acid Bacillus	CDSCO, North Zone, Ghaziabad	RDTL, Chandigarh
26.	Chlorhexidine Mouthwash I.P. 0.2% w/v	B. No.: 616-571, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Zee Laboratories Ltd., Behind 47, industrial Area, Paonta Sahib- 173025	Assay	CDSCO, West Zone, Mumbai	CDTL, Mumbai
27.	Chloroquine (Chloroquine Phosphate Tablet IP. 250mg)	B. No.: M-9504, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. Herb Edge Health Care Pvt. Ltd., 81-82- 86-87, Industrial Area, Dewas Road, Ujjain-456010.	Assay	CDSCO, West Zone, Mumbai	CDTL, Mumbai

28.	Chloroquine Phosphate Tablets IP	B. No.: MPC 6004, Mfg dt: 03/2016 Exp dt: 02/2019 Mfd by: M/s. Halewood Laboratories Pvt. Ltd., 319, Phase-II, G.I.D.C., Vatva, Ahmedabad-382445.	Assay	CDSCO, Sub-Zone, Indore	CDTL, Mumbai
29.	Diazepam Tablets I.P. 5mg	B. No.: DZT409 , Mfg dt: 10/2016 Exp dt: 09/2018 Mfd by: M/s. Unicure India Ltd., C-22 &23, Sector-3, Noida, Uttar Pradesh 201301.	Related Substances & Decomposition Products	CDSCO, Sub Zone/Port Office, Goa	CDTL, Mumbai
30.	Bisacodyl Tablets IP 5mg	B. No.: 603324, Mfg dt: 08/2016, Exp dt: 07/2018, Mfd by: M/s. Ciron Drugs & Pharmaceuticals Pvt. Ltd., Plot No. 35 to 37, 43 to 45, CFC-B, Dewan Udyog Nagar, Aliyali, Palghar, Dist-Thane-401404.	Assay	CDSCO, West Zone, Mumbai	CDTL, Mumbai
31.	Amikacin Sulphate Injection I.P. 100mg	B. No.: AK1611, Mfg dt: 06/2016, Exp dt: 05/2018, Mfd by: M/s. Nandani Medical Laboratories Pvt. Ltd., 221/5, Bicholi Hapsi, Kanadia Road, Indore.	Test for sterility	CDSCO, Sub Zone, Indore	CDTL, Mumbai

ANNEXURE E

2

THE GAZETTE OF INDIA : EXTRAORDINARY

[PART II—SEC. 3(i)]

542. डैसोएक्सिमेटासन
543. डेक्सामेथासोन
544. डिफ्लोरसन डाइएसीटेट
545. फ्लूओसीनोनाइड
546. फ्लूओसिनोलोन एसीटोनाइड
547. हालोबीटासन प्रोपिओनेट
548. हालोमेटासन
549. मिथाइलप्रेडिनसोन
550. प्रेडिनकार्बेट
551. ट्रिअमसिनोलोन एसीटोनाइड "

[फा.सं. एक्स- 11014/14/2017-डीआरएस]

सुधीर कुमार, संयुक्त सचिव

पाद टिप्पण: मूल नियम सरकारी राजपत्र में अधिसूचना सं. एफ.28-10/45-एच(1) दिनांक 21 दिसम्बर, 1945 में प्रकाशित हुए थे और अधिसूचना सं. सा.का.नि.....(अ) दिनांक द्वारा अंतिम बार संशोधित किए गए थे।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st November, 2017

G.S.R.1357(E).—The following draft of certain rules, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi – 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (.....Amendment) Rules, 2017.
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, in Schedule H, after serial number 537 and entries relating thereto, the following serial numbers and entries shall be inserted, namely,-
 - “538. Alclometasone
 539. Beclomethasone
 540. Bctamethasone
 541. Desonide
 542. Desoximetasone
 543. Dexamethasone
 544. Diflorasone diacetate

- 545. Fluocinonide
- 546. Fluocinolone acetonide
- 547. Halobetasol propionate
- 548. Halometasone
- 549. Methylprednisone
- 550. Prednicarbate
- 551. Triamcinolone acetonide³⁷

[F. No. X-11014/14/2017-DRS]

SUDHIR KUMAR, Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (I) dated 21 st December, 1945 and last amended vide notification number G.S.R.(E) dated.....