

## 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<br>0.584mg/ml Cutaneous Spray<br>Solution (Vet.)           | For symptomatic treatment of inflammatory and pruritic dermatosis in dogs.  | 06.01.17      |
| 2    | Dexlansoprazole Delayed<br>Release Capsule 30/60mg &<br>Bulk                        | For the treatment of<br><br>i) Healing of all grades of erosive esophagitis (EE).<br><br>ii) Maintaining healing of EE and relief of heartburn.<br><br>iii) Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).  | 16.01.17      |
| 3    | Carfilzomib Sterile<br>Lyophilized Powder for<br>Injection 60mg/vial (50ml<br>vial) | Relapsed or refractory multiple myeloma<br><br><ul style="list-style-type: none"><li>• 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.</li><li>• 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.</li></ul> | 17.01.17      |
| 4    | Dabrafenib 50mg/75mg<br>Capsules<br><br>(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.<br><br>In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma  | 18.01.17      |

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|    |  | with BRAF V600E mutation as detected by an appropriate test.   |            |
| 5  | Trametinib 0.5mg/2mg Tablets<br>(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<br>(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 |

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

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|    |   | 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"> <li>• Hypertension</li> <li>• Renal parenchymal hypertension</li> <li>• Angina</li> </ul>  | 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 |

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|    |   | (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"> <li>• 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.</li> <li>• For the treatment of adult patients with advanced systemic mastocytosis (Advanced SM)</li> </ul> | 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      |

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| 4  | Tofacitinib Tablets 5 mg(Tofacitinib Citrate)                                 | <p>"For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had</p> <p>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)".</p>                    | 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 |

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| 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 |

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| 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    | <b>Lixisenatide</b> pre-filled solution for injection 10 $\mu$ g/20 $\mu$ 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    |



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|   |  | <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:<br/>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 |

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|    |  | <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 <math>\geq 4</math> per 30 minutes</p> <p>-a cervical dilation of 1 to 3 cm (0-3</p>   | 16.09.15   |

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|    |   | for nulliparas) and effacement of $\geq 50\%$<br><br>- 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:-<br>-mantle cell lymphoma (MCL) who have received at least one prior therapy.<br>-Chronic Lymphocytic leukemia (CLL) who have received at least one prior therapy.<br>- 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  
" JS(R)

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,<br>Mfg dt: 12/2016,<br>Exp dt: 11/2018,<br>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,<br>Mfg dt: 04/2016,<br>Exp dt: 03/2018,<br>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,<br>Mfg dt: 08/2016,<br>Exp dt: 07/2018,<br>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,<br>Mfg dt: 04/2016,<br>Exp dt: 03/2018,<br>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,<br>Mfg dt: 03/2016,<br>Exp dt: 02/2018,<br>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,<br>Mfg dt: 02/2017,<br>Exp dt: 01/2019,<br>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,<br>Mfg dt: 03/2016,<br>Exp dt: 02/2018,<br>Mfd by: M/s. Macin Remedies India Ltd, B-21, Ind. Focal Point, Moga-                                    | Description & Particulate Matter           | CDSCO, East Zone, Kolkata  | CDL, Kolkata |



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|-----|--|---|-------------------------------------|---|-----------------|
|     |  | 142001  |                                     |   |                 |
| 8.  | Levocetirizine<br>Tablets I.P. 5 mg  | B. No.: 9700717,<br>Mfg dt: 05/2017,<br>Exp dt: 04/2020,<br>Mfd by: M/s. Karnataka<br>Antibiotics & Pharmaceuticals<br>Limited, Plot No. 14, II<br>Phase, Peenyar, Bangalore<br>560 068       | Related<br>Substances               | CDSCO,<br>East Zone,<br>Kolkata         | CDL,<br>Kolkata |
| 9.  | Amikacin Sulphate<br>Injection I.P.<br>250mg/ml  | B. No.: P7171,<br>Mfg dt: 04/2017,<br>Exp dt: 03/2019,<br>Mfd by: M/s. Bharat<br>Parenterals Ltd., Vill.<br>Hariupra, Ta. Savli, Dist-<br>Vadodara - 391520, Gujarat.                         | Description &<br>Particulate Matter | CDSCO,<br>East Zone,<br>Kolkata         | CDL,<br>Kolkata |
| 10. | L-BEX-OD (Alpha<br>Lipoic Acid,<br>Pyridoxine<br>Hydrochloride<br>Methylcobalamin,<br>Folic Acid &<br>Vitamin D <sub>3</sub><br>Tablets) | B. No.: LBDT16003,<br>Mfg dt: 08/2016,<br>Exp dt: 01/2018,<br>Mfd by: M/s. Ravian Life<br>Science Pvt. Ltd., Plot No. 34,<br>Sector-8A, IIE, SIDCUL,<br>Haridwar-249403                       | Disintegration                      | CDSCO,<br>East Zone,<br>Kolkata         | CDL,<br>Kolkata |
| 11. | Anodex<br>(Dexamethasone<br>Sodium Phosphate<br>Injection I.P.<br>4mg/ml )   | B. No.: FN-231,<br>Mfg dt: 11/2016,<br>Exp dt: 10/2018,<br>Mfd by: M/s. COAX<br>Bioremedies Pvt. Ltd.,<br>83, Sec-28, Industrial Area,<br>Delhi Road, Hisar 125 044                           | Description,<br>Particulate Matter  | CDSCO,<br>East Zone,<br>Kolkata         | CDL,<br>Kolkata |
| 12. | Tramicort 40<br>mg/ml<br>(Triamcinolone<br>Acetonide Injection<br>I.P. 1 ml)   | B. No.: VI7074,<br>Mfg dt: 05/2017,<br>Exp dt: 04/2019,<br>Mfd by: M/s. Scott-Edil<br>Pharmacia Limited, 56,<br>E.P.I.P, Phase - I, Jharmajri<br>173 205                                      | Extractable<br>Volume               | CDSCO,<br>Head<br>Quarter, New<br>Delhi | CDL,<br>Kolkata |
| 13. | Becomax Forte<br>(B-Complex with<br>Vitamin C<br>Capsules)   | B. No.: HL0099,<br>Mfg dt: 12/2016,<br>Exp dt: 05/2018,<br>Mfd by: M/s. Hindustan<br>Laboratories, Plot No. 5-9,<br>Survey No. 38/2, Aliyali<br>Village, Palghar (W),<br>Dist. Palghar-401404 | Assay of Folic<br>Acid              | CDSCO,<br>Head<br>Quarter, New<br>Delhi | CDL,<br>Kolkata |
| 14. | Prednisolone<br>Tablets I.P  | B. No.: AT17077,<br>Mfg dt: 05/2017,<br>Exp dt: 04/2020.<br>Mfd by: M/s. Arbro<br>Pharmaceuticals Pvt Ltd,<br>6/14, Kirti Nagar, Industrial   | Related<br>Substances               | CDSCO,<br>Head<br>Quarter, New<br>Delhi | CDL,<br>Kolkata |

|     |   |  |   |                              |              |
|-----|---|--|---|------------------------------|--------------|
|     |   | Area, New Delhi-110015   |   |                              |              |
| 15. | Gentamicin Injection I.P. 2 ml  | B. No.: 5000816,<br>Mfg dt: 05/2016,<br>Exp dt: 04/2018,<br>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,<br>Mfg dt: 05/2016,<br>Exp dt: 04/2018,<br>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,<br>Mfg dt: 05/2017,<br>Exp dt: 04/2020,<br>Mfd by: M/s. Ajanta Surgical Industries, Kanth (Moradabad, U.P).   | Threads/dm (Warp/Weft), Wt. in gm/m <sup>2</sup> , Length, Foreign Matter, Fluorescence | CDSCO, North Zone, Ghaziabad | CDL, Kolkata |
| 18. | Dexamethasone Sodium Phosphate Injection I.P 2ml  | B. No.: HLI612H,<br>Mfg dt: 08/2016,<br>Exp dt: 07/2018,<br>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,<br>Mfg dt: 04/2016,<br>Exp dt: 03/2018,<br>Mfd by: M/s. J. B. Remedies Pvt. Ltd., 11 <sup>th</sup> Mile Stone, Roorkee Road, KH. No. 298, Vill. Kurdi, Manglaur, Roorkee, Haridwar - 247 667 (U.K.). | Disintegration  | CDSCO, Hyderabad Zone        | CDL, Kolkata |
| 20. | CEZOTUM <sup>(R)</sup> 1g (Cefoperazone & Sulbactam for Injection)<br><br>&<br>Sterile Water for Injection I.P. | B. No.: UP16034,<br>Mfg dt: 12/2016,<br>Exp dt: 11/2018,<br>Mfd by: M/s. Unimark Remedies Ltd., At Plot No. 23, EPIP, Phase - II, Thana Baddi -173205, Dist- Solan (H.P.)<br><br>B. No.: WB6L10,<br>Mfg dt: 12/2016,   | Particulate Matter & Clarity of Solution  | CDSCO, Hyderabad Zone        | CDL, Kolkata |

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

|     |  |  |   |                                  |              |
|-----|--|--|---|----------------------------------|--------------|
| 28. | Chloroquine Phosphate Tablets IP       | B. No.: MPC 6004,<br>Mfg dt: 03/2016<br>Exp dt: 02/2019<br>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 ,<br>Mfg dt: 10/2016<br>Exp dt: 09/2018<br>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,<br>Mfg dt: 08/2016,<br>Exp dt: 07/2018,<br>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,<br>Mfg dt: 06/2016,<br>Exp dt: 05/2018,<br>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(D)]

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](mailto: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 acetonide<sup>37</sup>

[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.....