

ANNEXURE 4

List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, For the Month of September, 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. | Cefoclox-XL Tablets | B. No.: UTCCLA524, Mfg dt: 10/2015, Exp dt: 09/2017, Mfd by: M/s. Khandelwal Laboratories Pvt. Ltd., Plot No. 10, Sector 6, IIE, Sidcul, Pant Nagar, Uttarakhand-263153 | Disintegration | Drugs Control Department, Mizoram | RDTL, Guwahati |
| 2. | Diazepam Tablets I.P. 5 mg | B. No.: DZT411, Mfg dt: 12/2016, Exp dt: 11/2018, Mfd by: M/s. Unicure India Ltd., C-21, 22 & 23, Sector 3, Noida 201 301, Distt. Gautam Budh Nagar, (U.P.). | Related Substances and decomposition products | CDSCO, South Zone, Chennai | CDL, Kolkata |
| 3. | Clop Cream 30 g (Clobetasol Cream I.P. 0.05% w/w) | B. No.: BFT118, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Cadila Healthcare Limited, Sarkhej-Bavla, N.H. No. 8A, Moraiya, Tal: Sanand, Dist. Ahmedabad – 382 210, Mfg at 75/1, G.I.D.C. Vapi, Distt. Valsad – 396 195. | Assay | CDSCO, Head Quarter, New Delhi | CDL, Kolkata |
| 4. | Oxyline 250 (Oxytetracycline Capsules I.P. 250 mg) | B. No.: OXC-105, Mfg dt: 05/2017, Exp dt: 04/2018, Mfd by: M/s. Alco Formulation (I), 14/5, Mathura Road, Faridabad-121003 | Uniformity of weight and Loss on Drying | CDSCO, Head Quarter, New Delhi | CDL, Kolkata |
| 5. | Ceemox 250 DT (Amoxicillin Trihydrate Dispersible Tablet I.P.) | B. No.: AT7094, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Anrose Pharma, 147, Mauza, Sansiwala, Post Barotiwala, Teh. Kasauli, Dist. Solan, HP | Uniformity of Dispersion | CDSCO, Head Quarter, New Delhi | CDL, Kolkata |
| 6. | Diaset 2 (Glimepiride Tablets I.P. 2 mg) | B. No.: L33L11, Mfg dt: 03/2017, Exp dt: 02/2020, Mfd by: M/s. Stadmed Private Ltd, C- 18, Sarojini Nagar, Industrial Estate, Lucknow 226 008. | Dissolution | CDSCO, East Zone, Kolkata | CDL, Kolkata |

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| 7. | ELCITAPAM S-10 (Escitalopram Oxalate Tablets I.P.) | B. No.: AP7076, Mfg dt: 02/2017, Exp dt: 01/2019, Mfd by: M/s. Affy Parenterals, Vill: Gullarwala, P.O. Baddi, Distt. Solan 173205 (H.P.). | Assay | CDSCO, East Zone, Kolkata | CDL, Kolkata |
| 8. | Ceequin Injection (Chloroquine Phosphate Injection I.P.) | B. No.: PC-03, Mfg dt: 07/2016, Exp dt: 06/2018, Mfd by: M/s. Bio-Medica Laboratories Pvt. Ltd., 254, Sector – F, Sanwer Road, Indore- 452015. | Extractable Volume | CDSCO, Ahmedabad Zonal office | CDL, Kolkata |
| 9. | Pantoprazole Tablets I.P. 40 mg | B. No.: PRJT-1001, Mfg dt: 11/2016, Exp dt: 10/2018, Mfd by: M/s. Wings Biotech, 43 & 44, HPSIDC, Industrial Area, Baddi-173205 (H.P). | Dissolution | CDSCO, East -Zone, Kolkata | CDL, Kolkata |
| 10. | Ramil-5 (Ramipril Tablets IP) | B. No.: T-10694, Mfg dt: 01/2016, Exp dt: 12/2017, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar-143001 (India) | Dissolution and Assay | CDSCO, Sub-Zone, Indore | CDTL, Mumbai |
| 11. | Laxsum 40 mg (Frusemide Tablets I.P. 40 mg) | B. No.: T-9737, Mfg dt: 01/2017, Exp dt: 12/2018, Mfd by: M/s. Karnani Pharmaceutical (P) Ltd., Factory 38, Pharmacy Selaqui, Dehradun-248197 | Dissolution | CDSCO, West Zone, Mumbai | CDTL, Mumbai |
| 12. | AARPIK-20 Tablets (Atrovastatin Tablets I.P.) | B. No.: STN-170055, Mfg dt: 04/2017, Exp dt: 03/2019, Mfd by: M/s. Terrace Pharmaceuticals (P) Ltd., 3- B(a), Phase III, Industrial Area, Sansarpur Terrace- 176501 | Dissolution | CDSCO, West Zone, Mumbai | CDTL, Mumbai |
| 13. | Ispaghula Husk Granules BP (CREMADIET) | B. No.: TPC0195, Mfg dt: 05/2017, Exp dt: 04/2019, Mfd by: M/s. Tirupati Medicare Limited, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P.)-173025 | Swelling Index | Drugs Control Department, Himachal Pradesh | RDTL, Chandigarh |
| 14. | Enteric Coated Rabeprazole Sodium and Domperidone | B. No.: C-4516, Mfg dt: 06/2016, Exp dt: 05/2018, Mfd by: M/s. Senate | Assay of Rabeprazole | Drugs Control Department, | RDTL, Chandigarh |

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| | Sustained Release Capsules (RABETEL-DSR CAPSULES) | Laboratories, 252, 253, Sisona, Roorkee-247667 (UK) | | Haryana | |
| 15. | Diclofenac Potassium, Chlorpheniramine Maleate, Paracetamol and Magnesium Trisilicate Tablets (COMON TABLETS) | B. No.: TL-16085, Mfg dt: 12/2016, Exp dt: 05/2019, Mfd by: M/s. Horizon Bioceuticals Pvt Ltd., Plot No. 3A, Industrial Area, Kala Amb, Distt. Sirmour (H.P.) | Assay of Chlorpheniramine Maleate | Drugs Control Department, Haryana | RDTL, Chandigarh |
| 16. | Rabeprazole Tablets IP (RABSOL-20 TABLETS) | B. No.: BT-86, Mfg dt: 04/2017, Exp dt: 03/2019, Mfd by: M/s. Boffin Biotech Pvt. Ltd., Vill. Behral, Paonta Sahib, Distt. Sirmour-173025 (H.P.) | Dissolution | CDSCO, Sub Zone, Baddi | RDTL, Chandigarh |
| 17. | Tizanidine Hydrochloride Tablets IP 2 mg (TIZAPOL TABLETS) | B. No.: TT-030, Mfg dt: 04/2016, Exp dt: 03/2018, Mfd by: M/s. Medipol Pharmaceutical India Pvt. Ltd., 1199/3, Bhud, Baddi, Distt. Solan, H.P. | Description | CDSCO, North Zone, Ghaziabad | RDTL, Chandigarh |
| 18. | Aceclofenac, Paracetamol Tablets (OSEO-AP TABLETS) | B. No.: NT-1604, Mfg dt: 03/2016, Exp dt: 02/2018, Mfd by: M/s. H. L. Healthcare Pvt. Ltd., Plot No. 25, Ind, Area, Phase-II, Gagret-177201 (H.P.) | Identification and Assay of Aceclofenac | Drugs Control Department, N.C.T. Delhi | RDTL, Chandigarh |
| 19. | Amlodipine and Atenolol Tablets (AMTAS-AT 25 TABLETS) | B. No.: KT1192, Mfg dt: 05/2016, Exp dt: 04/2019, Mfd by: M/s. Intas Pharmaceuticals Ltd., Bhagey Khola, Rangpo, East Sikkim-737132. | Assay of Amlodipine Besylate Calculated as Amlodipine | CDSCO, North Zone, Ghaziabad | RDTL, Chandigarh |
| 20. | Silver Sulphadiazine Cream IP | B. No.: S7116, Mfg dt: 06/2017, Exp dt: 05/2019, Mfd by: M/s. Scott-Edil Phamracia Ltd., 56, E.P.I.P., Phase-I, Jharmajri-173205 | Assay | CDSCO, Sub Zone, Baddi | RDTL, Chandigarh |