NOT OF STANDARD QUALITY ALERT FOR THE MONTH OF JUNE – 2024.

| B. | B. State Laboratories | | | | | | | | | | |
|------|---|------------------|-----------------------|----------------|--|---|---|--|--|--|--|
| S.No | Product/Drug Name | Batch No. | Manufacturing Date | Expiry Date | Manufactured By | NSQ Result | Reported by CDSCO Laboratory | | | | |
| 1. | Liquid Paraffin IP | EP4032 | 01/24 | 12/26 | Repacked by :- Kerala State Drugs & Pharmaceuticals Ltd, Kalavoor.P.O, Alappuzha | It fails the test light absorption as per IP | Drugs Testing Laboratory Thiruvananthapura m | | | | |
| 2. | Losartan Potassium Tablets IP 50 mg | HLOA06 | 11/23 | 10/25 | Hindustan Antibiotics Ltd, at II, W.E.A, Faridabad- 121 001(Haryana) R.O, Pimpri, Pune -411 018 | It fails the test 'Dissolution' as per IP | Drugs Testing Laboratory Thiruvananthapura m | | | | |
| 3. | Amloheart-AT [Amlodipine Besylate and Atenolol Tablets] | LE223030 | 03/23 | 02/25 | Lividus Pharmaceuticals pvt.Ltd, ikeva, Level2, Agnito Tech park,141 Kandachavadi, Near, Perungudi, OMR, Chennai-600096 | It fails the test 'Assay' of Amlodipine Besylate | Drugs Testing Laboratory Thiruvananthapura m | | | | |
| 4. | Bacotil-200 [Cefpodoxime Proxetil Tablets USP] | ZTB-148 | 03/24 | 02/26 | Zenith Healthcare Ltd works: 388/34, Changodarlnd. Estate, Sarkhej Bavla Highway, Changodar- 382213 (Gujarat) | It fails the test 'Dissolution' as per USP | Drugs Testing Laboratory Thiruvananthapura m | | | | |
| 5. | Oseltamivir Cap IP 75 mg | D 0444/24- 25 | | | Supplied by Kerala Medical Services | The sample does not conform to IP | Drugs Testing Laboratory | | | | |

| 6. | Haridrakhandam | 207/23 | 03/24 | 02/26 | Corporation Ltd, Thycaud P.O, Thiruvananthapuram-14 Bhaskaravilasam Vaidyasala, Panayamuttom, Nedumangadu Thiruvananthapuram 695 | standard with respect to the 'Descriptive part' of hard gelatin capsules It fails the test 'pH' as per API | Thiruvananthapura m Drugs Testing Laboratory Thiruvananthapura m |
|----|---|-----------|--------|----------------------------------|---|--|---|
| 7. | Yogarajaguggulu | 209/21 | 03/22 | 3 yrs from the date of mfg | 561 Bhaskaravilasam Vaidyasala, Panayamuttom, Nedumangadu, Thiruvananthapuram 695 561 | It fails the test 'Alcohol soluble Extractive and pH' as per API | Drugs Testing Laboratory Thiruvananthapura m |
| 8. | CANDITRAL 100 (ITRACONAZOLE CAPSULE B.P. 100 MG) | 5230123 | Jan-23 | Jun-25 | GLENMARK PHARMACEUTICALS LTD. | THE SAMPLE DOES NOT COMPLY WITH B P REQUIREMENTS FOR DISSOLUTION TEST | Maharashtra |
| 9. | Lytraco 200 Itraconazole Capsules 200 mg | SLP-22445 | Feb-23 | Jan-25 | STERLIFE PHARMA PVT. LTD. | THE SAMPLE DOES NOT COMPLY WITH B P REQUIREMENTS FOR DISSOLUTION TEST THE SAMPLE IS OFFICIAL IN B P 2021 THEREFORE THE SAMPLE IS | Maharashtra |

| 10. | MONTOR -LC | B18523001 | Jan-23 | Dec-24 | TORQUE | MISBRANDED VIDE SECTION 17(b) AND RULE 96 OF THE DRUGS AND COSMETICS ACT 1940 AND RULES 1945. THE SAMPLE | Maharashtra |
|-----|--|-----------|--------|--------|------------------------------|--|-------------|
| | TABLET (MONTELUKAST SODIUM & LEVOCETRIZINE DIHYDROCHLORI DE TABLET I.P.) | | | | PHARMACEUTICALS PVT. LTD. | DOES NOT COMPLY WITH I P REQUIREMENTS FOR DISSOLUTION TEST | |
| 11. | MONTICET-L Tablets (Montelukast & Levocetirizine Hydrochloride Tablets) | TP-7581 | Sep-22 | Aug-24 | TICOMA PHARMACIA | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION TEST FOR MONTELUKAST. THE SAMPLE IS OFFICIAL IN 1 P 2018 THEREFORE THE SAMPLE IS MISBRANDED VIDE SECTION 17(b) AND RULE 96 OF THE DRUGS AND COSMETICS ACT 1940 AND RULES 1945. | Maharashtra |
| 12. | Levocetrizine Dihydrochloride & Montelukast Sodium Tablets I.P. Zeemont | T22H370C | Aug-22 | Jul-24 | Bajaj Formulations | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION | Maharashtra |

| | | | | | | TEST FOR | |
|-----|---|-----------------|--------|--------|---|---|-------------|
| | | | | | | MONTELUKAST. | |
| 13. | VolKast Kid Syrup 60 ml. | ABS- 2301022 | Jan-23 | Dec-24 | Amentis Biotech Pvt. Ltd. | CONTENT OF MONTELUKAST AND LEVOCETIRIZINE GYDROCHLORIDE IN THE SAMPLE IS LESS (i.e. MONTELUKAST IS 10.50% AND LEVOCETIRIZINE HYDROCHLORIDE IS 71.88% OF THE STATED AMOUNT) THAN THE PERMISSIBLE LIMITS. | Maharashtra |
| 14. | Levetiracetam Tablets U.S.P.500 Mg (LEVEEG-500) | T23D050A | Apr-23 | Mar-25 | BAJAJ FORMULATIONS | THE SAMPLE DOES NOT COMPLY WITH USP REQUIREMENTS FOR DISSOLUTION. | Maharashtra |
| 15. | M2 Pan-DSR (Pantoprazole Gastro-resistant & Domperidone Prolonged-release Capsules IP) | CWHC-283 | Oct-22 | Sep-24 | COSWAY PHARMACEUTICALS | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION OF PANTOPRAZOLE AT ACID STAGE | Maharashtra |
| 16. | Omeford - 40 | SNT-220421 | Sep-22 | Aug-24 | SVR HEALTHCARE (A GMP Certified Company) | THE CONTENT OF OMEPRAZOLE IN THE SAMPLE IS LESS (I.e. 40.84% OF LABELLED | Maharashtra |

| | | | | | | AMOUNT) THAN THE SCHEDULE V LIMITS | |
|-----|---|-----------------|--------|--------|------------------------------------|--|-------------|
| 17. | COZOL- D(Omeprazole with Domperidone Capsules) | AC1952 | Jul-23 | Jun-25 | ALICON PHARMACEUTICAL PVT LTD | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR OMEPRAZOLE AND DOMPERIDONE CAPSULES FOR THE DISSOLUTION TEST (OMEPRAZOLE). THE SAMPLE IS OFFICIAL IN IP. | Maharashtra |
| 18. | DRPLAN-DSR (Pantoprazole Gasto-resistant & Domperidone Prolonged-release Capsules IP) | AC2209003A | Sep-22 | Aug-24 | ADDII BIOTECH PVT. LTD. | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR PANTOPRAZOLE AND DOMPERIDONE CAPSULES FOR THE DISSOLUTION TEST (PANTOPRAZOLE) | Maharashtra |
| 19. | SOFTOM-D Omeprazole and Domperidone Capsules IP | UD2C- 23252B | Apr-23 | Mar-25 | ULTRA DRUGS PVT. LTD. (UNIT-II) | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR OMEPRAZOLE AND | Maharashtra |

| | OMEPRAZOLE & DOMPERIDONE CAPSULES (REMIZOLE-D) | SPC230578 C | Mar-23 | Feb-25 | SALUS PHARMACEUTICALS | DOMPERIDONE CAPSULES FOR THE DISSOLUTION TEST (OMEPRAZOLE). THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR OMEPRAZOLE AND DOMPERIDONE CAPSULES FOR THE DISSOLUTION TEST (OMEPRAZOLE). | Maharashtra |
|-----|---|----------------|--------|--------|--------------------------|--|-------------|
| 21. | (EC) & DOMPERIDONE (SR) CAPSULES IP (PANTIAC-DSR) | PTRC-149 | Feb-23 | Jan-25 | IOSIS REMEDIES PVT. | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR PANTOPRAZOLE AND DOMPERIDONE CAPSULES FOR THE DISSOLUTION TEST (PANTOPRAZOLE) | Maharashtra |
| 22. | DYNACID SUSPENSION (aluminium, magnesium & simethicone oral suspension IP.) | BULH23008 | Apr-23 | Mar-25 | Leeford Healthcare Ltd. | 1) THE SAMPLE DOES NOT COMPLY WITH I.P. REQUIREMENTS FOR TOTAL AEROBIC VIABLE | Maharashtra |

| | | | | | | COUNT IN TEST FOR MICROBIAL CONTAMINATION. 2) TOTAL AEROBIC VIABLE COUNT OF THE SAMPLE IS 20993128 CFU/GM. (1.P. LIMIT-TOTAL AEROBIC VIABLE COUNT OF THE SAMPLE - NOT MORE THAN 100 CFU/GM | |
|-----|--|------------|--------|--------|---------------------------------|--|-------------|
| 23. | (Azithromycin oral suspension IP) 15ML | G-042/5045 | May-23 | Apr-25 | ELFIN DRUGS PVT. LTD. | CONTENT OF AZITHROMYCIN IN THE SAMPLE IS LESS (72.96% OF LABELLED AMOUNT) THAN THE IP LIMIT WITH RESPECT TO ABOVE PROTOCOL. (IP LIMIT-90.0%- 110.0%) | Maharashtra |
| 24. | Alpracan 0.5 Tablets (Alprazolam Tablets) | T2455 | Oct-22 | Sep-25 | Evolet Pharmaceutical Pvt. Ltd. | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR ALPRAZOLAM TABLETS FOR THE DISSOLUTION TEST WITH RESPECT TO ABOVE PROTOCOL. | Maharashtra |

| 25. | RABEPP TABLETS (Rabeprazole Sodium Tablets IP) | ATG2K135 | Nov-22 | Oct-24 | ANROSE PHARMA | CONTENT OF RABEPRAZOLE SODIUM IM THE SAMPLE IS LESS (65.04% OF THE LABELLED AMOUNT) THAN THE IP LIMIT WITH RESPECT TO ABOVE PROTOCOL. (IP LIMIT 90.0% - 110.0%) | Maharashtra |
|-----|---|----------------|--------|--------|-----------------------------|---|-------------|
| 26. | INFI-650 TABLETS (PARACETAMOL TABLETS I.P. 650 mg) | AT-100008 | Dec-22 | Nov-25 | ABARIS HEALTHCARE | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION TEST. | Maharashtra |
| 27. | CUCID-DM | CDMC501 | May-23 | Apr-25 | TULBROS FORMULATIONS | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION TEST FOR OMEPRAZOLE IN ACID STAGE. | Maharashtra |
| 28. | Virpan-40 | T-2306031A | Jun-23 | May-25 | WHITE ENGLE LABORATORIES | THE SAMPLE DOES NOT COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION IN BUFFER STAGE. | Maharashtra |
| 29. | Pantakos-40 (Pantoprazole | CCT231092 B | Sep-23 | Aug-25 | Cent Cure Pvt Ltd. | THE SAMPLE DOES NOT | Maharashtra |

| | Gastro-resistant Tablets IP) | | | | | COMPLY WITH IP REQUIREMENTS FOR DISSOLUTION IN BUFFER STAGE. | |
|-----|---------------------------------|---------|--------|--------|-------------------------------------|--|-------------|
| 30. | Rosumep ASP 10/75mg Capsules | PBWGM04 | Sep-23 | Aug-25 | Pure & Care Healthcare Pvt. Ltd. | THE SAMPLE DOES NOT COMPLY WITH IP FOR THE TEST "RELATED SUBSTANCES – ROSUVASTATIN". | Maharashtra |

NOTE:

- 1. NSQ data was not received as per Format & in EXCEL SHEET from State Drugs Licensing Authorities of Rajasthan (PDF format) and Orissa (PDF Format). for the Month of June, 2024 as per DCG(I) Circular dated 09.02.2024.
- 2. State Drugs Licensing Authorities of Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Goa, Gujarat, Haryana, Himachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Odisha, Punjab, Sikkim, Tamil Nadu, Pondicherry, Telangana, Delhi, Uttarakhand, West Bengal, Andaman & Nicobar, Dadar and Nagar Haveli; Daman and Diu, Lakshadweep have not submitted any data in respect of the Not of Standard Quality (NSQ) Alert for the Month of June, 2024 as per DCG(I) Circular dated 09.02.2024.