

## **NOT OF STANDARD QUALITY (NSQ) ALERT FOR THE MONTH OF JANUARY-2025**

As part of the continuous regulatory surveillance, drug samples are picked from sales/distribution point, analyzed and list of Not of Standard Quality (NSQ) drugs are displayed on CDSCO portal on monthly basis. The purpose of displaying the NSQ list is to make stakeholders aware about the NSQ batches identified in the market.

| <b>A. CDSCO/Central Laboratories</b> |   |                  |                           |                    |  |  |                                     |
|--------------------------------------|---|------------------|---------------------------|--------------------|--|--|-------------------------------------|
| <b>S.No</b>                          | <b>Product/Drug Name</b>  | <b>Batch No.</b> | <b>Manufacturing Date</b> | <b>Expiry Date</b> | <b>Manufactured By</b>   | <b>NSQ Result</b>                        | <b>Reported by CDSCO Laboratory</b> |
| 1.                                   | Monopropylene Glycol USP  | 9971702044       | 04/2024                   | 04/2026            | M/s. Shell Eastern Chemicals, the Metropolis Tower 1, 9, North Buona Vista Drive#0701, Singapore-138588        | Water                                    | CDL, Kolkata                        |
| 2.                                   | Ticagrelor Tablets IP 90 mg (Tigamon 90)                                      | MT230087         | 11/2023                   | 10/2026            | M/s. MONIQUE PHARMACEUTICAL S PVT. LTD., Plot No-676, Sector-69, IMT, Faridabad, Haryana-121004                | Dissolution                              | CDL, Kolkata                        |
| 3.                                   | Calcium Aspartate, Calcium Orotate, Calcitriol, Minerals And Vitamins Tablets | EZF-1989         | 07/2024                   | 12/2026            | M/s. Overseas Healthcare Pvt. Ltd., 335 Km Milestone, National Highway No.1, P.O. Box-25, Phillaur-144410 (Pb) | Assay/content of 'Calcitriol' and 'Zinc' | CDL, Kolkata                        |
| 4.                                   | Diclofenac Sodium Injection I.P (DEPAIN-75)                                   | SNDA23801        | 08/2023                   | 07/2025            | M/s. Srinija Parenterals, D.No. 283, Doctors Estate, Perecherla 522 009  | pH                                       | CDL, Kolkata                        |

|     |  |            |         |         |   |   |              |
|-----|--|------------|---------|---------|---|---|--------------|
| 5.  | Iron Sucrose Injection USP 100mg/5ml   | 24RS04     | 01/2024 | 12/2025 | M/s. SAI Parenterals Limited, D1 & D4, Survey No.280, Phase-V, IDA, Jeedimetla, Hyderabad-500055.TS | pH  | CDL, Kolkata |
| 6.  | Iron Sucrose Injection USP 100mg/5ml   | 24RS08     | 02/2024 | 01/2026 | M/s. SAI Parenterals Limited, D1 & D4, Survey No.280, Phase-V, IDA, Jeedimetla, Hyderabad-500055.TS | pH  | CDL, Kolkata |
| 7.  | Tramadol Hydrochloride Injection 50 mg/ml (Tramacop )                        | RP-04      | 07/2023 | 06/2025 | M/s. Bio Medica Laboratories Pvt. Ltd., 254, Sector-F, Sanwer Road, Industrial Area, Indore-452015  | 'Acidity or Alkalinity' and 'Assay of Tramadol' | CDL, Kolkata |
| 8.  | Metformin Hydrochloride Sustained Release Tablets I.P. 500mg (Conmet SR-500) | C21D934003 | 06/2024 | 05/2027 | M/s. Concept Pharmaceuticals Ltd., A-28/3, MIDC, Chikalthana, Aurangabad-431006                     | Dissolution                                     | CDL, Kolkata |
| 9.  | Cefuroxime Axetil Tablets IP 500 mg  | 4617001    | 05/2024 | 04/2026 | M/s. Bengal Chemicals and Pharmaceuticals Ltd., 164, Maniktala Main Road, Kolkata-700054            | Dissolution                                     | CDL, Kolkata |
| 10. | Cefixime & Ofloxacin Tablets   | CT5853A    | 03/2024 | 02/2026 | M/s. J.M.LABORATORIES Village-Bhanat, P.O.-Ghatti, Subathu  | Assay of Cefixime                               | CDL, Kolkata |

|     |   |          |         |         |  |  |              |
|-----|---|----------|---------|---------|--|--|--------------|
|     | (CEPHAFLU-400)  |          |         |         | Road, Solan (HP)-173211  |  |              |
| 11. | Ambroxol HCL, Levosalbutamol sulphate and Guaiphenesin Drops (Breath-LS Drops ) | HBD 2403 | 04/2024 | 03/2026 | M/s. HIPPO LABS PVT. LTD, Plot No-17, R. G. Nagar, IDA, Prashanthi Nagar, Kukatpally, Hyderabad-72                           | Description  | CDL, Kolkata |
| 12. | Ofloxacin Ophthanmic Solution IP (Ocuex Eye Drops)                              | ED4648   | 11/2024 | 10/2026 | M/s. Captab Biotec, Unit-II, Plot No. 125, E.P.I.P. Road, Mauja, Jharmajri, Baddi, Dist. Solan (H.P.)-173205                 | Assay of Ofloxacin   | CDL, Kolkata |
| 13. | Gentamicin Injection I.P. 30 ml   | GM-19    | 04/2024 | 03/2026 | M/s. New Lab Industry, Ramnagar, Kurthoul, Patna   | SPURIOUS Particulate Matter, Extractable Volume, Composition of Gentamicin Sulphate, Identification and Assay of Gentamicin Sulphate and Description | CDL, Kolkata |
| 14. | Non-Sterile Not for Intravenous Administration Concentrated Acidic Solution     | BT229    | 07/2024 | 06/2025 | M/s. Bio Tech Formulation, Block A-10, Plot No-136, D.No. 17-65, Penamaluru Mandal, New Autonagar, Kanuru, Vijayawada-520007 | Appearance of solution, assay of sodium, potassium, calcium, magnesium and total chloride. Particulate contamination and description                 | CDL, Kolkata |

|     |  |            |         |         |   |  |              |
|-----|--|------------|---------|---------|---|--|--------------|
| 15. | Clobazam Tablets IP 5 mg   | TPT-012058 | 01/2024 | 12/2026 | M/s. Tanpal Pharmaceuticals, D-12-13, Focal Point, Nabha-147 201  | Dissolution  | CDL, Kolkata |
| 16. | Vitamin B-Complex with Vitamin C and Zinc Capsules (Nutribest-Plus )   | 1724-226   | 05/2024 | 10/2025 | M/s. ZEE LABORATORIES LTD., Behind 47, Industrial Area, Paonta Sahib-173025   | Assay of 'Cyanocobalamin' and 'Calcium Pantothenate'                               | CDL, Kolkata |
| 17. | Metoclopramide Injection BP  | 4EC038092  | 08/2024 | 07/2027 | M/s. Ciron Drugs & Pharmaceuticals Pvt. Ltd., N-118/119, M.I.D.C., Tarapur, Boisar, Dist-Palghar-401506                 | Description and Particulate Contamination  | CDL, Kolkata |
| 18. | Sodium Chloride and Glycerine Sterile Diluent for fowl pox vaccine and its combinations for wing web application | ACF24159   | 11/2024 | 10/2026 | M/s. Safe Parenterals Pvt. Ltd. Gollapadu 522408, Palnadu Dist, Andhra Pradesh, India                                   | Description, Appearance of solution and Particulate matter                         | CDL, Kolkata |
| 19. | Rabeprazole Sodium Injection I.P.  | MD23H13    | 08/2023 | 07/2025 | M/s. Martin & Brown Bio-Sciences Pvt. Ltd., K. No. 918/419, Malkumajra, Nalagarh Road, Baddi, Dist- Solan (H.P.)-173205 | pH, Water, Clarity of Solution, Particulate matter and Assay of Rabeprazole Sodium | CDL, Kolkata |
| 20. | Ofloxacin & Ornidazole Tablets IP (Zeof-O)   | SCZAG23007 | 06/2023 | 11/2025 | M/s. Sano-Cito Therapeutics Inc., Vill. Loharan, P.O. Ghatti, Solan-173211 (H.P.)                                       | Dissolution  | CDL, Kolkata |

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|-----|---|-------------|---------|---------|--|--|----------------|
| 21. | Calcium Gluconate Injection I.P. 10% w/v (REOCAL)   | CG-386      | 03/2024 | 02/2026 | M/s. Rathi Laboratories(Hindustan) Pvt. Ltd., Industrial Area, Patna-800013  | pH, Particulate matter, Sterility and Description  | CDL, Kolkata   |
| 22. | Dexamethasone Sodium Phosphate Injection (Dexamethasone 30ml)                                     | DX-18       | 04/2024 | 03/2026 | M/s. New Lab Industry, Ramnagar, Kurthoul, Patna   | SPURIOUS pH, Extractable volume, Particulate matter, Sterility, Identification and Assay of Dexamethasone Sodium Phosphate and Description | CDL, Kolkata   |
| 23. | Dmex Colecalciferol (Vitamin D3) Tablets B.P.   | 4D077301    | 09/2023 | 08/2026 | M/s. 4Care Lifescience Pvt. Ltd. Survey No. 23/3P & 24, Opp. Jeans Factory, Daduram Vistar, Village-Bagdol, Tal. Kathlal, Dist. Kheda-387630, Gujarat, India | Assay of Cholecalciferol   | CDL, Kolkata   |
| 24. | Rabeprazole Sodium 20mg (EC) & Domperidone 10mg (IR), Domperidone 20mg (SR) Capsules (Rebast-ARD) | LC-6943     | 01/2024 | 12/2025 | Lifevision Healthcare, Plot No. 140-141, E.P.I.P., Phase-1, Jharmajri, Baddi, Distt. Solan (H.P.) 174 103  | Dissolution  | RDTL, Guwahati |
| 25. | Montelukast & Levocetirizine Hydrochloride  | VLB-GT-2219 | 09/2023 | 08/2025 | Vee Laboratories,, Village-Kalier, Subathu, Road-  | Dissolution  | RDTL, Guwahati |

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|     | Tablets IP<br>(SOLIKAST-L)   |                |         |         | Saproon (Post Office)<br>Solan-173211,<br>Himachal Pradesh  |   |                |
| 26. | Zinc Sulphate<br>Dispersible<br>Tablets IP 20<br>mg  | LMT240811      | 07/2024 | 06/2026 | Life Max Cancer<br>Laboratories, Plot No.<br>106 & 106 A,<br>Sector6A, IIE,<br>SIDCUL,<br>Haridwar249403<br>(U.K) | Uniformity of<br>dispersion &<br>Disintegration | RDTL, Guwahati |
| 27. | Nimesulide &<br>Paracetamol<br>Tablets<br>(SOMOO)  | T-24004        | 04/2024 | 03/2026 | Kshipra Drugs Pvt.<br>Ltd., 40- 41/22-B,<br>Industrial Area, No. 1,<br>Dewas (M.P.)-<br>455001                    | Disintegration                                  | RDTL, Guwahati |
| 28. | Fexofenadine<br>Hydrochloride<br>Tablets I.P. 120<br>mg.   | UGT231163      | 08/2023 | 07/2025 | Unimarck Healthcare<br>Ltd., Plot No.: 24, 25<br>& 37 Sector 6A,<br>SIDCUL, Haridwar -<br>249403 (Uttarakhand)    | Dissolution                                     | RDTL, Guwahati |
| 29. | HYPODERMIC<br>SYRINGE WITH<br>NEEDLE<br>(Nusafe 2ml)   | 2407154        | 07/2024 | 06/2029 | NUBENO<br>HEALTHCARE<br>PRIVATE LIMITED,<br>Plot No. 10A,<br>Sector23, Mihan<br>Nagpur- 441108                    | Sterility                                       | RDTL, Guwahati |
| 30. | Rabeprazole<br>Sodium (as<br>enteric coated)<br>& Domperidone<br>(As Sustained<br>Release)<br>Capsules<br>(Rabito-DSR) | RTD.23010<br>5 | 08/2023 | 07/2025 | M/s Cartel<br>Laboratories, 10/A,<br>11/A, Chengicherla,<br>Medchal-Malkajgiri<br>(Dist.), Hyderabad-92           | Assay of<br>Rabeprazole<br>Sodium               | RDTL, Guwahati |
| 31. | Losartan<br>Tablets IP 50<br>mg  | LMT240826      | 07/2024 | 06/2026 | Life Max Cancer<br>Laboratories, Plot No.<br>106 & 106 A, Sector  | Dissolution                                     | RDTL, Guwahati |

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|     |  |           |         |         | 6A, IIE, SIDCUL,<br>Haridwar249403<br>(U.K)   |   |                |
| 32. | Albendazole<br>Tablets IP 400<br>mg<br>(Albendazole<br>400)                          | T-3159    | 01/2024 | 12/2025 | Jackson Laboratories<br>Pvt.Ltd, 22-24,<br>Majitha Road, Bye<br>Pass, Amritsar-143<br>001(India)                                      | Dissolution   | RDTL, Guwahati |
| 33. | Itraconazole<br>Capsules IP 100<br>mg  | CTA-01    | 02/2024 | 01/2026 | Agron Remedies Pvt.<br>Ltd., Sarverkhara,<br>Moradabad Road,<br>Kashipur-244713<br>(Uttarakhand)                                      | Dissolution   | RDTL, Guwahati |
| 34. | Diclofenac<br>Sodium<br>Injection IP (AL-<br>DICLO)                                  | A-1694    | 02/2024 | 01/2026 | ALCHEMIST<br>REMEDIES PVT.<br>LTD., 133-139,<br>Industrial Estate,<br>At13, Road, Dewas   | pH , Sterility,<br>Particulate<br>Matter, and<br>Assay                        | RDTL, Guwahati |
| 35. | Calcium 500 mg<br>with Vitamin D3<br>250 IU Tablets<br>IP                            | LMT240431 | 04/2024 | 03/2026 | Life Max Cancer<br>Laboratories, Plot No.<br>106 & 106 A,<br>Sector6A, IIE,<br>SIDCUL,<br>Haridwar249403<br>(U.K)                     | Identification<br>and Assay of<br>Vitamin D3 and<br>Dissolution of<br>Calcium | RDTL, Guwahati |
| 36. | Levocetirizine<br>Hydrochloride &<br>Montelukast<br>Sodium Tablets<br>IP (Montura-L) | ZT23547C  | 11/2024 | 10/2025 | M/s Zenon<br>Lifesciences Pvt. Ltd.,<br>Survey-no. 343/P,<br>Bavla Sanand<br>Highway, Modasar,<br>Ahmedabad, Gujarat,<br>INDIA 382220 | Dissolution of<br>Montelukast   | RDTL, Guwahati |
| 37. | Paracetamol<br>Oral<br>Suspension BP<br>(100 ml) 120<br>mg/ 5 ml                     | ZA23019   | 07/2023 | 06/2026 | Brussels Laboratories<br>Pvt. Ltd., 33,<br>Changodar Ind.<br>Estate, Sarkhej Bavla<br>Road, Changodar                                 | Assay of<br>Paracetamol   | CDTL-Mumbai    |

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|     |  |           |         |         | Ahmedabad - 382<br>210, (Gujarat)  |  |             |
| 38. | Amlodipine<br>Tablets IP 5 mg<br>(Systogan-5)  | CT062     | 08/2024 | 07/2026 | Ryzer<br>Pharmaceutical Pvt.<br>Ltd., Plot No. 901,<br>Dholakuva, Mansa,<br>Gandhinagar,<br>Gujarat- 382845.   | Related<br>substances                                | CDTL-Mumbai |
| 39. | Lorazepam<br>Tablets IP 1 mg<br>(PROLINE - 1)  | 06P23T03  | 08/2023 | 04/2027 | Shine<br>Pharmaceuticals<br>Limited., Plot No.<br>132, Karjan-Vermardi<br>Road, Juni Jitherdi,<br>Ta. Karjan- 391240,<br>Dist : Vadodara,<br>(Gujarat) | Assay  | CDTL-Mumbai |
| 40. | Itraconazole<br>Capsules (Trax<br>- 200)   | AFC - 102 | 05/2024 | 04/2026 | APEX<br>FORMULATIONS<br>PVT. LTD., 1276,<br>Rajpur Ahmedabad-<br>Mehsana Highway,<br>Dist. Mehsana,<br>Gujarat.  | Dissolution  | CDTL-Mumbai |
| 41. | Enteric Coated<br>Rabeprazole<br>Sodium And<br>Domperidone<br>Sustained<br>Release<br>Capsules<br>(Dorab SR<br>Capsules) | AFC - 111 | 08/2024 | 07/2026 | APEX<br>FORMULATIONS<br>PVT. LTD., 1276,<br>Rajpur Ahmedabad-<br>Mehsana Highway,<br>Dist. Mehsana,<br>Gujarat.  | Dissolution for<br>Domperidone                       | CDTL-Mumbai |
| 42. | Aceclofenac<br>Tablets IP 100<br>mg  | T042304   | 11/2023 | 04/2025 | Bengal Chemicals &<br>Pharmaceuticals Ltd.,<br>(A Govt. of India<br>Enterprise) at 11,   | Related<br>substances and<br>Assay of<br>Aceclofenac | CDTL-Mumbai |



|     |   |            |         |         |   |  |                  |
|-----|---|------------|---------|---------|---|--|------------------|
|     |   |            |         |         | W.E.A. Faridabad - 121001 (Haryana)   |  |                  |
| 43. | Montelukast Sodium and Levocetirizine Hydrochloride Dispersible Tablets (ROMILAST® L 4) | 18RT2401   | 04/2024 | 09/2026 | Adnova Healthcare Pvt. Ltd. 156, 157 A, Siddhi Industrial Infrastructure Park, Waghodia, Vadodara - 391760, Gujarat | Description and Uniformity of dispersion       | CDTL - Indore    |
| 44. | Metoprolol Succinate Prolonged Release Tablets IP 25 mg                                 | DT 2403    | 10/2026 | 09/2027 | M/s. Triveni Formulations Limited, Plot No.52, 53, 54 ALEAP Industrial Estate, Surampalli-521212                    | Dissolution                                    | CDTL, Hyderabad  |
| 45. | Ciprofloxacin Injection IP  | LV4210     | 03/2024 | 02/2026 | Captab Biotec, Unit-II, Plot No. 125, E.P.I.P.Road, Mauja, Jharmajri, Baddi, Distt. Solan (H.P.)-1732025            | In test of Lactic Acid per mg of Ciprofloxacin | RDTL, Chandigarh |
| 46. | Ceftriaxone Injection IP (Cefiglax-1 Injection)   | SRIJ240041 | 10/2024 | 09/2026 | SYSTOLE REMEDIES PVT. LTD., Vill. Ogli, Kala Amb. Teh. Nahan, Distt. Sirmour (H.P.)-173030                          | Particulate matter                             | RDTL, Chandigarh |
| 47. | Cefixime and Lactic Acid Bacillus Tablets (CEFIZOC-200 LB TABLETS)                      | BT-240511  | 05/2024 | 04/2026 | A.N.D. HEALTHCARE LTD, Plot No. C-24, Focal Point, Kurali, Mohali-140103  | Assay of Lactic Acid Bacillus                  | RDTL, Chandigarh |
| 48. | Hyoscine Butylbromide Tablets IP  | PT-102441  | 10/2024 | 09/2026 | Primus Pharmaceuticals, Sadhoura Road, Mouza Ogli Khari Vill  | Assay of Hyoscine Butylbromide                 | RDTL, Chandigarh |

|     |   |                 |         |         |   |  |                  |
|-----|---|-----------------|---------|---------|---|--|------------------|
|     | (BUSCOPRIME<br>-10 TABLETS)   |                 |         |         | Asgarpur Majra, Kala<br>Amb, Dist. Sirmour-<br>(H.P.) 173030  |  |                  |
| 49. | Ambroxol HCl,<br>Guaiphenesin,<br>Terbutaline<br>Sulphate and<br>Menthol Syrup<br>(BRONKOREX<br>AM Syrup) | BALS-2005       | 11/2023 | 10/2025 | Wings Novitas<br>Healthcare LLP,, 43<br>& 44, HPSIDC,<br>Industrial Area,<br>Baddi-173205 (H.P.)                        | Assay of<br>Ambroxol<br>Hydrochloride<br>and Terbutaline<br>Sulphate | RDTL, Chandigarh |
| 50. | Ramipril Tablets<br>IP 5 mg   | TPT-<br>0102040 | 10-2024 | 09-2026 | Tanpal<br>Pharmaceuticals, D-<br>12-13, Focal Point,<br>Nabha-147201  | Assay of<br>Ramipril   | RDTL, Chandigarh |
| 51. | Pyridoxine<br>Tablets IP 10<br>mg (Pyrotan-10)  | TPT-<br>0102064 | 10-2024 | 09-2026 | Tanpal<br>Pharmaceuticals, D-<br>12-13, Focal Point,<br>Nabha-147201  | Assay of<br>Pyridoxine   | RDTL, Chandigarh |
| 52. | Aceclofenac,<br>Paracetamol<br>and<br>Serratiopeptidas<br>e Tablets (ST-<br>SP Tablets)                   | NBT-<br>240624  | 11/2024 | 10/2026 | Soft Touch<br>Pharmaceuticals<br>India Lt., Plot No. 8,<br>Industrial Area,<br>Waknaghat, Distt.<br>Solan (H.P.)-173234 | Assay of<br>Aceclofenac<br>and<br>Paracetamol                        | RDTL, Chandigarh |

### Not of Standard Quality (NSQ) drugs:

The drugs that fail to meet the quality standards or specifications are known as Not of Standard Quality (NSQ) drugs.

(Further, the term 'standards of quality' is defined under the Section 16 (1) (a) of Drugs & Cosmetics Act, 1940, that the 'standards of quality' mean that the drug complies with the standards set out in the Second Schedule of the said Act.)