

**NOT OF STANDARD QUALITY ALERT FOR THE MONTH OF SEPTEMBER– 2024.**

<b>B. State 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.	Neurotem-NT	CPT-2698	Mar-24	Feb-26	Catasta Pharmaceuticals Plot No. 113, DIC, Industrial Area, Baddi Distt. Solan (H.P) Mrk. By : Cosway Biosciences Coporate Office : Khasra No. 2054/1724, 1725 SCO No. 11 Baddi Barotiwala Road The. Baddi Distt. Solan H.P 173205	The given Drug Sample does not comply to the contents of Assay with respect to Pregabalin ( 23.26% of claim)	Drug Testing Laboratory Srinagar (J&K) vide report on Form 13 bearing No. L/DA/2024- 25/1191 Dated: 05.09.2024. <b>(Report attached as Annexure A)</b>
2.	Cefuroxime Axetil Tablets IP 500 mg (JKMSCL Supply)	JAK-23	Jul-23	Jun-25	Agron Remedies Pvt Ltd Sarverkhera Moradabad Road Kashipur 244 713 (Uttarakhand)	The sample fails in the Description, Dissolution and Assay of Cefuroxime Axetil w.r.t the sample portion received as above	Combined Food & Drug Testing Laboratory Jammu (J&K) vide report on Form 13 bearing No. CFDL/J/2024-25/1120 Dated: 26.09.2024. <b>(Report attached as Annexure B)</b>
3.	Loperamide Hydrochloride Tablets IP (JKMSCL Hospital Supply)	T-16201	May-24	Apr-26	Karnani Pharmaceuticals Pvt. Ltd , 38 Pharma City , Selaqui Dehradun -248011	The sample does not conform to IP with respect to the test for Dissolution & Assay	Drug Testing Laboratory Srinagar (J&K) vide report on Form 13 bearing No. L/DA/2024-25/1311 Dated: 27.09.2024. <b>(Report attached as Annexure C)</b>

4.	Floxages-OZ (Ofloxacin and Ornidazole Tablets IP)	SPY41223	12/23	11/26	Suraksha Pharma pvt.Ltd, 410, Karondi, Roorkee-247 667, Uttarakhand	It fails the test 'Dissolution' as per IP	Drugs Testing Laboratory Thiruvananthapuram
5.	Wintel 40 Tablets	HTN257D	04/24	03/26	Himalaya Meditek pvt.Ltd, Plot No. 35 & 36, Pharmacy, Selaqui, Industrial Area, Dehradun - 248 197	It fails the test 'Dissolution' as per IP	Drugs Testing Laboratory Thiruvananthapuram
6.	Moxica -250 [Amoxicillin Dispersible Tablets IP 250 mg]	SD 243	08/23	07/25	Indica Pharmaceuticals (P) Ltd, Bapunagar, Ahmedabad- 382 345	It fails the test 'Disintegration' and 'Uniformity of Dispersion' specified in the Laboratory Protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram
7.	Frusamide Injection IP 20 mg	FRIB-03	01/24	12/25	Nestor Pharmaceuticals Ltd, 11, Western Extension Area, Faridabad -121001	It fails the test 'Sterility' as per IP	Drugs Testing Laboratory Thiruvananthapuram
8.	Cloxacillin Sodium Capsules IP 250 mg	CLCA-04	04/23	03/25	Nestor Pharmaceuticals Ltd, 11, Western Extension Area, Faridabad -121001	The sample does not conform to IP Standards with respect to 'Descriptive part' of hard gelatin capsules and further tests cannot be performed due to reasons secified in the laboratory protocol	Drugs Testing Laboratory Thiruvananthapuram
9.	Fluorometholone Eye Drops IP	CHE-3044	05/23	04/25	Cotec Healthcare pvt.Ltd, K.H.No.593/1, Roorkee, Dehradun Highway,	It fails the test 'Uniformity of Volume' and	Drugs Testing Laboratory Thiruvananthapuram

					Kishanpur, Roorkee- 247 667, UK	'Assay' as per IP	
10.	Panlib 40 Tablets	HTN 102A	01/24	12/25	Himalaya Meditek pvt.Ltd, Plot No. 35 & 36, Pharmacy, Selaqui, Industrial Area, Dehradun	It fails the test 'Dissolution' and 'Assay' as per IP	Drugs Testing Laboratory Thiruvananthapuram
11.	B - Cidal 625	UT232859	03/24	08/25	VADSP Pharmaceuticals, Plot No. 124, EPIP Indl.Area, Phase 1, Jharmajri, Baddi (HP)- 174103	The content of Clavulanic acid is not with in the limit of 'Schedule V' of Drugs and Cosmetics Act & Rules thereunder	Drugs Testing Laboratory Thiruvananthapuram
12.	Trypsin, Bromelain & Rutoside Trihydrate Tablets [Flavoshine]	TTF24065	06/24	11/25	Tiruvision Medcare, Plot No. 177, HPSIDC, Indl.Area, Baddi, Dist Solan HP 173 205	The sample fails the test 'Disintegration' specified in the Laboratory protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram
13.	C Mont LC Kid 60 ml (Montelukast & Leveocetirizine Dihydrochloride syrup)	AL 23206	11/23	10/25	Cian Healthcare Ltd, kh No.248, Village sisonia, Bhagwanpur, Roorkee, Haridwar, Uttarakhand- 247 661	The content of montelukast is not within the limits of Schedule 'V' of Drugs & Cosmetics Act & Rules	Drugs Testing Laboratory Thiruvananthapuram
14.	Yogaraja Guggulu Tablet	P 592324	10/23	09/26	Oushadhi, The Pharmaceutical corporation (IM) , Kerala Ltd, Kuttanellur, Thrissur- 68 0014	The sample does not conform to API Standards. It fails the tests 'Total Ash' as per API Standards.	Drugs Testing Laboratory Thiruvananthapuram

15.	Telmisartan Tab IP 40 mg	D1153/24-25			Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram-14	The sample does not conform to IP Standards with respect to 'Descriptive part' of tablets and further tests cannot be performed due to above reasons.	Drugs Testing Laboratory Thiruvananthapuram
16.	Pantoprazole Inj.BP 40 mg	D 0923/24-25			Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram-14	It fails the test 'Sterility' specified in the laboratory protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram
17.	Glimepiride Tab IP	D1272/24-25			Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram-14	The sample fails the descriptive part for tablets as they are not sufficiently hard to withstand handling without crumbling or breaking and further tests cannot be performed due to above reason	Drugs Testing Laboratory Thiruvananthapuram
18.	Cough Syrup	D 1278/24-25			Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram-14	The sample fails the 'Descriptive part' for oral dosage forms of Schedule V of drugs and cosmetics Act and Rules, as	Drugs Testing Laboratory Thiruvananthapuram

						the syrup contains red coloured suspended particles	
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NOTE:

1. NSQ data was not received as per Format & in EXCEL SHEET from State Drugs Licensing Authorities of Karnataka (PDF format), Thiruvanthapuram (Excel format), and Jammu Kashmir (Excel Format) for the Month of August, 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, Rajasthan, 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 August, 2024 as per DCG(I) Circular dated 09.02.2024.