

NOT OF STANDARD QUALITY ALERT FOR THE MONTH OF MAY – 2024

B. STATE LABORATORIES							
S.No	Name of Drugs/medical device/cosmetics	Batch No.	Date of Manufacture	Date of Expiry	Manufactured By	NSQ Result	Reported by CDSCO Laboratory
1.	Cyra Tablets, Rabeprazole Sodium Tablets IP	CA21868	07/2023.	06/2025.	Mfg By: Mepro Pharmaceuticals Pvt.Ltd, Unit-II, Q Road, Phase - IV, G.I.D.C. Wadhwan - 363035, Dist. Surendranagar, Gujrat.	NOT OF STANDARD QUALITY The tablets does not complies in buffer stage for the dissolution test parameter, hence it is NOT OF STANDARD QUALITY.	State Lab Drugs Control Laboratory, Telangana.
2.	Rabedin tablet Tablets, Rabeprazole Sodium Gastro-Resistant Tabelts IP,	LV23HT-034B	08/2023.	01/2025.	Mfg By: LV life Sciences VPO Gurumajra, BaddiDistt. Solan(H.P)-174101. Himachal Pradesh. Mrkt: Odin Healthcare Pvt.Ltd, Plot No. 1, Industrial Area, ChambaghatSolan, H.P. - 173 213.	NOT OF STANDARD QUALITY The sample does not meet the acid stage acceptance criteria as per IP specifications, hence it is declared as NOT OF STANDARD QUALITY.	State Lab Drugs Control Laboratory, Telangana.
3.	Moxtas Distab 250 Tablets, Amoxicillin trihydrate dispersible tablets IP.	MALT-2019	10/2023.	09/2025.	Mfg By: Wings Novitas Healthcare LLP 43 & 44, HPSIDC, Industrial area, Baddi - 173 205. (H.P). Himachal Pradesh.	NOT OF STANDARD QUALITY Tablets are with uneven surface and are crumbling while taking out of the strip. Hence failed with respect to the test Description of Tablets.	State Lab Drugs Control Laboratory, Telangana.
4.	Tolcenta-P Tablets,	ZT22806	12/2022.	11/2024.	Mfg By: Zenomed Health Care Pvt.Ltd. (ISO &	NOT OF STANDARD QUALITY	State Lab Drugs Control

	Tolperisone Hydrochloride and Paracetamol tablets,				GMP) Certified NO. 70-73, First Cross, Rainbow Nagar, Vazthuthavuran Pattai, Navamkapper, Villupuram (Dt), Tamil Nadu - 605102 Tamil nadu. Mrkt: Elinova Pharma Pvt.Ltd, D.No. 5-74/301, Panchavati Colony, Hyderabad, Telangana.	1. While Opening the strip, the tablets are sticky in nature and adhering to the foil, hence the sample does not complies with respect to description. 2. The assay content of Tolperisone Hydrochloride is not within the prescribed limit, hence the sample does not complies as per manufacturing method of analysis.	Laboratory, Telangana.
5.	Nagris Pakeezah Art Henna (3 Henna Cones)	-	Nil	Nil	Mfg By: Nagris Herbs, LN Nagar, Jiyaguda, Hyderabad.	NOT OF STANDARD QUALITY A. The sample does not conform to the test for determination of absence of Picramic Acid as per BIS standard IS 17318:2020 as required as per rule 39 (Standard of Cosmetics) 2020. B. As the cautions do not use for colouring eyelashes or eyebrows. Do not use on cut, Irritated or abranded skin as per Bis Standard IS 17318: 2020 is not mentioned on the label of the cosmetic sample. Hence, the sample not labeled in the prescribed manner and deemed to be Misbranded Cosmetics as	State Lab Drugs Control Laboratory, Telangana.

						per Section 17Cof Drugs and Cosmetics ACT, 1940.	
6.	Oxifer-XT Tablets, Ferrous ascorbate elemental iron, Folic acid & Zinc sulphate Tablets,	EOX 2306	12/2023.	05/2025.	Mfg By: Eminent Remedies Plot No. 9/1/A, Road, NO.14 Near Telangana Foods IDA, Nacharam, Hyderabad - 500076 (TS), Telangana. Mrkt: Organic Pharma, H.No. 7-67/G3, Hyderabad.	NOT OF STANDARD QUALITY Sample does not meets the Specifications wrt Assay of elemental Iron (Ferrous Ascorbate).	State Lab Drugs Control Laboratory, Telangana.
7.	Levolets- M Kid Syrups, Montelukast Sodium & Levocetizine Dihydrochloride syrup	RC24BL-521	02/2024.	01/2026.	Mfg By: Rikencare Life sciences villmessaTibba, Pharmaceuticals O Manjholi, Tehsil-Nalagarh, DistSolan, HP-174101 Himachal Pradesh. Mrkt: Manvi Life Sciences, 1-1-289, Ashoknagar, Hyderabad - 500020.	NOT OF STANDARD QUALITY Sample does not comply Description of syrup and Assay of Montelukast.	State Lab Drugs Control Laboratory, Telangana.
8.	Meazon Plus injection Parenteral Preparations, Mecobalamine, Folic acid & Niacianamideinj 1 ml,	23MP07	10/2023.	09/2025.	Mfg By: Sai parentrals limited D1&D4, Survey No. 280, Phase-V Hyderabad - 500 055 Telangana.	NOT OF STANDARD QUALITY Sample does not comply Assay of Folic Acid.	State Lab Drugs Control Laboratory, Telangana.
9.	XERONAC-SP Tablets, Aceclofenac, Paracetamol &	RP-T243/C	12/2023.	11/2025.	Mfg By: Roma Pharma Pvt.Ltd, Unit-II, Village Nagali, P.O. Barog, Tehsil &Distt. Solan, (H.P) - 173 211,	MISBRANDED The label of the drug does not indicate the comon name of the colour used as requied as per Rule 127(2)	State Lab Drugs Control Laboratory, Telangana.

	Serratiopeptidase Tablets				Himachal Pradesh. Mrkt: Fornax Pharmaceuticals, No. 6-Anew no. 17, 2nd Floor, VOC Colony, 3rd Street, Amijikrai, Chennai - 600029. TN.	of Drugs Rules, 1945. Label only bears the words Approved colored used. Hence the drug is not labelled in the prescribed manner and is deemed to be Misbranded drug as per section 17(c) of the Drugs and Cosmetics Act 1940.	
10	Pedxim-200 Tablets, Cefpodoximeproxetil Tablets 200 mg,	TBL-2676	04/2023.	03/2025.	Mfg By: Ticomapharmaciae-17 Focal Pont, Derabassi-140507, Distt. Mohali (Punjab) Punjab.	MISBRANDED The product name (title) indicated on the label is as CefpodoximeProxetil Tablets 200 mg instead of CefpodoximeProxetil Dispersible Tablets 200 mg. The label of the product does not state that the tablets should be dispersed in water immediately before use. Hence the product is not labeled in the prescribed manner and is deemed to be Misbranded drug as per section 17(c) of Drugs and Cosmetics Act.	State Lab Drugs Control Laboratory, Telangana.
11	DofloxOZT Tablets, Ofloxacin&Ornidazole Tablets	DDX2301	06/2023.	05/2026.	MfgBy: Doctor's Vet-Pharma Pvt.Ltd, P.R. Palem (V), Kovur(M), SPSR Nellore Dist. Andhra Pradesh. Mrkt: Doctor's Life Sciences (India) Ltd, Survey NO. 263/1, 264/1, P.R. Palem (V),	MISBRANDED The drug product Ofloxacin and Ornidazole Tablets is official in Indian Pharmacopoeia. But the letters IP is not mentioned on the strip after the product name Ofloxacin and Ornidazole Tablets.	State Lab Drugs Control Laboratory, Telangana.

					Kovur (M), SPSR Nellore Dist - 524 137, A.P. India.	Hence it is Misbranded Drugs under Section 17(c) of drugs and cosmetics act.	
12	Disinfectants, Surgical Spirit BP	SS- 053011	05/2023.	04/2025.	Mfg By: Transflexjawaharnagar, Raipur, (C.G)- 492001, Chhattisgarh.	MISBRANDED As per rule R.124 the drug is included in the current edition of Indian Pharmacopoeia 2022. Hence standards shall be of those as specified in Indian Pharmacopoeia 2022. But the subject drug Surgical spirit bears the letters B.P after the drug name instead of IP. As per rule 96 and 104 as the drug shall be in accordance with standards set out in Indian Pharmacopoeia, the name of the drug surgical spirit shall be followed by the letters IP. As the subject drug is not confirming to the said labelling requirements the drug shall be deemed to be Misbranded as per section 17.	State Lab Drugs Control Laboratory, Telangana.
13	Sif Alben Suspension, Albendazole Oral Suspension 2.5% w/v (Vet)	AL80012 3	05/2023.	04/2025.	Mfg By: Siflon Drugs & Pharmaceuticals Pvt.Ltd., Plot no. 20&21, Aleap IE, Gajularamaram (V), Hyderabad - 55 Telanga.	MISBRANDED The given sample Albendazole oral suspension is official included in the IP and required as per schedule of the Drugs and Cosmetics	State Lab Drugs Control Laboratory, Telangana.

						<p>Act 1940. The given sample shall comply with the standards set out in IP but, the designation IP is conjunction with the official title Albendazoleoral suspension on label of the drug product was not mentioned as indication that the drug product purports to comply with IP standards. Hence the Drug product shall be deemed to be Misbranded drug as per section 17 of Drugs and Cosmetics Act.</p>	
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Based on the data received from respective state laboratories.

1. NSQ data was not received as per Format & in EXCEL SHEET from State Drugs Licensing Authorities of Jharkhand, Jammu & Kashmir (MD and ED not appropriate), Kerala (Expiry date not specified). for the Month of May, 2024 as per DCG(I) Circular dated 09.02.2024.
2. Sate Drugs Licensing Authorities of Goa have stated that the NSQ data as “NIL” for the Month of May, 2024.
3. State Drugs Licensing Authorities of Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Gujarat, Haryana, Himachal Pradesh, Maharashtra, Manipur, Meghalaya, Mizoram, Nagaland, Odisha, Punjab, Rajasthan, Sikkim, Tamil Nadu, 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 May, 2024 as per DCG(I) Circular dated 09.02.2024.