

NOT OF STANDARD QUALITY ALERT FOR THE MONTH OF OCTOBER- 2024.

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. State Laboratories							
S.No	Product/Drug Name	Batch No.	Manufact uring Date	Expiry Date	Manufactured By	NSQ Result	Reported by CDSCO Laboratory
1.	Fer-XT Tablets, Ferrous Ascorbate & Folic Acid Tablets	FXT.2309	09-2023.	02-2025.	M/s. Alfansa Bio Pvt.Ltd #5-5-35/23, 2nd Floor, Murthy Building, Prasanth Nagar, Hyderabad-500072 Telangana	NOT OF STANDARD QUALITY & MISBRANDED The drug product ferrous Ascorbate and Folic Acid Tables is official in Indian Pharamacopoeia 2022. But the letters IP is not mentioned on the strip after the product name Ferrous Ascorbate and Folic Acid tablets. Hence it is a Misbranded Drug under section 17 of Drugs and Cosmetics Act 1940. So the drug product Ferrous Ascorbate & Folic Acid Tablets is Not of Standard Quality and Misbranded.	State Lab, Drugs Control Laboratory, Telangana.
2.	Zyfer-XT Tablets, Ferrous Ascorbate, Folic Acid Tablets	WW-2405	05-2024.	10-2025.	M/s. Hindustan Nutraceuticals INC Plot No.14, Sai Nagar, Boduppall, Hyderabad-039 Telangana	NOT OF STANDARD QUALITY Sample Does not meets the Specifications wrt. Assay of Folic Acid as per STP.	State Lab, Drugs Control Laboratory, Telangana.
3.	Tablets, Cefixime Tablets IP 400 mg	CTTB-01	06-2024.	05-2026.	M/s. Nestor Pharmaceuticals Limited 11, Wetern Extension area, Faridabad-121 001, India HARYANA	NOT OF STANDARD QUALITY Tablets does not complies in respect of Description.	State Lab, Drugs Control Laboratory, Telangana.

4.	Cefem -200 Tablets, Cefixime with Lactic Acid Bacillus tablets	DB240126	2024-04	2026-03	Daxin Pharmaceuticals Pvt Ltd., Plot No. 121-122 EPIP, Jharmajri Phase 1, The. Baddi, Distt. Solan (H.P.) - 174 103 HIMACHAL PRADESH	NOT OF STANDARD QUALITY 1. Thirteen Individual weights deviated from the average weight 636.0 mg i.e 6 tablets deviated by less than 5 percent and 7 tablets deviated by more than 5 percent . Hence the sample does not complies the test Uniformity of weight. 2. Assay of Cefixime does not complies. Hence the sample is of NOT OF STANDARD QUALITY	State Lab, Drugs Control Laboratory, Telangana.
5.	Myoplus Tablets, Paracetamol & Chlorzoxazone Tablettes	MT24-1	04-2024.	03-2026.	M/s. LEOSTAR Healthcare Pvt.Ltd Plot no.10, Biotech Park, Phase-III, Genome Valley, Karkapatla, Telangana-502281 Telangana	NOT OF STANDARD QUALITY 18 Tablets were tested. All the 18 tablets did not Disintigrate within the time limit (i.e 15 Minutes) specified as per IP.	State Lab, Drugs Control Laboratory, Telangana.
6.	VRIZAROX-100DT Tablets Cefpodoxime Proxetil Dispersible Tablets	CABQ4001	01-2024.	12-2025,	Chiros Pharma Vill: Loharon , P.O.: Ghatti, Solan-173211(H.P) HIMACHAL PRADESH	MISBRANDED The monograph of Cefpodoxime Tablets in the current edition of Indian Pharamacopoeia i.e. IP-2022. is also applicable for Cefpodoxime Dispersible Tablets as indicated under labelling section of the monograph. However the firm failed to indicate the latters IP after the product name CefpodoximeDispersible Tablets. Hence, the drug is deemed to be Misbranded as per section 17 of the Drugs and Cosmetics Act, 1940, since it is not labeled in the prescribed mannar.	State Lab, Drugs Control Laboratory, Telangana.
7.	Dulhan Special	Nil	Nil	Nil	Mohsin Idustries,	MISBRANDED	State Lab, Drugs Control

	Kharachi Mehandi Cone				Hyderabad Telangana State	Misbranded: As the Cautions 'DO NOT USE FOR COLOURING EYELASHES OR EYEBROWS. DO NOT USE ON CUT, IRRITATED OR ABRADED SKIN' as per BIS standard IS 17318:2020 is not mentioned on the label of the cosmetic sample.	Laboratory, Telangana.
8.	Tablets, Divalproex Sodium SR Tablets 500 mg	TMT-0211	06-2024	05-2026	Tas Med (Indi) Pvt. Ltd., Plot No. -8, Phase IV. Industrial Area HIMUDA, Bhatoli Kalan, Baddi, Distt. Solan (H.P.) 173205 HIMACHAL PRADESH	MISBRANDED The drug product Divalproex Sodium SR Tablets is official in the current edition of IP 2022. and as required as per second schedule of the Drugs and cosmetics Act, 1940, the said drug product shall comply with the standards set out in the Indian Pharmacopoeia. But the designation IP in conjunction with the official title Divalproex Sodium SR Tablets on the label of the drug product was not mentioned as an 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 the drug and Cosmetics Act 1940 as it not labeled in the prescribed manner	State Lab, Drugs Control Laboratory, Telangana.
9.	Divalproex Sodium SR Tablets	TMT-0165	06-2024.	05-2024.	M/s. Tas Med (India) Pvt.ltd. Plot No. phase IV, Industrial Area Himuda, Bhatoli Kalan, Baddi Distt, solan (H.P) 173205.	MISBRANDED The drug product Divalproex Sodium SR Tablets is official in the current edition of IP 2022. and as required as per second schedule of the Drugs and cosmetics Act, 1940, the said drug product shall comply with the standards set out in the	State Lab, Drugs Control Laboratory, Telangana.

						Indian Pharmacopoeia. But the designation IP in conjunctin with the official title Divalproex Sodium SR Tablets on the label of the drug product was not mentioned as an indication that the drug product purports to comply with IP standrds. Hence the drug product shall be deemed to be MISBRANDED DRUG as per Section 17 of the drug and Cosmetics Act 1940 as it not labeled in the prescribed manner	
10.	Divalproex Sodium SR Tablets 500 mg	TMT-0164	06-2024.	05-2024.	M/s. Tas Med (India) Pvt.ltd. Plot No. phase IV, Industriael Area Himuda, Bhatoli Kalan, Baddi Distt, solan (H.P) 173205.	MISBRANDED The drug product Divalproex Sodium SR Tablets is official in the currect edition of IP 2022. and as required as per second schedule of the Drugs and cosmetics Act, 1940, the said drug product shall comply with the standards set out in the Indian Pharmacopoeia. But the designation IP in conjunctin with the official title Divalproex Sodium SR Tablets on the label of the drug product was not mentioned as an indication that the drug product purports to comply with IP standrds. Hence the drug product shall be deemed to be MISBRANDED DRUG as per Section 17 of the drug and Cosmetics Act 1940 as it not labeled in the prescribed manner	State Lab, Drugs Control Laboratory, Telangana.
11.	CYPROHEPTADINE HCl & TRICHOLINE CITRATE	WHL-00623	02-2024	01-2026	M/s. Warner Hindusthan Pvt Ltd., 24-85/7, Sy. No. 548 & 551,	The label of the container in the drug is mentioned as 'Approved colour used' but the common name of the	State lab (Puducherry)

	SYRUP (Cyproan Syrup)				Laxmi Narayana Nagar Colony, New IDA, Uppal, Hyderabad-39 (T.S)	permitted colour used in the formulation as prescribed under rule 127 (2) of the drug rule was not mentioned.- MISBRANDED	
12.	BETAHISTINE DIHYDROCHLORIDE TABLETS IP(CGHEST-8)	CT2425028 4B	03-2024	04-2026	M/s CMG BIOTECH PVT LTD.,(Unit-II), Plot No.58,Phase III , Industrial Area,Sansarpur Terrace,Tehsil Jaswan, Distt. Kangra, Himachal Pradesh-176501	On the received sample presence of spots were observed which should not be present As per DCC Guidelines on Not Of Standard Quality (NSQ) Drugs Approved in 1993 (Annexure A) Tablets vide serial No.(i) Presence of Spot/discolouration- NSQ	State lab (Puducherry)
13.	Vitamin B Complex Tablets N.F.I	VBT2442	04-2024	03-2026	Modern Laboratories, 45-47, Sector D-2, Industrial Area, Sanwer Road, Indore (M.P.)-452015	Description	State Drugs Testing Laboratory, Agartala, Tripura.
14.	Vitamin B Complex Tablets N.F.I	VBT2498	06-2024	05-2026	Modern Laboratories, 45-47, Sector D-2, Industrial Area, Sanwer Road, Indore (M.P.)-452015	Description	State Drugs Testing Laboratory, Agartala, Tripura.
15.	Itraconazole Capsules USP 100 mg	IZC2401	04-2024	03-2026	Modern Laboratories, 45-47, Sector D-2, Industrial Area, Sanwer Road, Indore (M.P.)-452015	Dissolution	State Drugs Testing Laboratory, Agartala, Tripura.
16.	Itraconazole Capsules USP 100 mg	IZC2401	04-2024	03-2026	Modern Laboratories, 45-47, Sector D-2, Industrial Area, Sanwer Road, Indore (M.P.)-452015	Dissolution	State Drugs Testing Laboratory, Agartala, Tripura.
17.	cefexime Dispersible Tablets IP 100mg	CT240783	07-2024	06-2026	Theon Pharmaceuticals LTD, Vill. Saini Majra, Tehsil Nalagarh, Distt. Solan (H.P) 174101.	Assay & Disintegration	State Drugs Testing Laboratory, Agartala, Tripura.

18.	Biocetamol -500	SPD230078	03-2023	02-2025	Mfg. By : Skymap Pharmaceuticals Pvt. Ltd . Khasra No. 63 Village Juddi Kalan , Baddi , Distt. Solan (HP) Mrk. By : German Remedies Pharmaceuticals Pvt. Ltd. PF 61 & 62 , Sanad II Industrial Estate , Tal : Sanand Ahmedabad , Gujarat- 382110, India	The sample does not conform to the IP requirements with respect to the test, Dissolution.	Drug Testing Laboratory Srinagar (J&K) vide report on Form 13 bearing No. L/DA/2024-25/1593 Dated: 29.10.2024. (Report attached as Annexure A)
19.	Torseamide Tablets IP (Torverge-10 Tablets)	GT7137A	03-2023	02-2025	J.M. Laboratories Village Bhanat P.O. Ghatti Subathu Road Solan (H.P.) 173211	Assay of Torseamide (86.85%)	RDTL Chandigarh
20.	(COUGH-DM Cough Syrup)	SHL3037	11-2023	10-2025	Sunfine Healthcare, Plot no. 63, Ind. Area, Lodhimajra, Tehsil Baddi, Distt. Solan HP	Assay of Phenylephrine Hydrochloride	RDTL Chandigarh
21.	Paracetamol Tablets IP 650 mg [Nopain-650]	URDT2433	10-2023	09-2026	Unicare India Ltd., Plot No. 46(B)/49B Village Raipur, Bhagwanpur ,Roorkee Dist, Haridwar, 247661 Uttarakhand	It fails the test 'Dissolution' Specified in the Laboratory Protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram
22.	Theophylline & Etophylline Tablets	TE4029	04-2024	03-2027	Kerala State Drugs & Pharmaceuticals Ltd, Kalavoor.P.O, Alappuzha	It fails the test 'Disintegration' Specified in the Laboratory Protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram
23.	Montelukast Tablets IP 10 mg	F4E0425	05-2024	04-2026	Morepan Laboratories Ltd, Unit-V, Plot No. 12C, sector-2,	It fails the test 'Dissolution' Specified in the Laboratory Protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram

					Parwanoo, Dist.Solan (HP)- 173 220		
24.	Panlib -D [Pantoprazole and Domeperidone Tablets]	HTN253D	04-2024	03-2026	Himalaya Meditek pvt.Ltd, Plot No. 35 & 36, Pharmacy, Selaqui Industrial Area, Dehradun 248 197	It fails the test 'Disintegration' as per IP and the contents of active ingredients of Pantoprazole and Domeperidone are not with in the limits of 'Schedule V' of Drugs and Cosmetics Act & Rules thereunder as specified in the Laboratory Protocol	Drugs Testing Laboratory Thiruvananthapuram
25.	C Mont LC KID 60 ml[Montelukast and Levocetirizine Dihydrochloride syrup 60 ml]	AL 23206	11-2023	10-2025	Cian Healthcare Ltd, (An ISO 9001: 2015 &WHO GMP certified Co) Kh No. 248, village sisona, Bhagwanpur, Roorkee, Haridwar, Uttarakhand – 247661	The content of Montelukast sodium is not with in the limits of 'Schedule V' of Drugs and Cosmetics Act & Rules thereunder as specified in the Laboratory Protocol	Drugs Testing Laboratory Thiruvananthapuram
26.	Montelukast Sodium and Levocetirizine Hydrochloride Tablets IP 10 mg/5 mg	MLHT-1022	09-2023	08-2026	Wings Biotech LLP, 43&44, HPSIDC, Ind.Area, Baddi-173205 HP	It fails the test 'Dissolution' Specified in the Laboratory Protocol as per IP	Drugs Testing Laboratory Thiruvananthapuram
27.	EMITIL [Prochlorperazine Mesylate Injection IP]	MA 24E27	05-2024	04-2026	Martin & Brown Bio Science Pvt Ltd, K No. 918/419, Malkumajra, Nalgrath Road, Baddi, Dist Solan HP 173 205	It fails the test 'pH' as per IP as specified in the Laboratory Protocol	Drugs Testing Laboratory Thiruvananthapuram
28.	International dona Beauty Soap Jasmine	DNJN1/24	01-2024	use befoe 36 months from packed	Excel+ Health care products, CP- V/1092, XL Garden Palachira (P.O), Varkala, PIN – 695	The sample does not conform to IS 2888:2004 for the test 'matter insoluble in alcohol , percent by Mass, Max ' as per the	Drugs Testing Laboratory Thiruvananthapuram

					143	specifications of toilet soap for Grade III	
29.	Elcipro 500[Ciprofloxacin Hydrochloride Tab IP 500 mg]	AGT31256	12-2023	11-2026	Alventa Pharma Ltd, Vill, Krishnapura, Baddi, Nalagarh Road, Tehsil Baddi, Distt. Solan, HP 174 101	It fails the test 'Dissolution' as per IP as specified in the Laboratory Protocol	Drugs Testing Laboratory Thiruvananthapuram
30.	Vitamin B Complex Tablet	S0010/24-25			Supplied by Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram -14	The sample does not conform to IP Standards with respect to 'Descriptive part' for tablets	Drugs Testing Laboratory Thiruvananthapuram
31.	Vitamin B Complex Tablet	S0008/24-25			Supplied by Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram -14	The sample does not conform to IP Standards with respect to 'Descriptive part' for tablets	Drugs Testing Laboratory Thiruvananthapuram
32.	Vitamin B Complex Tablet	S0009/24-25			Supplied by Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram -14	The sample does not conform to IP Standards with respect to 'Descriptive part' for tablets	Drugs Testing Laboratory Thiruvananthapuram
33.	Trenaxa Inj. [Tranexamic Acid injection I.P]	TNA2407	03-2024	02-2026	Sanjivani Paranteral Ltd, R-40, T.T.C, Industrial Area, Rabale, Thane, Belapur Road, Navi Mumbai -400701	It fails the test Sterility as per IP	Drugs Testing Laboratory Thiruvananthapuram
34.	Telmisartan Tab IP 40 mg	S0007/24-25			Supplied by Kerala Medical Services Corporation Ltd, Thycaud P.O, Thiruvananthapuram -14	It fails the test 'Dissolution' as per IP	Drugs Testing Laboratory Thiruvananthapuram

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.)

NOTE:

1. NSQ data was received as per Format & in EXCEL SHEET from State Drugs Licensing Authorities of Himachal Pradesh ,Jammu Kashmir, Puducherry, Telangana,Kerala, Tripura , Goa(PDF format Nil), Jharkhand (PDF Format) , Karnataka (PDF Format), Ladakh (PDF format Nil), Maharashtra (PDF format), Rajasthan (PDF format), for the Month of October, 2024 as per DCG(I) Circular dated 09.02.2024.
2. State Drugs Licensing Authorities of Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Gujarat, Haryana, Manipur, Meghalaya, Mizoram, Nagaland, Odisha, Punjab, Sikkim, Tamil Nadu, 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 October, 2024 as per DCG(I) Circular dated 09.02.2024.