

## Press Note

Drug Control Administration, Telangana, detected several substandard drugs circulating in the State.

DCA adopted a **risk-based sampling** approach. DCA issued directions to all field officers, i.e., Drug Inspectors, outlining the risk indicators to be considered for collecting samples from the supply chain and manufacturing facilities, which significantly increased the detection of substandard drugs circulating in the market.

Drugs Control Laboratory, Hyderabad reported **93 Not of Standard Quality (substandard) drugs** from January to August 2024.

In **September-2024**, the Drug Control Laboratory reported **14 Not of Standard Quality (substandard) drugs.**

The drugs declared as Not of Standard Quality in September included antibiotics, antiulcer drugs, anti-allergics, haematinics, etc. The samples failed in the tests for assay, dissolution, and description, which may render the medicines ineffective in treating diseases.

The **details of the drugs declared as Not of Standard Quality (NSQ) or substandard** by the Drug Control Laboratory in Hyderabad in **September-2024** are listed as follows:

Sl. No.	Product/Drug Name	Batch No.	Manufacturing Date	Expiry Date	Manufactured by /Marketed by	Not of Standard Quality - Details
1	Pantlar Tablets, Pantoprazole GastroResistant Tablets I.P.	PTR230601	02/2024	01/2026	<b>Manufactured by:</b> Cartel Laboratories Plot No. 10/A & 11/A, Chengicherla, Medchal - Malkajgiri Dist. – 92, Telangana. <b>Marketed by:</b> Medler Pharma, Reg. Off: Plot No. 4-12-1068/6, S.S. Nagar, VNSP, RR Dist. Telangana-500 070.	<b>NOT OF STANDARD QUALITY – Dissolution</b>  In acid stage out of 24 tablets tested, 18 tablets are not in intact condition in Acid media. Hence dissolution does not complies in acid media as per IP specifications.
2	Parasyp 250 Suspension, Paracetamol Paediatric Oral Suspension IP 250 mg	PGAC08	02/2023	01/2025	<b>Manufactured by:</b> Akums Drugs and Pharmaceuticals Ltd Plot No. 22, Sector-6A, IIE Sidcul, Ranipur, Haridwar - 249403, Uttarakhand UTTARAKHAND. <b>Marketed by:</b> Auspharma Pvt.Ltd., 10-3-316/A/2, Masabtank, Hyderabad - 500 028. Telangana.	<b>NOT OF STANDARD QUALITY – Assay and Description</b>  Sample failed with respect to the test Assay for Paracetamol as per IP and also failed with respect to the description for oral suspensions. Pink-coloured suspension with cake formation sedimentation observed in the sample bottle and cannot be re-dispersed by shaking.

3	FERRVIS-XT Tablets, Ferrous Ascorbate Folic Acid & Zinc Tablets	RFS-2368	01/2024	12/2025	<p><b>Manufactured by:</b> M/s. Ridge Formulations Private Ltd, Near Govt Middle School, Subathu road Vill: Saproon, Dist: Solan - 173 2011(H.P). Himachal Pradesh</p> <p><b>Marketed by:</b> M/s. Sanvis Life Sciences, Hyderabad - 500017.</p>	<p><b>NOT OF STANDARD QUALITY - Description</b></p> <p>1. Out of 20 tablets received, dark spots observed on 9 tablets. Hence description does not Complies.</p> <p>2. In the composition the label should be mentioned as Ferrous Ascorbate equivalent ot Elemental Iron but the label mentioned only as Ferrous Ascorbate 100 mg, equivalent to elemental Iron. The drug is not labelled in the prescribed manner, hence the drug is Misbranded as per Section 17 of Drugs and Cosmetics Act 1940.</p>
4	Dixim -O Dry Syrup Suspension, Cefixime & Ofloxacin for Oral Suspension	D240015F	01/2024	12/2025	<p><b>Manufactured by:</b> Polestar Power Industries Vill. Damuwala, Haripur Road, Barotiwala, Baddi, Distt(H.P). - 174 103 Himachal Pradesh.</p> <p><b>Marketed by:</b> DM Pharma Village Maloya, Chandigarh - 160039.</p>	<p><b>NOT OF STANDARD QUALITY – Assay of Ofloxacin</b></p> <p>Sample does not meet the Specifications with respect to. Assay of Ofloxacin.</p>

5	Pepsain Syrups, Pepsain Digestive Enzyme Syrup	DBB-442	02/2024	07/2025	<b>Manufactured by:</b> M/s. Sain Medicaments Pvt.Ltd, P-2/4, IDA Uppal, Hyderabad - 39. Telangana.	<b>NOT OF STANDARD QUALITY - Assay of Fungal Diastase</b>  The Assay of fungal diastase does not complies as per IP.
6	Cefixime Dispersible tablets	KLH-1199	10/2023	09/2025	<b>Manufactured by:</b> Park Pharmaceuticals Vill: Kalujhanda, Near Nanakpur, Tesh. Baddi, Dist. Solan (H.P) 174 103 Himachal Pradesh. <b>Marketed by:</b> Knoll Health care Pvt. Ltd, Pharma Tower, Badli Industrial area, New Delhi - 110042 .	<b>NOT OF STANDARD QUALITY - Assay of Cefixime</b>  1. The Assay of Cefixime does not complies as per IP specifications, hence it is of Not Of Standard Quality.  2. The drug product Cefixime Dispersible tablets is official in Indian Pharmacopoeia 2022. But the letter IP is not mentioned on the strip after the prodect name Cefixime dispersible tablets. Hence it is a Misbranded Drug under section 17 of Drugs And Cosmetics ACT 1940.

7	Cefx-O-200 Tablets, Cefixime Dispersible Tablets IP	DB240047	02/2024	01/2026	<b>Manufactured by:</b> Daxin Pharmaceuticals Pvt.Ltd., Plot No. 121-122EPIP Plot No. 121-122EPIP, Jhamajri Phase-I Tech, Baddi, Distt. Solan(H.PO) - 174 103 Himachal Pradesh.	<b>NOT OF STANDARD QUALITY – Cefixime</b>  Assay of Cefixime does not complies as per IP specification.
8	Cefxi-200 Tablets, Cefixime Dispersible Tablets I.P. 200 mg	DB230143	06/2023	05/2025	<b>Manufactured by:</b> Daxin Pharmaceuticals Pvt.Ltd, Plot NO. 121-122 EPIP, Jharmajri, Phase-1, The. Baddi, Distt. Solan (H.P) - 174103 Himachal Pradesh. <b>Marketed by:</b> Medley Pharmaceuticals Ltd, Regd. Office: Medley House, D2, MIDC Area, Andheri (East) Mumbai - 400 093.	<b>NOT OF STANDARD QUALITY - Assay of Cefixime</b>  Assay of Cefixime is not within the specified limits as per IP specification, hence it is of <b>Not of Standard Quality.</b>

9	PAZO-40 Tablets, Pantoprazole Gastro-Resistant Tab I.P. 40 mg	GTE0230E	01/2024	12/2025	<p><b>Manufactured by:</b> Digital Vision 176, Mauza Ogli, Nahanroad, Kala- Amb, Distt. Sirour-173 030 Himachal Pradesh.</p> <p><b>Marketed by:</b> Mabo Pharmacls, New NO. 2, 1st Floor, Sowrastranagar, Choolaimedu High Road, Chennai - 600 094.</p>	<p><b>NOT OF STANDARD QUALITY - Dissolution</b></p> <p>The tablets does not complies Dissolution test in buffer stage, hence dissolution does not complies as per IP specifications.</p>
10	Nimpan-40 Tablets, Pantoprazole Tablets IP	NMPN- 2401	01/2024	12/2025	<p><b>Manufactured by:</b> M/s. Konis Pharmaceuticals Pvt.Ltd, Jagriti Sadan, Subathu Road, Solan - 173 212 Himachal Prasesh.</p> <p><b>Marketed by:</b> M/s. Nimbel Pharmaceuticals, Hyderabad.</p>	<p><b>NOT OF STANDARD QUALITY – Dissolution</b></p> <p>The tablets does not complies Dissolution test in buffer stage, hence the samples is <b>Not Of Standard Quality</b> per IP specifications.</p>

11	Zinfe-SR Capsules, Sustained Release Haematinic & Zinc Capsules with Vitamins	FZCK-117	09/2023	02/2025	<p><b>Manufactured by:</b> Ruby Organics Pvt.Ltd, D-79, T.T.C M.I.C. Turbhe, Navi Mumbai - 400 705. Maharashtra.</p> <p><b>Marketed by:</b> Karnataka Anitibiotics &amp; Pharmaceuticals Limited, (A Govt. of India Interprise), No. 37, Site NO. 34/4, NTTF Main Road, 2nd Phase, Peenya Industrial Area, Bengaluru - 560058.</p>	<p><b>NOT OF STANDARD QUALITY - Description</b></p> <p>Red colour cap and white colour body, inside white, pink, yellow, brick brown colored pellets. While opening the capsules the pellets are sticky in nature and cake or lump formation of the pellets is observed in the capsule. Hence Description does not complies.</p>
12	Rovipod-100 Tablets, Cefpodoxime Dispersible Tablets	TB23-0499B	10/2023	09/2025	<p><b>Manufactured by:</b> Athens Life Sciences Mauzarampur Jattan, Nahan Road, Kala amb, Distt. Simour, H.P. - 173030 Himachal Pradesh.</p>	<p><b>NOT OF STANDARD QUALITY - Description</b></p> <p>Sample does not complies in respect of <b>DESCRIPTION</b>.</p>

13	Vertin 8 mg Tablets, Betahistine tablets IP	RBIA23009	09/2023	08/2026	<b>Manufactured by:</b> Abbott India Limited Village Bhatauli Khurd, Po Badi, 173 205 Solan, Dist. Himachal Pradesh,	<b>NOT OF STANDARD QUALITY – Description</b>  Sample does not complies in respect of <b>DESCRIPTION</b> .
14	TRIZENE Tablets, Levocetirizine Dihydrochloride Tablets IP	T24-007	01/2024	12/2025	<b>Manufactured by:</b> Oaksun Lifesciences Plot No. NO. 36, 37, 38, 46 & 47, Chengicherla (V), Meidipally (M), Medchal - Malkajgiri (Dist) Telangana. <b>Marketed by:</b> M/s. Innovin Formulations, H.No. 2-3-896, GSI Post, Medchal Dist. 500068. Telangana	<b>NOT OF STANDARD QUALITY – Description</b>  Out of 60 tablets, 20 tablets have the tablet defect - Lamination, characterized by cracks or splits partially extending into the layers at the edges. Hence the sample failed with respect to the test description for tablets. Hence it is <b>Not Of Standard Quality</b> .



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The public may report any suspected manufacturing activity related to drugs, including narcotic drugs and psychotropic substances, in residential, commercial, or industrial areas, as well as any other complaints regarding illegal activities concerning medicines, through the **Drugs Control Administration, Telangana Toll-Free Number 1800-599-6969**, which is operational from 10:30 am to 5:00 pm on all working days.

Date: 03-10-2024

V.B. KAMALASAN REDDY, IPS  
DIRECTOR GENERAL