

CDSCO Declares 5 Formulations As Spurious: Details

New Delhi: In the latest spurious drug alert, the apex drug regulatory body, the Central Drug Standard Control Organization (CDSCO), has declared 5 formulations to be spurious, which include antiretrovirals, antihypertensives, NSAIDs, and antibiotics.

The list includes Instgra Tablets (Dolutegravir Tablets IP 50 mg) manufactured by as per label Emcure Pharmaceutical, Telmisartan 40 mg and Amlodipine 5 mg Tablets I.P. (TelmaAM) manufactured by as per label Glenmark Pharmaceuticals, Rifaximin Tablets (Rifagut 400) manufactured by as per label Sun Pharma laboratories, and others.

Section 17B and Section 33EEA of the Drugs Act define spurious drugs. According to the 1940 Drugs and Cosmetics Act,



"A drug shall be deemed to be spurious,—

- (a) if it is manufactured under a name which belongs to another drug; or
- (b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
- (c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
- (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product."

The CDSCO recently issued an alert in which it stated that certain products, including Instgra Tablets manufactured by as per label Emcure Pharmaceutical, TelmaAM manufactured by as per label Glenmark Pharmaceuticals, Rifagut 400 manufactured by as per label Sun Pharma laboratories, Presef 200 LB Tablets manufactured by as per label Pragti Remedies and Naxdom 500 manufactured by as per label Pure and Cure Healthcare, are found to be spurious.

SPURIOUS ALERT FOR THE MONTH OF APRIL - 2024.

NCT of DELHI								
S. No.	Product/Drug Name	B. No.	Manufacturing Date	Expiry Date	Manufactured By as per label	Sales Outlets Involved in Distribution of Spurious Drugs (Name and address of outlet with pin code and pharmacist name with registration number)	Response of Original Manufacturer stating how to identify the original product from reported spurious product	Reported by CDSCO/ State/Manufacturer
1	Instgra Tablets (Dolutegravir Tablets IP 50 mg)	E16DV23001	Feb.2023	Sep.2026	Emcure Pharmaceuticals Ltd., Lane No. 3, Phase II, SIDCO, Bari-Brahmana, Jammu - 181133, India	1) M/s. Harsh Pharma Capital Delhi 2) M/s. Vedas Healthcare Delhi 3) M/s. Mili Healthcare Mumbai 4) M/s. Khushi Enterprises Jaipur 5) M/s. V. K. Enterprises Jaipur	Based on physical verification with original product on spot and SLA email dt. May 10, 2024	NCT of Delhi
2	Telmisartan 40mg and Amlodipine 5mg Tablets	18230073	Feb.23	Jan.26	Glenmark Pharmaceuticals Ltd. Samlik Marchak,	1) M/s. Dass Medical Store Delhi (on direction of court)	As per SLA email dt. May 10, 2024	NCT of Delhi

	I.P. (Telma-AM)				Industrial Growth Centre, East Sikkim, Sikkim-737135	2) M/s. Shree Giriraj Ji Pharma Delhi 3) M/s Amba Medicose Delhi		
3	Domperidone and Naproxen Sodium Tablets (Naxdom 500)	FHA0966	Dec.2023	Nov. 2026	Pure and Cure Healthcare Pvt. Ltd. Plot No. 26A, 27-30, Sector-8A, I.I.E., Sidcul, Ranipur, Haridwar-249 403 (Uttarakhand)	1) M/s. Jai Mata Di Bhagirath Palace Delhi 2) M/s. JMD Enterprises Patna	Based on physical comparison and analytical tests done by manufacturer and SLA email dt. May 10, 2024	NCT of Delhi
4	Rifaximin Tablets (Rifagut 400)	GKE0938 A	June. 2023	May. 2025	Sun pharma laboratories ltd. Plot No. 754, Setipool, Nandok Block, R.O. Ranipool, East Sikkim-737	1) M/s. Jai Mata Di Bhagirath Palace Delhi 2) M/s. JMD Enterprises Patna	Based on physical comparison and analytical tests done by manufacturer and SLA email dt. May 10, 2024	NCT of Delhi

JHARKHAND								
5	Cefixime Trihydrate with Lactic Acid Bacillus Tablets LP. (Presef 200	BHCJ- 009	Nov. 2022	Oct. 2024	Pragti Remedies Plot No. 143 GS Road Link Ulubari Guwahathi	1. M/s. Pragti Remedies Plot No. 143 GS Road Link Ulubari Guwahathi Assam 781008;	Based on SLA email dt. May 13, 2024	SLA, Jharkhan d

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	LB Tablets) ★Serial No. 14 of NSQ alert of April, 2024				Assam 781008 (This firm does not exist at the given address as per SDC, Assam vide letter no- CFDA/2019/05/ PT-1/1073, Dt. 19.03.2024)	2. M/s. Pama Pharmaceuticals Devi Mandap Road Ratu Road Ranchi; 3. M/s. Sarthak Agency Kathitand Ratu Road Ranchi; 4. M/s. Life Saver 11/1 Dewan Gazi Road Kolkata West Bengal		
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The notice further added,

1. Spurious Alert data was not received as per Format and in EXCEL SHEET from State Drugs Licensing Authorities of Uttar Pradesh for the Month of April 2024 as per DCG (I) Circular dated 09.02.2024.
2. Sate Drugs Licensing Authorities of Mizoram, Tripura, and Pondicherry have stated that the Spurious data as “NIL” for the Month of April, 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, Telangana, Uttarakhand, West Bengal, Andaman & Nicobar, Dadar and Nagar Haveli; Daman and Diu, Lakshadweep have not submitted any data in respect of the Spurious Alert for the Month of April, 2024 as per DCG(I) Circular dated 09.02.2024.

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