

List of Drugs, Medical Devices, Vaccine and Cosmetics declared as Spurious for the Month of November– 2024

As part of the continuous regulatory surveillance, drugs samples are picked from sales/distribution point, analysed and list of spurious drugs are displayed on CDSCO portal on monthly basis. The purpose of displaying the spurious drugs list is to make stakeholders aware about the spurious drug batches identified in the market.

S.No.	Name of Drugs/medical device/cosmetics	Batch No.	Date of Manufacture	Date of Expiry	Manufactured By	Reason for failure	Drawn By	Firm's reply	Remarks
1.	Pantoprazole Gastro-Resistant Tablets I.P. (PAN-40)	23443074	Aug-2023	Jan-2026	Under Investigation	Dissolution (Acid Stage) and Assay	Drugs Inspector, Bihar	The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug.	The product is purported to be spurious, however, the same is subject to outcome of investigation.
2.	Amoxicillin and Potassium Clavulanate Tablets IP (AUGMENTIN 625 DUO)	824D054	Feb-2024	Jul-2025	Under Investigation	Identification and Assay	Drugs Inspector, Ghaziabad	The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug.	The product is purported to be spurious, however, the same is subject to outcome of investigation.

Spurious Drugs: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 term “Spurious Drug” has been defined under Section 17-B of the Drugs and Cosmetics Act, 1940.