DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/10-25-99

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.

Date: 22nd October, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Central Drugs Laboratory Karachi informed that the sample of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Zolint Suspension** Each 5ml contains: FURAZOLIDONE…… 25 mg Metronidazole ……. 75 mg (Reg. # **016494**)	25024	M/s Libra (Pvt) Ltd. 77 Industrial Estate Hayatabad Peshawar. (DML # 000369)	The sample has been declared **'substandard'** on the basis of assay test of Furazolidone & Metronidazole.
2.	**Cytobion Capsule** Each capsule contains: Mecobalamin …… 500 mcg (Reg. # 062462)	H575	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No.16 Zain Park Industrial Area Saggian By Pass Road Lahore. (DML # 000676)	The sample has been declared **'substandard'** on the basis of description test wherein dark red crystals not found in sample while description is white capsule containing almost white fine powder with dark red crystals.

Risk Statement:

The use of these defective medicines may result in therapeutic failure and ineffective treatment, particularly affecting vulnerable groups such as children, elderly, diabetic, and anemic patients. Substandard quality of Zolint Suspension used for infectious diarrhea may lead to prolonged illness, dehydration, and microbial resistance, while the defective Cytobion Capsule used for neuropathies and Vitamin B12 deficiency may cause delayed neurological recovery and worsening of deficiency symptoms.

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

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Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers/general public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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