



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/11-25-113

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 20th November, 2025

Target Audience:

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

Alert Summary:

Provincial Drug Testing Laboratories informed that the sample of below mentioned drug product has been declared as '**Substandard**'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	Injection Freclomide Each Ampoule contains Metoclopramide HCl10mg (Reg. # 071331)	25MC09	M/s Friends Pharma (Pvt) Ltd. 31-Km Ferozepur Road Lahore. (DML # 000531)	The above sample is Sub-Standard on the basis of "Particulate contamination: visible particles" performed as per BP.
2.	Infusion SAFEMED Each 100ml contains: Metronidazole 500mg (Reg. # 045824)	SAU-2501	M/s Ahad International Pharmaceutical Limited. 13-Km Gomal University Multan Road Dera Ismail Khan. (DML # 000433)	The above sample is Sub-Standard , on the basis of Particulate contamination: visible particles performed as per BP.
3.	Tablet Loratamin Each Tablet Contains: Loratadine 10mg (Reg. # 062647)	23	M/s Murphy Pharmaceuticals (Pvt) Ltd. 8-Km Raiwind Road Lahore. (DML # 000543)	The sample is "Adulterated" as defined under clause (iv) of sub-section (a) of section 3 of The Drugs Act, 1976 as it contains "Paracetamol" as an ingredient a substance other than the prescribed substance i.e., Loratadine.



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Risk Statement:

All three products present a high public health risk due to critical quality defects. Injection Freclomide and Infusion SAFEMED contain visible particulate contamination, which can lead to severe reactions such as embolism, sepsis, organ damage, or death, especially when administered intravenously. Tablet Loratamin is adulterated with Paracetamol, exposing patients to incorrect therapy, potential allergic reactions, and failure to treat the intended condition. The population most likely to be affected includes acutely ill patients in hospitals, emergency departments, and general public using these medicines for routine treatment, placing them at a heightened risk of adverse outcomes due to compromised product quality.

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.

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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