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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-72

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 18th September, 2025

Target Audience:

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

Alert Summary:

Directorate of Drugs Control Punjab (DDCP) informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Satafenac Injection.** Each 3mL contains: Diclofenac Sodium (B.P) 75mg	DS25-152	M/s Saturn Pharmaceuticals (Pvt) Ltd. 23-Km, Thokar Raiwind Road Lahore. (DML # 000734)	The Drug Testing Laboratory, Lahore has declared the product '***substandard'*** *on the basis of* ***'visible particulate matter'***.
2.	**Infusion METROIN 100ML** Metronidazole 500mg/100ml	MT25-029 & MT25-083	M/s Saturn Pharmaceuticals (Pvt) Ltd. 23-Km, Thokar Raiwind Road Lahore. (DML # 000734)	The Drug Testing Laboratory, Bahawalpur has declared the Batch # MT25-029 of product as '***substandard'*** *on the basis of* ***'Bacterial Endotoxin test***. & The Drug Testing Laboratory, Lahore has declared the Batch # MT25-083 of product as '***substandard'*** *on the basis of* ***'Particulate contamination: visible particles' & 'sterility test'***

3.	**Aqua-P Injection** Sterile water for injection 5ml	P-678	M/s Ipram International. Plot # 26 SS-3 National Industrial Zone Rawat. (DML # 000551)	The Drug Testing Laboratory, Lahore has declared the product as '***substandard'*** *on the basis of* ***'visible particulate matter'*** **&** ***'Bacterial endotoxin test'***
4.	**Injection Cara-Fer 5ml** Each ampoule (5ml) contains: iron sucrose complex eq. to elemental iron ……. 100mg (Reg # 052523)	24G001	M/s Caraway Pharmaceuticals. Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat. (DML # 000629)	The Drug Testing Laboratory Rawalpindi has declared the product as "Substandard" with respect to pH test, Turbidity test and Alkalinity test performed.

Risk Statement:

The defects identified include presence of visible particulate matter, bacterial endotoxin contamination, sterility failure, and particulate contamination. Use of such defective injectable products may pose serious health risks, including infection, sepsis, and adverse clinical complications, particularly in vulnerable patient populations. Healthcare professionals, distributors, and patients are strongly advised to stop the use of the above-mentioned batches immediately and follow DRAP's recall and reporting procedures.

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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