



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/05-26-25

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI

Date: 04th May, 2026

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 informed that the samples of below mentioned drug products have been declared as '**Substandard**'.

S#	Product Name	Batch	Manufacturers	Remarks
1.	WAFIN Injection Each ampule contains: - Water for Injection 5ml (Reg # 066643)	250101	M/s Crest Pharmaceuticals. 43 Industrial Triangle Kahuta Road. Islamabad (DML # 000694)	The sample has been declared " substandard " on the basis of sterility test.
2.	Maverick 500 mg Injection Each vial contains: - Ceftriaxone Sodium eq. to Ceftriaxone 500 mg (Reg # 065444)	250901		The sample has been declared " substandard " on the basis of sterility test.

Risk Statement:

Both **WAFIN Injection (Water for Injection 5 ml)** and **Maverick 500 mg Injection (Ceftriaxone Sodium)** have been declared substandard due to sterility failure, posing a serious risk of microbial contamination that may lead to severe infections, including septicemia. The most likely affected population includes hospitalized patients, especially those in ICUs, immunocompromised individuals, pediatric and elderly patients, and those receiving intravenous antibiotic therapy.

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 batches of drug products. The remaining stocks should be quarantined and returned to the supplier/company.



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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 batches of the drug 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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