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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/02-26-05

DRUG PRODUCT DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.

Date: 25th February, 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 Karachi informed that the samples of below mentioned drug product has been declared as '***Substandard'***.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Teczone Forte** Powder for Injection Each vial contains: Cefoperazone (as Sodium) .....1gm. Sulbactum .....1gm. (Reg # 045516)	02	M/s SPL Pharmaceuticals (Pvt) Ltd. Plot No.4 Phase-III Industrial Estate Hattar. (DML # 000605)	The sample has been declared **"substandard"** on the basis of pH test of reconstituted powder for injection.

Risk Statement:

An abnormal pH may compromise drug stability, efficacy, and patient safety, potentially leading to reduced therapeutic effect, injection site irritation, phlebitis, or systemic adverse reactions. Hospitalized patients receiving intravenous antibiotic therapy, particularly those with severe infections (e.g., sepsis, pneumonia, intra-abdominal infections), immunocompromised individuals, elderly patients, and critically ill patients in ICU settings, as this product is administered parenterally in institutional healthcare facilities.

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).

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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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