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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-26-56

DRUG PRODUCT DECLARED SUBSTANDARD BY DRUG TESTING LABORATORIES PUNJAB.

Date: 16th November, 2026

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals.
- General Public.

Alert Summary:

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

S#	Product Name	Batch	Manufacturers	Remarks
1.	**FERSIMIDE Diuretic Powder** (Each 1000gm powder contains: Furosemide 20mg of Potassium Chloride 4gm, Calcium Carbonate 45 gm, Magnesium Sulphate 1 gm)	FER 504265	Sauve Pharmaceuticals (Pvt.) Ltd, 2-C Value Addition City, Faisalabad.	Drug testing Laboratory (DTL) Punjab, Faisalabad has declared the sample of FERSIMIDE Diuretic Powder "SPURIOUS" on the basis of Assay of Furosemide (0 gm / 1000 gm; 0% found vs. stated 20 gm) as per Section 3 (z-b) (i), "SUBSTANDARD" on the basis of Assay of Potassium Chloride (219%), Calcium Carbonate (58%) and Magnesium Sulphate (987%), pH test (8.07 vs. 3.0–5.0) and Physical Description, and "MISBRANDED" with regards to labelling (Urdu version of Name of the Drug, dosage and instructions not printed on the label) as per Rule 3 (h) of The Drugs (Labelling and Packing) Rules, 1986, in compliance to Section 3 (s)(i), of the Drugs Act 1976.

Risk Statement:

The use of the above-mentioned drug product may cause treatment failure, serious unwanted effects in target species.

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
محفوظ، موثر اور معیاری اشیائے