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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-25-107

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.

Date: 12th November, 2025

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 sample of below mentioned drug product has been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Isobaj Injection 10ml** Each ml contains: Isosorbide Dinitrate ……. 1mg (Reg # 100721)	IB-0925	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km Lahore Gujranwala Road Khori District Sheikhupura. (DML # 000805)	Sample is **Sub-Standard** on the basis **"Bacterial Endotoxin test"**.

Risk Statement:

The sample of **Isobaj Injection 10 mL (Batch No. IB-0925)** has been declared **"Substandard"** on the basis of failure in the **Bacterial Endotoxin Test**, indicating the possible presence of pyrogenic contamination. Use of such injectable preparations may cause **fever, chills, hypotension, or severe adverse reactions**, particularly in **hospitalized, cardiac, or elderly patients** for whom this product is commonly prescribed. As the defect directly affects the **safety and quality** of the product, the batch poses a **high public-health risk** and warrants an **immediate Class I recall**, with retrieval of all distributed stock to prevent potential harm to patients.

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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