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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-26-62

Adulterated Lebterex Injection 50mg/10mL by Bajwa Pharamceuticals (Pvt.) Ltd., Sheikhupura

Date: 24th November, 2026

Target Audience:

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

Alert Summary:

Drug, Water and Food Testing Laboratory, Gilgit Baltistan, Gilgit has declared the above-mentioned product as "Adulterated" on the basis of visible particles in the ampoule. Following are the details:

S#	Product Name	Batch	Manufacturer	Remarks
1.	**Lebterex Injection 50mg/10mL** (Labetalol HCl)	BCL32	Bajwa Pharmaceuticals (Pvt.) Ltd., 36-km, Lahore-Gujranwala Road Khori, Dist, Sheikhupura	The sample is declared as "Adulterated".

Risk Statement:

Parenteral administration of particulate-contaminated products may result in adverse events such as local irritation, inflammation, embolic phenomena, or other clinically significant complications.

Action initiated: -

The Provincial Drug Control departments have been asked 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
محفوظ، موئثر اور معیاری اشیائے