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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-79

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 25th September, 2025

Target Audience:

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

Alert Summary:

Directorate of Drugs Control Punjab (DDCP) informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection. Lignozin-A 2mL** Each ml ampoule contains: Lignocaine HCI B.P..... 20mg Adrenaline B.P.....1:80,000	LG-001	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8- Km Thokar Raiwind Road Lahore. (DML # 000342)	**"Misbranded"** as per Section 3(s)(iv) of The Drugs Act 1976 and **"Sub-Standard"** on the basis of Physical Test i.e Physical Description Test (Visible Particles), pH Test & Assay of Adrenaline.
2.	**Satamin Injection** Each ampoule contains: (Mecobalamin J.P) 500ug	MC24-030	M/s Saturn Pharmaceuticals (Pvt) Ltd. 23-Km, Thokar Raiwind Road Lahore. (DML # 000734).	**'Adulterated'** as per Section_3 (a) (v) of The Drugs Act 1976.

Risk Statement:

The defects identified in the sampled injections pose serious risks to patient safety and therapeutic effectiveness. **Injection Lignozin-A 2 mL (Batch LG-001)** manufactured by *M/s Trigon Pharmaceuticals (Pvt.) Ltd.* has been declared *Misbranded* under Section 3(s)(iv) of the Drugs Act, 1976, and *Substandard* on the basis of physical description (visible particles), pH, and assay of adrenaline, raising concerns of compromised sterility, safety, and efficacy. Similarly, **Satamin Injection (Batch MC24-030)** manufactured by *M/s Saturn Pharmaceuticals (Pvt.) Ltd.* has been declared *Adulterated* under Section 3(a)(v) of the Drugs Act, 1976, which represents a severe violation of product quality and purity standards. The circulation and use of these defective products may lead to therapeutic failure, unpredictable adverse reactions, and potential harm to patients, warranting urgent regulatory and recall action.

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).

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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