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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-76

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 24th 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)	The Sample is declared as **"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.	**Aqua-P Injection** Sterile water for injection 5ml	P-679	M/s Ipram International. Plot # 26 SS-3 National Industrial Zone Rawat. (DML # 000551)	'**Sub-standard'** on the basis of "Visible particulate matter" as per USP.
3.	Neocobal Injection 0.5 mg Each ml contains: Mecobalamin.0.5 mg	S-2705	M/s Pulse Pharmaceuticals (Pvt) Ltd. Mozay Badoke Raiwind Road (Sua Asil Road) Lahore. (DML # 000564)	**'Substandard'** with regards to Assay and '**Adulterated'** as per Section 3 (a) (v) of The Drugs Act 1976.
4.	**Kanadex-N Cream** Each gram contains: 1 mg of dexamethasone-21 phosphate in the form of disodium salt U.S.P. 3500 i.u. of Neomycin in the form of Sulphate U.S.P.)	F7-27	M/s ISIS Pharmaceutical & Chemical Works. 25/1-3 Sector 12-C North Karachi Industrial Area Karachi. (DML # 000126)	**'Substandard'** with regards to Assay of Dexamethasone Phosphate and Adulterated as per Section 3 (a) (v) of The Drugs Act 1976.

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5.	Remedy Injection 500 mcg Each 1ml ampoule contains: 500mcg of Mecobalamin	R-2419	M/s Pak Risen Pharmaceuticals. Plot No. 3 Block B Phase-I-II Industrial Estate Hattar. (DML # 000573)	**'Adulterated'** as per Section 3 (a) (v) of The Drugs Act 1976.

Risk Statement:

The presence of visible particles, failed assays, incorrect active ingredient levels, and adulteration with undeclared or unsafe components renders these medicines unsafe, ineffective, and potentially harmful to patients. Their use may result in treatment failure, unpredictable adverse effects, and serious safety risks including allergic reactions, infections, or toxicity.

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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