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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/12-25-120

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 16th December, 2025

Target Audience:

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

Alert Summary:

Provincial Drug Testing Laboratories, Punjab informed that the sample of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection Neudex** Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate: 4mg/ml **(Reg. # 32876)**	DX029, DX039, DX040, DX041, DX033, DX031, DX045, DX042, DX044, DX046, DX047, DX048, DX049, DX050, DX051, DX053, DX052, DX060, DX059.	M/s Neutro Pharma (Pvt) Ltd. 9.5-Km Sheikhupura Road Lahore. (DML # 000576)	The sample is declared as **"Adulterated"** as per section 3 (iv) of The Drugs Act 1976.
2.	Injection Ame-Pin Each 2ml contains: Tramadol HCI... 100 mg **(Reg. # 065943)**	TD-042	M/s Ameer Pharma (Pvt) Ltd. 23-Km Sheikhupura Road, Lahore. (DML # 000604)	The sample "**Sub-Standard"** on the basis "Particulate contamination" visible particles" as per BP.

Risk Statement:

The use of **Injection Neudex (Dexamethasone)** declared as **adulterated**, and **Injection Ame-Pin (Tramadol)** found **sub-standard due to visible particulate contamination**, poses a **serious risk to patient safety**, particularly among **critically ill patients, surgical patients, emergency care recipients, elderly individuals, and those with compromised immunity**. Administration of adulterated or contaminated injectable products may result in **treatment failure, severe allergic reactions, embolism, infections, organ toxicity, or even fatal outcomes**. Healthcare professionals and patients are therefore urged to **immediately discontinue use** of the affected batches to prevent any potential adverse health consequences.

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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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