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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/12-25-118

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 08th 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.	**AOTILAS 120 ML SUSPENSION** Each mL Contains: Domperidone ……. 1 mg (Reg. # 112505)	S8B05	M/s Astellas Pharmaceutical (Pvt) Ltd. 15-C Industrial Estate Hayatabad Peshawar. (DML # 000677)	The sample is **"Substandard"** as it contains the impurity "Diethylene Glycol" above the permissible limit.
2.	**Injection. Neudex** Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate: 4mg/ml (Reg. # 32876)	DX032, DX034, DX035 & DX036	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.

Risk Statement:

The substandard quality of AOTILAS 120 mL Suspension containing Diethylene Glycol (DEG) above the permissible limit**,** and the adulterated status of Neudex Injection (Dexamethasone) pose a severe and immediate threat to public health**.** The populations most likely to be affected include infants, children, elderly patients, pregnant women, and critically ill patients who are prescribed these medicines for gastrointestinal disorders, inflammation, allergic reactions, and emergency medical conditions**.** Exposure to **Diethylene Glycol is highly toxic and may cause acute kidney failure, neurological damage, metabolic acidosis, and death**, especially in pediatric patients.

The use of an adulterated injectable corticosteroid significantly increases the risk of systemic toxicity, treatment failure, severe infections, shock, and fatal outcomes**.** Continued availability or use of these products may lead to rapid deterioration of patient health, mass poisoning incidents, irreversible organ damage, and loss of life**,** representing a highest-level public health emergency requiring immediate recall and strict regulatory enforcement.

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.

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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، موثر اور معیاری اشیائے علاج