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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/03-26-07

DRUG PRODUCT DECLARED SUBSTANDARD & ADULTERATED BY DRUG TESTING LABORATORIES, PUNJAB.

Date: 11th March, 2026

Target Audience:

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

Alert Summary:

Drug Testing Laboratories of Punjab Province informed that the samples of below mentioned drug products have been declared as '***Substandard & Adulterated***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection SORIDE** Each mL contains: Sodium Chloride USP....9mg (Reg # 044017)	SR260004	M/s Bosch Pharmaceuticals (Pvt) Ltd. 221 Bosch House Sector 23 Korangi industrial Area Karachi. (DML # 000350)	The sample is declared as **"Misbranded"** under Section 3(s)(iv) of the Drugs Act, 1976 due to non-compliance with USP labelling requirements (osmolar concentration not stated on the label as required). The sample is also declared **"Sub-Standard"** on the basis of visible particulates in injection.
2.	**Injection Neudex** Each ml contains: Dexamethasone sodium phosphate eq. to dexamethasone phosphate.....4mg (Reg # 042943)	DX030	M/s Neutro Pharma (Pvt) Ltd. 9.5-Km Sheikhupura Road Lahore. (DML # 000576)	The above sample is **Adulterated** as per The Drugs Act 1976, 3 (a)(iv) on the basis of Identification and Quantification of Dexamethasone (base).

Risk Statement:

The cited products, Injection SORIDE (Sodium Chloride 0.9%) and Injection Neudex (Dexamethasone Sodium Phosphate 4 mg/mL), present significant clinical and regulatory risk. SORIDE has been declared *misbranded* due to non-compliance with USP labeling requirements (absence of osmolar concentration), which may lead to improper clinical use in sensitive populations such as neonates, critically ill, or electrolyte-imbalanced patients. More critically, the presence of visible particulates in a parenteral preparation classifies it as *sub-standard*, posing a direct risk of embolism, phlebitis, pyrogenic reactions, and systemic inflammatory responses.

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Injection Neudex has been declared *adulterated* based on failure in identification and quantification of dexamethasone (base), indicating potential presence of incorrect strength, substitution, or degradation. This may result in therapeutic failure in emergency conditions such as anaphylaxis, cerebral edema, severe asthma, or shock, where corticosteroids are life-saving.

The population most likely to be affected includes hospitalized patients, emergency cases, pediatric and ICU patients receiving IV fluids or corticosteroid injections. The overall risk level is assessed as high, particularly because both products are injectable formulations administered systemically, and any quality defect may result in immediate and serious patient harm.

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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