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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/01-26-130

DRUG PRODUCTS DECLARED SUBSTANDARD BY DRUG TESTING LABORATORIES, PUNJAB.

Date: 14th January, 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***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection Neocobal** Mecobalamin: 0.5 mg/ML (Reg. # 071447)	S-2901	M/s Pulse Pharmaceuticals (Pvt) Ltd. Mozay Badoke Raiwind Road (Sua Asil Road) Lahore. (DML # 000564)	The samples have been declared **Sub-standard** with regards to Assay and Adulterated as per Section 3 (a) (v) of The Drugs Act 1976.
2.	**Injection Kamedex 1 ml** Each ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone phosphate …... 4 mg (Reg. # 074983)	DX-2485	M/s Amaan Pharma. 30-Km Sheikhupura Road Lahore (DML # 000808)	The sample has been declared **Adulterated** as per Section 3 (a) (v) of The Drugs Act 1976 *(label claims Dexamethasone Sodium Phosphate equivalent to Dexamethasone Phosphate 4 mg/mL, laboratory analysis identified Dexamethasone base at a much lower level, rendering the composition false and misleading).*
3.	**Unisol NS Infusion 100ml** Each 100 ml contains: Sodium Chloride …. 0.9g	5109040	M/s Unisa Pharmaceutical Industries Ltd. Main GT Road Adamzai Akora Khattak District Nowshera. (DML # 000740)	The sample has been declared **Sub-standard** on the basis of Bacterial Endotoxin test.

4.	**Isobaj Injection 10ml** Each ml contains: Isosorbide Dinitrate ……. 1mg (Reg # 100721)	IB-1125	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km Lahore Gujranwala Road Khori District Sheikhupura. (DML # 000805)	The sample is declared as **"Sub-Standard"** on the basis of Bacterial Endotoxins Test (BET) & **"Misbranded"** as per section 3 (s) (iv) of the Drugs Act 1976. *(sample does not comply with definition of BP monograph of "Isosorbide Dinitrate Injection" which states that "It is supplied as a ready-to-use solution". While label mentions "Must be Diluted Prior to use on primary as well as secondary package of sample, that is contradictory with definition. Therefore, the sample is MISBRANDED).*
5.	**Infusion ZEESOL-H** **(RINGER LACTATE)** Each 1000 ml contains: Calcium chloride 2H2O 0.27gms, Potassium Chloride 0.40 gms, Sodium Chloride 6.00gms, sodium lactate 3.20gms water for injection q.s (Reg # 019752)	2503281	M/s Shazeb Pharmaceutical Industries Ltd. Hazara Trunk Road Sarai Gadaee Dist.: Haripur. (DML # 000380)	The sample has been declared **Sub-standard** on the basis of Sterility test.
6.	**Injection Neudex** Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate: 4mg/ml **(Reg. # 32876)**	DX079, DX080, DX064, DX060, DX042, DX063, DX072, DX067, DX068, DX070, DX065 DX080	M/s Neutro Pharma (Pvt) Ltd. 9.5-Km Sheikhupura Road Lahore. (DML # 000576)	The sample has been declared **Adulterated** as per Section 3 (a) (v) of The Drugs Act 1976 *(label claims Dexamethasone Sodium Phosphate equivalent to Dexamethasone Phosphate 4 mg/mL, laboratory analysis identified Dexamethasone base at a much lower level, rendering the composition false and misleading).*

7.	**Entagyl Oral Suspension 400ml** Each 5ml suspension contains: Benzoyl Metronidazole equivalent to 200mg of Metronidazole BP. (Reg # 087947)	272	M/s BJ Pharmaceuticals. Mandialai Stop Bhattianwala Road 18-Km Lahore Sheikhupura Road, Lahore. (DML# 000770)	The sample is Sub-Standard with regards to presence of impurity (Ethylene Glycol), above the permissible limit.

Risk Statement:

The identified quality defects in Neocobal Injection (mecobalamin), Kamedex Injection (dexamethasone), and Unisol NS Infusion present a serious risk to patient safety. Sub-standard potency and adulteration in injectable medicines may lead to treatment failure, incorrect dosing, and unpredictable clinical response, while contamination with bacterial endotoxins can cause fever, shock, and life-threatening reactions. The public most likely to be affected includes hospitalized patients, emergency and critically ill patients, children, pregnant women, and patients receiving steroid therapy, vitamin B12 injections, or intravenous fluids, where even small deviations in quality can result in severe and potentially fatal outcomes.

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
محفوظ، موثر اور معیاری اشیائے علاج