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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/02-26-01

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

Date: 12th February, 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.	**PSOL 2 ml** Sterile water for injection (Reg. # 098431)	AK144	M/s Pharmasol (Pvt) Ltd. Plot 549, Sunder Industrial estate, Lahore. (DML # 000872)	The sample has been declared **"Substandard"** with respect to Endotoxin test performed.
2.	**Nafen Ophthalmic Suspension** Each ml conatins: Nepafenac 1 mg (Reg # 075907)	4231	M/s Helix Pharma (Pvt) Ltd. A/56 SITE Mangopir Karachi. (DML # 000030)	The sample has been declared **"Substandard"** on the basis of **Sterility test**.
3.	**Metrorise Infusion** Metronidazole....500mg/100ml (Reg # 040412-D)	LV-2506	M/s Pak Risen Pharmaceuticals. Plot No. 3 Block B Phase-I-II Industrial Estate Hattar. (DML # 000573)	The sample has been declared **"Substandard"** on the basis of **Bacterial Endotoxin Test & Visible particles**.
4.	**Metroin Infusion IV** Metronidazole....500mg/100ml (Reg # 071279)	MT25-331	M/s Saturn Pharmaceuticals (Pvt) Ltd. 23-Km, Thokar Raiwind Road Lahore. (DML # 000734)	The sample has been declared **"Substandard"** on the basis of **Bacterial Endotoxin Test**.
5.	**Satamin Injection** Mecobalamin.....500mcg (Reg # 071284)	MC24-022, MC24-023, MC24-026, MC25-001	M/s Saturn Pharmaceuticals (Pvt) Ltd. 23-Km, Thokar Raiwind Road Lahore. (DML # 000734)	The sample has been declared **Substandard** on the basis of Assay test and **Adulterated** on the Quantification of Cyanocobalamin.

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Risk Statement:

These findings indicate a **high public health risk**, primarily affecting **hospitalized patients and vulnerable groups**. The most likely to be harmed are **neonates, children, elderly patients, immunocompromised individuals, post-surgical patients, and those receiving IV therapy or ophthalmic treatment**. Substandard **sterile water and infusions** failing endotoxin/sterility tests can lead to **serious bloodstream infections, septic shock, pyrogenic reactions, and even fatalities**, especially in intensive care settings. The presence of **visible particles** further increases the risk of embolic or inflammatory complications. The adulteration and incorrect potency in **Satamin injection** may result in **therapeutic failure, delayed neurological recovery, or unexpected adverse effects**, undermining patient safety. Overall, these products pose the greatest risk in **clinical and emergency care environments**, where sterile injectable medicines are critical.

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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