MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/03-25-26

SUBSTANDARD PRODUCTS DECLARED BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 4th March, 2025

Target Audience:

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

Alert Summary:

Directorate of Drugs Control (DDC) Punjab and Senior Drug Inspector ICT Islamabad has informed DRAP that samples below product has been reported substandard due to presence of impurities by Drug Testing Laboratory (DTL) Lahore and Rawalpindi:

S#	Product Name	Batch No.	Manufacturer stated on label	Test Results
01	Ame-Pin injection 2ml (Tramadol HCl 100mg)	TD-038	Ameer Pharma (Pvt.) Ltd., 23 KM, Sheikhupura road, Lahore	Substandard on the basis of visible particles
02	Aqua-P Injection (Sterile WFI)	P-665	Ipram International, Plot No. 26, SS-3, NIZ, Rawat Islamabad	Substandard on the basis of Bacterial Endotoxin test
03	Flagyl Infusion (Metronidazole 500mg)	AD460	Sanofi-Aventis Pakistan Ltd., Plot No. 23, Sector 22, KIA, Karachi	Substandard on the basis of presence of visible particles
04	Metroin Infusion (Metronidazole 500mg)	MT24-103	Saturn Pharmaceuticals, 23Km,Thokar-Raiwind Rd, Lahore	Substandard on the basis of presence of visible particles
05	Euro-Flow Cannula	24/87	Euromed for Medical Industries SAE Cairo Egypt	Substandard on the basis of sterility test
06	Rudazole Injection (Metronidazole 500mg)	RD-044	Rukha Pharmaceutical & Laboratories, 537-D&E Sundar Industrial Estate Lahore	Substandard on the basis of presence of visible particles
07	Safemed Injection (Metronidazole 500mg)	S-699	Ahad Intl., Pharmaceutical, 13KM Gomal Uni, Multan Road, DI Khan	Substandard on the basis of presence of visible particles
08	Pulmowell 120ml syrup (Ammonium Chloride 30mg, Liquorice Ext. 50mg, Aniseed Oil 2.6ml)	PLW-001	Vital Phyto Parma (Pvt.) Ltd., 7 KM from GT Road, Sohawa Chakwal Road, Rawalpindi	Contains Diethylene Glycol above permissible limits

Risk Statement:

Use of substandard products can lead to therapy failure which can increase chances of complications in susceptible users including immunocompromised patients, pediatric and geriatric population.

Action initiated:

The regulatory field force of DRAP and Provincial Drug Control departments have been requested to immediately conduct market surveys for detection and removal of these products from the market.

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk

Advice for Healthcare Professionals:

DRAP urges heightened vigilance in affected supply chains and requests reporting of adverse reactions or quality issues to the National Pharmacovigilance Centre (NPC), DRAP via the Adverse Event Reporting Form or online via this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers / general public:

Consumers with the affected batches should report to the Drug Regulatory Authority of Pakistan (DRAP) and consult their healthcare provider if they experience any issues related to the drug.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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