



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/06-26-35

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL LABORATORIES

Date: 18th June, 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 (DTL) Punjab informed that the samples of below mentioned drug products have been declared as '**Substandard/Adulterated**'.

S#	Product Name	Batch	Manufacturers	Remarks
1.	Neocobal 0.5 mg Injection Each ml contains: Mecobalamin0.5mg (Reg. # 071447)	S-3052	M/s Pulse Pharmaceuticals (Pvt) Ltd. Mozay Badoke Raiwind Road (Sua Asil Road) Lahore. (DML # 000564)	The sample is declared as “ sub-standard ” on the basis of Assay Test & “ adulterated ” as per section 3 (a) (iv) of The Drugs Act 1976 (Cyanocobalamin is Identified).
2.	GAMMARAAS Injection Immune Globulin Injection (Human) 5%, 2.5g, 50ml/vial (Reg. # 031350)	202311G042	Imported & Distributed by Popular International (Pvt.) Ltd. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Karachi.	The sample is declared as “ sub-standard ” with regards to Description & Sterility test.
3.	Injection. KAMEDEX 1mL Each ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone phosphate 4 mg (Reg. # 074983)	DX-2642	M/s Amaan Pharma. 30-Km Sheikhpura Road Lahore (DML # 000808)	The sample has been declared Adulterated as per Section 3 (a) (v) of The Drugs Act 1976 (<i>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</i>).
4.	BRZOLE 500mg/100ml Infusion Each vial contains: Metronidazole....500mg/100ml (Reg. # 099612)	25055	M/s Berlex Lab. International, 10-Km Nangshah Chowk Karachi Road Multan (DML # 000678)	The sample is declared as “ sub-standard ” with regards to Bacterial Endotoxin test.



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5.	Metrorise Infusion Metronidazole....500mg/100ml (Reg. # 040412-D)	LV-2514	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.
6.	Murcobal Injection 500 mcg Each ml Contains Mecobalamin...500mcg (Reg. # 045904)	109	M/s Murfy Pharmaceuticals (Pvt) Ltd. 8-Km Raiwind Road Lahore. (DML # 000543)	The sample is declared as “sub- standard” on the basis of Assay Test & “adulterated” as per section 3 (a) (iv) of The Drugs Act 1976 (Cyanocobalamin is Identified).
7.	Premvil Infusion 1gm/100 ml Each 100ml contains: Paracetamol.....1gm (Reg. # 125218)	PNO-2510	Ahad International Pharmaceutical LTD 13-Km, Multan Road, Dera Ismail Khan	The sample is declared as “sub- standard” with regards to Visible Particulates
8.	Aqua-P Injection Sterile water for injection 5ml	P-673	M/s Ipram International. Plot # 26 SS-3 National Industrial Zone Rawat. (DML # 000551)	Sub-standard’ on the basis of Bacterial Endotoxin Test.
9.	ZYOCAIN Gel Lignocaine Hydrochloride B.P 2% w/v (Reg # 012523)	008	M/s PharmaWise Labs (Pvt) Ltd. 25-M Industrial Area Kot Lakhpur Lahore. (DML # 000182)	Sub-standard’ on the basis of Sterility test
10.	Injection Cara-Lac 30mg/1ml Each 1ml contains: - Ketorolac Tromethamine equivalent to Ketorolac.....30mg (Reg. # 054997)	25G022	M/s Caraway Pharmaceuticals. Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat. (DML # 000629)	The sample is declared as “sub- standard” on the basis of Test for Impurities i.e. Organic Impurities.
11.	Sterile Water for Injection 5ml	20334	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km Ferozepur Road Lahore (DML # 000590)	Sub-standard’ on the basis of Bacterial Endotoxin Test.

Risk Statement:

The affected products have been found to possess critical quality defects, including failure of sterility, bacterial endotoxin, assay, impurity, and visible particulate tests, while certain products were also declared adulterated



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due to misidentified active ingredients or misleading composition. Use of these products may result in treatment failure, serious infections, pyrogenic reactions, adverse health effects, or other patient safety risks. Healthcare professionals, distributors, and retailers are therefore advised to immediately cease distribution and use of the affected batches and ensure their prompt recall from the market.

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 batches of drug 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 batches of the drug 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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