



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/09-25-63

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 15th September, 2025

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 from Provinces informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been declared as '**Substandard**'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1	STERILE OPHTHALMIC SUSPENSION 5 ML BROMYCIN-D Each ml contains: TOBRAMYCIN 3MG, DEXAMETHASONE 1MG	6892	M/s Innvotek Pharmaceuticals. Plot No.35 Industrial Estate Kahuta Triangle Islamabad. (DML # 000487)	Drug Testing Laboratory, Rawalpindi declared the sample as ' substandard ' quality on the basis of the result of Sterility test .
2.	Injection Metrorise Each 100ml vial contains: Metronidazole USP ... 500mg (0.5% w/v)	LV-2504	M/s Pak Risen Pharmaceuticals. Plot No. 3 Block B Phase-I-II Industrial Estate Hattar. (DML # 000573)	Drug Testing Laboratory, Bahawalpur declared the sample as ' substandard ' quality on the basis of the result of Bacterial Endotoxin test .
3.	Sterile water for injection 5ml Each glass ampoule contains Sterile water for injection 5ml	24L608	M/s Medisave Pharmaceuticals. Plot No.578-579 Sundar Industrial Estate Lahore. (DML # 000681)	DDCP Alert No. 172/2025 declared the sample as ' substandard ' on the basis of the result of Bacterial Endotoxin test .
4.	Sterile water for injection 5 ml Each glass ampoule contains Sterile water for injection 5ml	25WF01	M/s Friends Pharma (Pvt) Ltd. 31-Km Ferozepur Road Lahore. (DML # 000681)	DDCP Alert No. 172/2025 declared the sample as ' substandard ' on the basis of visible particulate matter .



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5.	ELPOMIDE INJ 10mg/2ml Metoclopramide HCl BP 10mg/2ml	332	M/s Elite Pharma (Pvt) Ltd. 9.5 Km Sheikhpura Road Lahore. (DML # 000455)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of visible particulate matter .
6.	Injection Aqua-P 5ml Each glass ampoule contains Sterile water for injection 5ml	P-672	M/s Ipram International. Plot # 26 SS-3 National Industrial Zone Rawat. (DML # 000551)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of visible particulate matter .
7.	Water for injection 5 ml Sterile water for injection 5ml.	130	M/s Wilshire Laboratories (Pvt) Ltd. 124/1 Industrial Estate Kot Lakhpat Lahore. (DML # 000232)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of the result of Bacterial Endotoxin test .
8.	Sterile water for injection 10 ml Each glass ampoule contains Sterile water for injection 10 ml	084L24	M/s Brookes Pharma (Pvt) Ltd. Plot No. 58-59 Sector No. 15 Korangi Industrial Area Karachi. (DML # 000275)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of the result of sterility test .
9.	Syrup Salbovent 60ml Each 5ml contains: Salbutamol (as sulphate) 2mg	L25D52	M/s Synchro Pharmaceuticals. 77-Industrial Estate Kot Lakhpat Lahore. (DML # 575)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of the result of impurity (ethylene glycol) above the permissible limits .
10.	Injection Vitamin K1 Each ml contains: Phytomenadione 2 mg	H-18825	M/s Venus Pharma. 23 Km Multan Road Lahore. (DML # 000300)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of the result of sterility test .
11.	SNDOL Suspension 60 ml Each 5ml contains: Paracetamol 120 mg	917	M/s S.N.B Pharma (Pvt) Ltd. Plot No. 142 Industrial Estate Hayatabad Peshawar. (DML # 000759)	DDCP Alert No. 173/2025 declared the sample as 'substandard' on the basis of the result of impurity (ethylene glycol) above the permissible limits .



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12.	Resgyl Suspension 60 ml Benzoyl Metronidazole eq. to Metronidazole 200mg / 5ml	4E566	M/s Rasco Pharma (Pvt) Ltd. 5.5 Km Raiwind Road Ali Razabad, Lahore. (DML # 000530)	DDCP Alert No. 173/2025 declared the sample as 'substandard' on the basis of the result of impurity (ethylene glycol) above the permissible limits.
13.	Syrup Syandin 60 ml Each 5ml contains: Loratadine 5 mg	L25E57	M/s Synchro Pharmaceuticals. 77-Industrial Estate Kot Lakhpur Lahore. (DML # 575)	DDCP Alert No. 173/2025 declared the sample as 'substandard' on the basis of the result of impurity (ethylene glycol) above the permissible limits.
14.	Injection Neocobal 1 ml Mecobalamin 0.5mg/ml	S-2621	M/s Pulse Pharmaceuticals (Pvt) Ltd. Mozay Badoke Raiwind Road (Sua Asil Road) Lahore. (DML # 000564)	DDCP Alert No. 173/2025 declared the sample as 'substandard' and 'adulterated' .
15.	Infusion NIDA 100 ML Metronidazole 500mg/100ml	25D055	M/s GMP Pharmaceuticals. 28-Km Sheikhpura Road Lahore. (DML # 000815)	DDCP Alert No. 177/2025 declared the sample as 'substandard' on the basis of visible particulate matter .
16.	Metrorise injection Metronidazole 500mg/100ml	LV-2422	M/s Pak Risen Pharmaceuticals. Plot No. 3 Block B Phase-I- II Industrial Estate Hattar. (DML # 000573)	DDCP Alert No. 177/2025 declared the sample as 'substandard' on the basis of Bacterial Endotoxin Test .
17.	Infusion Revasol-H 500ml (Hartmann solution) Each 100 ml contains: Potassium Chloride 0.04gm, Sodium Lactate 0.32gm, Sodium Chloride 0.60gm, Calcium Chloride 2H ₂ O 0.027gm	25D1037	M/s Revive Pharmakon. 10-Km Raiwind Road Lahore. (DML # 000819)	DDCP Alert No. 177/2025 declared the sample as 'substandard' on the basis of Bacterial Endotoxin Test .
18.	Infusion Parapals 100 ml Paracetamol USP 1g/100ml	PPV-384	M/s Inventor Pharma. Plot No. K/196, S.I.T.E Phase-II, Karachi (DML # 000866)	DDCP Alert No. 177/2025 declared the sample as 'substandard' on the basis of visible particulate matter .



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19.	Injection Freclomide Metoclopramide 10mg/2ml	25MC05	M/s Friends Pharma (Pvt) Ltd. 31-Km Ferozepur Road Lahore. (DML # 000681).	DDCP Alert No. 177/2025 declared the sample as ' substandard ' on the basis of visible particulate matter & Sterility test .
20.	Syrup Allerphene 120ml Chlorpheniramine maleate2mg/5ml	4047	M/s P.D.H Pharmaceuticals (Pvt) Ltd. 19 Km Ferozepur Road Lahore. (DML # 000459)	DDCP Alert No. 179/2025 declared the sample as ' substandard ' on the basis of the result of impurity (ethylene glycol) above the permissible limits .
21.	Injection Aqua-P 5ml Sterile water for injection 5 ml	P-676	M/s Ipram International. Plot # 26 SS-3 National Industrial Zone Rawat. (DML # 000551)	DDCP Alert No. 179/2025 declared the sample as ' substandard ' on the basis of the result of visible particulate matter & Bacterial Endotoxin Test .

Risk Statement:

The above-mentioned batches have been declared *substandard* due to serious quality defects including sterility failure, presence of bacterial endotoxins, visible particulate matter, and impurities such as ethylene glycol. Use of these defective medicines may lead to severe health risks including infections, sepsis, organ toxicity, or treatment failure.

This alert particularly concerns patients receiving ophthalmic preparations, sterile injections/infusions (including antibiotics, metronidazole, paracetamol, vitamin K, and electrolyte solutions), as well as children and adults using oral syrups and suspensions. Healthcare professionals and the general public are advised to immediately stop use of the affected batches and report any adverse events.

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



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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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