

MOST URGENT



**NO. SO(RMC)2-21/2025
GOVERNMENT OF THE PUNJAB
SPECIALIZED HEALTHCARE &
MEDICAL EDUCATION DEPARTMENT
(TECHNICAL WING)**

Dated Lahore, the 3rd October, 2025

To

1. Vice Chancellors of all public sector Medical Universities in Punjab
2. Principals / Deans / EDs of all public sector Medical Colleges / Specialized Medical Institutions in Punjab
3. Medical Superintendents of all public sector Teaching Hospitals in Punjab

**SUBJECT DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL
DRUG TESTING LABORATORIES**

I am directed to refer the subject cited above and to enclose herewith copy of a letters No. F.13-30/2024-DD(QA-VIII)-P-001 dated 17.09.2025 received from the Deputy Director-IX (QA & LT), Drug Regulatory Authority of Pakistan, Division of Quality Assurance & Laboratory Testing, Prime Minister's National Health Complex, Islamabad.

2. Submitted for information and further necessary action.

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SECTION OFFICER (RMC)

NO & DATE EVEN:

Copy is forwarded for information to the:

1. Deputy Director-IX (QA & LT), Drug Regulatory Authority of Pakistan, Division of Quality Assurance & Laboratory Testing, Prime Minister's National Health Complex, Islamabad w/r to letter referred above.
2. PSO to Secretary to Government of the Punjab, Specialized Healthcare & Medical Education Department.
3. PS to Special Secretary (Operations), Specialized Healthcare & Medical Education Department.
4. P.A. to Additional Secretary (Technical), Specialized Healthcare & Medical Education Department.

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SECTION OFFICER (RMC)

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No. F. 13-30/2024-DD(QA-VIII)-P-001
Government of Pakistan
Drug Regulatory Authority of Pakistan
Division of Quality Assurance & Laboratory Testing
Prime Minister's National Health Complex, Islamabad.

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MOST IMMEDIATE

T. Wing
Islamabad, the 17th September, 2025.

Subject: DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

I am directed to refer to the subject cited above and Alerts issued by Directorate of Drugs Control Punjab (DDCP) wherein below mentioned **Drug Products** declared '**Substandard**' quality. Details of products are as under:

S#	Product Name	Batch No.	Manufacturers	Remarks
1	STERILE OPHTHALMIC SUSPENSION 5 ML BROMYCIN-D Each ml contains: TOBRAMYCIN 3MG, DEXAMETHASONE IMG	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 .
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 .

FA/DS (T)
SHC & ME Deptt.
Diary No. _____
Date: 2/10/25
SO (RMC) _____
SO (PH) _____
SO (OPS) _____
SO (AS) _____
SC (CH) _____

PA to A.S
(PROCUREMENT)
PUC No. _____
Date: 26/09/25
SO (P-I) _____
SO (P-II) _____
SO (P-III) _____
SO (P-IV) _____
SO (Stand) _____
BME _____
C. Manager _____
DS (Proc) _____

DSCT
49993
DS (Proc) SHC&ME Deptt.
Diary No. 5304
Date: 25/9/25

Special Secretary
(DAR)
Diary No. _____
Date: 23-9
AS (D) _____
AS (P) _____
CPO _____
AS _____
AS (F) _____
AS (ME) _____
SM&IPU _____
DS _____

SECRETARY SHC&ME
Diary No. 9206
Date: 23/9/25
SS (OPS) _____
ASA _____
ASE _____
AST _____
DS () _____
SLO _____

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 .
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 Lakhpat 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 .
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 maleate 2mg/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 .
22.	Tablet Ortizin 10mg Each film coated tablet contains: Cetirizine 2HCl 10 mg	24L377	M/s Obsons Pharmaceuticals. 209-S Industrial Estate Kot Lakhpat Lahore. (DML # 000416)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of assay and impurities testing .
23.	Tablet Daisy 10 mg Each film coated tablet contains: Cetirizine 2HCl 10 mg	25B084 & 25B085	M/s Mega Pharmaceuticals Ltd. 27 Km Raiwind Road Lahore. (DML # 000537)	DDCP Alert No. 172/2025 declared the sample as 'substandard' on the basis of impurities testing (Organic impurities) .
24.	Tablet Ascard 75 Each enteric coated tablet contains:	AR076K	M/s Atco Laboratories Limited. B-18 S.I.T.E Karachi.	DDCP Alert No. 173/2025 declared the sample as 'substandard' on the

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	Acetyl Salicylic acid 75 mg		(DML # 000188)	basis of test for related substance (Impurity C: Salicylic Acid).
25.	Tablet Bytec 10mg Each film coated tablet contains: Cetirizine 2HCl 10 mg	E604, E605 & E606	M/s Batala Pharmaceuticals. 23/B Small Industrial Estate No. 2 Gujranwala. (DML # 000477)	DDCP Alert No. 179/2025 declared the sample as 'substandard' on the basis of impurities testing.
26.	Tablet Vivin 10 mg Each film coated tablet contains: Cetirizine 2HCl 10 mg	315	M/s Murfy Pharmaceuticals (Pvt) Ltd. 8-Km Raiwind Road Lahore. (DML # 000543)	DDCP Alert No. 179/2025 declared the sample as 'substandard' on the basis of impurities testing.

2. All the above mentioned firms are hereby directed to immediately alert your sales officers/suppliers/distributors to issue instructions to the pharmacies/hospitals/point of sales/purchase/use, for the **return of suspected stocks** of the above mentioned batch of the medical device & **within three working (03) days**, you are directed to submit 'Recall Assessment Form' to this division in light of guidance provided in the "Guidelines on Recall of Defective Therapeutic Goods (Edition 02)" available on DRAP's website i.e. <https://www.dra.gov.pk/wp-content/uploads/2024/11/Recall-Guidelines-Edition-2-V1-1-Final-08-10-2024-1-2.pdf>.

(SALATEEN WASEEM PHILIP)
Deputy Director-IX (QA<)

Copy for information and necessary action – with request to issue necessary directions to points of use/sale under administrative control/ fall under area of jurisdiction to ensure recall of defective product from the market, please.

- ① The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Population Welfare Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary Health Department (Government of KP).
5. The Secretary Health Department (Government of Baluchistan).
6. The Secretary, Ministry of Health (Government of AJ&K).
7. The Additional Director / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
8. The Chief Drug Controller / Inspector Punjab, Sindh, Khyber Pakhtunkhwa, Baluchistan, AJ&K, GB and ICT.

Copy to: -

- i. Area FIDs, to coordinate with concerned manufacturer regarding oversight of the recall process within the required time.
- ii. Office copy


 Deputy Director - IX (QA<)