MOST URGENT

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

Dated Lahore, the 6th January, 2026

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. 13-30/2024-DD(QA-VIII) dated 18.12.2025 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.

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.

SECTION OFFICER (RMC)

13-30/2024-DD(QA-VIII)

MOST IMMEDIATE

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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Islamabad, the 18th December, 2025.

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

I am directed to refer to the subject cited above and report received from DTL Punjab wherein below mentioned **Drug Products** declared ***'Substandard'*** quality. Details of products are as under:

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection Neudex** Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate: 4mg/ml **(Reg. # 32876)**	DX029, DX039, DX040, DX041, DX033, DX031, DX045, DX042, DX044, DX046, DX047, DX048, DX049, DX050, DX051, DX053, DX052, DX060, DX059.	M/s Neutro Pharma (Pvt) Ltd. 9.5-Km Sheikhupura Road Lahore. (DML # 000576)	The sample is declared as **"Adulterated"** as per section 3 (iv) of The Drugs Act 1976.
2.	Injection Ame-Pin Each 2ml contains: Tramadol HCL... 100 mg **(Reg. # 065943)**	TD-042	M/s Ameer Pharma (Pvt) Ltd. 23-Km Sheikhupura Road, Lahore. (DML # 000604)	The sample **"Sub-Standard"** on the basis "Particulate contamination" visible particles" as per BP.

2. The above mentioned firm is hereby directed to immediately alert your sales officers/suppliers/distributors to issue instructions to the distributors, for the **return of suspected stocks** of the above mentioned batch of the product & **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.

3. Furthermore, the Area Federal Inspector of Drugs is requested to visit the premises of the firm to verify the physical specifications of the product as mentioned in the approved product testing SOP. The Inspector shall also check and report when the firm last informed the Registration Division, DRAP regarding the approval of any minor variation (MiV-PA14) in the said drug product as per guidelines of **Post Registration Variation** (https://www.dra.gov.pk/wp-content/uploads/2023/09/Post-Registration-Variation-Guidelines-Edition-02.pdf). Additionally, please verify whether the firm has complied with the conditions of registration by timely updating the concerned Drug Testing Laboratories about the approved testing method.

(SALATEEN WASEEM PHILIP)
Deputy Director-IX (QA&LT)

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, Health Department (Government of AJ&K).
7. The Secretary, Health Department (Government of Gilgit Baltistan).
8. The Additional Director / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
9. The Chief Drug Controller / Inspector Punjab, Sindh, Khyber Pakhtunkhwa, Baluchistan, AJ&K, GB and ICT **with request to oversight recall at distributor level and sales point.**

Copy to: -

i. Area FID, to coordinate with concerned manufacturer regarding oversight of the recall process and also investigate as per para .3 of this letter within the required time.

ii. Office copy

18/12/2025

Deputy Director - IX (QA&LT)