

MOST URGENT



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

Dated Lahore, the 5th 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 8.12.2025 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)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Division of Quality Assurance & Laboratory Testing
Prime Minister's National Health Complex, Islamabad.

MOST IMMEDIATE

Islamabad, the 08th 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.	Tablet Virtec 10 mg Each Tablet Contains: Cetirizine Dihydrochloride 10mg	FK-25-001	M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31-Km Ferozepur Road Lahore. (DML # 000395)	The sample is Substandard on the for Organic Impurities, performed as per USP.
2.	Tablet Megadip 5mg Each Tablet Contains: Amlodipine as Besylate 5mg (Reg. # 32876)	25G337	M/s Mega Pharmaceuticals Ltd. 27 Km Raiwind Road Lahore. (DML # 000537)	The sample is declared as "Sub-Standard" on the basis of Test for Impurities (Organic Impurities).

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.

to the
days.
(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, 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 recall at distributor level only.

Copy to:-

i. Area FID, to coordinate with concerned manufacturer regarding oversight of the recall process and also investigate as per para 13 of this letter.

Office copy

PA/DS (P)
SHC & ME
Diary No.
Date: 16/12/25
SO (RMC)
SO (PHP)
SO (OPs)
SO (ABs)
SO (TECH)

SECRETARY SHC&ME
Diary No. 11863
Date: 16/12/25
SS
AS
AS
AS
AS
DS
SL

Special Secretary (N&R)
Diary No.
Date: 11-12
AS (D)
AS (F)
AS (P)
AS (ME)
AS (M&IPU)
AS

Deputy Director - IX (QA<)

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15/12/25