DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/12-25-117

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 08th December, 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, Punjab informed that the sample of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Tablet Virtec 10 mg** Each Tablet Contains: Cetrizine 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).

Risk Statement:

The substandard quality of Tablet Virtec 10 mg (Cetirizine) and Tablet Megadip 5 mg (Amlodipine) due to failure in organic impurities testing poses a significant risk to public health. The populations most likely to be affected include patients suffering from allergies, hypertension, and cardiovascular diseases, particularly elderly individuals, children, and patients with chronic illnesses who regularly depend on these medicines for symptom control and disease management. The presence of excessive or unidentified organic impurities may lead to reduced therapeutic effect, unexpected side effects, toxic reactions, or long-term health complications**.** Continuous use of such substandard medicines may result in treatment failure, worsening of disease conditions, hospitalization, and in severe cases, life-threatening outcomes**,** thereby representing a serious public health concern.

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.

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk

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 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

محفوظ، موثر اور معیاری اشیائے علاج