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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/10-25-89

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 15th October, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Provincial Health Department informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Tablet Virtec** Each film coated tablet contains: Cetirizine Dihyrochloride 10 mg (Reg # 021870)	FK-24-007	M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31-Km Ferozepur Road Lahore. (DML # 000395)	Sample is **"Adulterated"** as defined under clause (iv) of sub-section (a) of section 3 of The Drugs Act, 1976 as it contains **"Paracetamol"** as an ingredient a substance other than the prescribed substance i.e., Cetirizine Hydrochloride.

Risk Statement:

The presence of an undeclared pharmacologically active substance poses a **serious risk to patient safety**, as it may lead to **unintended therapeutic effects, drug interactions, or dosing errors**, particularly in patients concurrently taking Paracetamol-containing preparations or with hepatic impairment.

This adulteration compromises the **safety, efficacy, and quality** of the product and indicates a **critical lapse in manufacturing and quality assurance systems** at the firm.

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.

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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
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