



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° II/S/03-26-08

DRUG PRODUCT DECLARED SUBSTANDARD BY DRUG TESTING LABORATORIES, PUNJAB.

Date: 11th March, 2026

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 of Punjab Province informed that the samples of below mentioned drug products have been declared as '*Substandard*'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	Tablet Sapizine 10 mg Each Tablet Contains: Cetirizine Dihydrochloride 10mg (Reg # 054261)	13208	M/s Sapient Pharma. 123-S Industrial Area Kot Lakhpat Lahore. (DML # 000207)	The sample has been declared " substandard " on the basis of organic impurities.

Risk Statement:

Tablet **Sapizine 10 mg (Cetirizine Dihydrochloride 10 mg)** has been declared *sub-standard* due to the presence of organic impurities beyond acceptable pharmacopeial limits. Elevated organic impurities may indicate degradation, poor manufacturing control, or inadequate storage conditions, potentially leading to reduced potency, altered pharmacological effect, or increased risk of adverse reactions such as hypersensitivity or gastrointestinal disturbances.

The population most likely to be affected includes general out-patient users, particularly children, elderly patients, and individuals with allergic rhinitis, urticaria, or other hypersensitivity conditions relying on consistent antihistaminic therapy. Although cetirizine is not a life-saving drug, compromised quality may result in therapeutic failure and unnecessary exposure to impurities.

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.

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).



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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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