



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° II/S/11-25-116

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 27th November, 2025

Target Audience:

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

Alert Summary:

Provincial Drug Testing Laboratories informed that the sample of below mentioned drug product has been declared as '**Substandard**'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	Tablet Sapizine 10 mg Each Tablet Contains: Cetirizine Dihydrochloride 10mg (Reg. # 054261)	13028	M/s Sapient Pharma, 123-S Industrial Area Kot Lakhat Lahore. (DML # 000207)	The sample has been declared substandard on the basis of Impurities Test (Organic Impurities).
2.	Tablet ORTIZIN 10mg Each Tablet Contains: Cetirizine Dihydrochloride 10mg (Reg. # 025405)	25C052	M/s Obsons Pharmaceuticals. 209-S Industrial Estate Kot Lakhat Lahore. (DML # 000416)	The sample has been declared substandard on the basis of Impurities Test (Organic Impurities).

Risk Statement:

Use of medicines containing excessive organic impurities may lead to reduced therapeutic effect, unpredictable adverse reactions, allergic responses, or toxicity, particularly in sensitive individuals such as children, pregnant women, and elderly patients. Since these products are commonly used for allergy related conditions, a large portion of the public, including patients self-medicating with over-the-counter antihistamines is most likely to be affected. Immediate discontinuation of the affected batches is advised to prevent potential harm.

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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