



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° II/S/09-25-64

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 15th September, 2025

Target Audience:

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

Alert Summary:

Directorate of Drugs Control Punjab (DDCP) informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been declared as '*Substandard*'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	Tablet Ortizin 10mg Each film coated tablet contains: Cetirizine 2HCl10 mg	24L377	M/s Obsons Pharmaceuticals. 209-S Industrial Estate Kot Lakhpat Lahore. (DML # 000416)	DDCP Alert No. 172/2025 declared the sample as ' substandard ' on the basis of assay and impurities testing .
2.	Tablet Daisy 10 mg Each film coated tablet contains: Cetirizine 2HCl10 mg	25B084 & 25B085	M/s Mega Pharmaceuticals Ltd. 27 Km Raiwind Road Lahore. (DML # 000537)	DDCP Alert No. 172/2025 declared the sample as ' substandard ' on the basis of impurities testing (Organic impurities) .
3.	Tablet Ascard 75 Each enteric coated tablet contains: Acetyl Salicylic acid 75 mg	AR076K	M/s Atco Laboratories Limited. B-18 S.I.T.E Karachi. (DML # 000188)	DDCP Alert No. 173/2025 declared the sample as ' substandard ' on the basis of test for related substance (Impurity C: Salicylic Acid) .
4.	Tablet Bytec 10mg Each film coated tablet contains: Cetirizine 2HCl10 mg	E604, E605 & E606	M/s Batala Pharmaceuticals. 23/B Small Industrial Estate No. 2 Gujranwala. (DML # 000477)	DDCP Alert No. 179/2025 declared the sample as ' substandard ' on the basis of impurities testing .
5.	Tablet Vivin 10 mg Each film coated tablet contains: Cetirizine 2HCl10 mg	315	M/s Murfy Pharmaceuticals (Pvt) Ltd. 8-Km Raiwind Road Lahore. (DML # 000543)	DDCP Alert No. 179/2025 declared the sample as ' substandard ' on the basis of impurities testing .



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Risk Statement:

The above-mentioned batches of tablets have been declared *substandard* due to failure in assay and impurities testing, including elevated levels of related substances. Use of these defective medicines may lead to reduced therapeutic effect, unpredictable side effects, and potential toxicity.

Patients, pharmacists, and healthcare providers are advised to discontinue the affected batches immediately and report any adverse events to DRAP.

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).

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