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

# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº I/S/11-25-109

**DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.**

**Date:** 17th November, 2025

**Target Audience:**

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

**Alert Summary:**

Central Drugs Laboratory informed that the sample of below mentioned drug product has been declared as '***Substandard***'.

| S# | Product Name | Batch No. | Manufacturers | Remarks |
|---|---|---|---|---|
| 1. | **Zayzine Syrup**<br>Each 5 ml Contains:<br>Cetirizine Dihydrochloride … 5 mg<br>(Reg # 096969) | 25289 | M/s Zaynoon Pharmaceuticals (Pvt) Ltd.<br>27-28/B, Industrial Estate, Hayatabad, Peshawar<br>(DML # 000358) | The sample has been declared Substandard on the basis of the Assay Test and Physical Description, as the syrup was found to be a clear, colourless liquid in an amber plastic bottle, whereas the manufacturer's specification describes it as a light green, translucent, viscous, and sugar-free preparation. |

**Risk Statement:**

As the product was found to contain excessive amount of the labeled active ingredient and to differ in appearance from the approved specifications. **The excessive assay value indicates** overdose of Cetirizine Dihydrochloride**,** which may cause drowsiness, dizziness, headache, or other antihistaminic side effects**,** particularly in children and sensitive individuals for whom this syrup is commonly prescribed. The defect therefore poses a potential risk to public health, especially in pediatric and allergic patients, and warrants a **Class I recall** of the affected batch to prevent further exposure and ensure patient safety.

**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