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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/02-26-02

DRUG PRODUCT DECLARED SUBSTANDARD & ADULTERATED BY DRUG TESTING LABORATORIES, PUNJAB.

Date: 12th February, 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 & Adulterated***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**TABLET ASCARD-75** Each enteric coated tablet contains: Acetylsalicylic Acid (Aspirin) 75mg (Reg # 016600)	AR065L, AR047L	M/s Atco Laboratories Limited. B-18 S.I.T.E Karachi. (DML # 000188)	The sample has been declared **"Substandard"** with respect to test performed for **"Related Substances"**
2.	**Tablet Daisy 10 mg** Each film coated tablet contains: Cetirizine dihydrochloride USP 10mg (Reg # 032865)	24F213	M/s Mega Pharmaceuticals Ltd. 27 Km Raiwind Road Lahore (DML # 000537)	The sample has been declared **"Sub-Standard"** with regards to Impurities Tests.
3.	**Tablet Sapizine 10 mg** Each Tablet Contains: Cetrizine Dihydrochloride 10mg (Reg # 054261)	13098	M/s Sapient Pharma. 123-S Industrial Area Kot Lakhpat Lahore. (DML # 000207)	The sample has been declared **"Sub-Standard"** with regards to Impurities Tests.
4.	**Tablet Rozen 10mg** Each Tablet Contains: Cetrizine Dihydrochloride 10mg (Reg # 040161)	5F006	M/s Rasco Pharma (Pvt) Ltd. 5.5 Km Raiwind Road Ali Razabad, Lahore. (DML # 000530)	The sample has been declared **"Sub-Standard"** with regards to Impurities Tests.
5.	**Cream Kanadex-N** Each gram contains: Dexamethasone-21 phosphate in the form of disodium salt 1mg Neomycin in the form of sulphate 3500I.U **(Reg #** 012475**)**	17-54, C8-26	M/s ISIS Pharmaceutical & Chemical Works. 25/1-3 Sector 12-C North Karachi Industrial Area Karachi. (DML # 000126)	The sample is declared **"Substandard"** on the basis of the **assay of Dexamethasone Phosphate (as disodium salt),** and **"Adulterated"** on the basis of the **identification and quantification of Dexamethasone (base)** in HPLC analysis (which is an **undeclared active pharmaceutical ingredient not stated on the product label.**

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk

Risk Statement:

These products present a **moderate to high public health risk**, mainly affecting the **general outpatient population**, especially **cardiac patients, allergy sufferers, children, and chronic medicine users**. Substandard aspirin (Ascard-75) with excessive related substances may increase the risk of **gastrointestinal irritation, bleeding, or reduced cardiovascular protection** in patients using it for long-term prevention of heart attack or stroke. Multiple cetirizine brands failing impurity tests could expose the public—particularly **children and individuals with liver or kidney compromise**—to **unexpected toxic effects or reduced safety margins**, even though the medicine is generally used for minor allergic conditions. The highest concern is **Kanadex-N cream**, where adulteration with an undeclared corticosteroid base can lead to **misuse, skin thinning, hormonal suppression, masking of infections, and serious harm in infants or prolonged users**, making dermatology patients and self-medicating consumers the most likely to be affected.

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

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk