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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/09-25-78

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 25th 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 drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Tablet Ascard-75** Each enteric coated tablet contains: Acetylsalicylic Acid (Aspirin BP).....75 mg	AR046L	M/s Atco Laboratories Limited, B-18 S.I.T.E Karachi. (DML # 000188)	**'Sub-Standard'** with regards to Related Substances Test (Impurity C: Salicylic Acid).

Risk Statement:

The Drug Testing Laboratory has declared the given sample as **'substandard'** on basis of failure in the **Related Substances Test**, showing the presence of **Impurity C (Salicylic Acid)** beyond the permissible pharmacopeial limits. The presence of such impurity may lead to adverse effects including gastric irritation and related complications, particularly in sensitive patient populations. While not considered immediately life-threatening, this defect poses a significant quality concern that may cause temporary or medically reversible adverse health consequences.

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
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