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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/01-26-131

DRUG PRODUCTS DECLARED SUBSTANDARD BY DRUG TESTING LABORATORIES PUNJAB.

Date: 14th January, 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 Provinces informed that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Tablet. Megadip** Each tablel contains: Amlodipine as Besylate USP.... 5mg (Reg. # 071447)	25F278	M/s Mega Pharmaceuticals Ltd. 27 Km Raiwind Road Lahore (DML # 000537)	The samples have been declared Sub-standard with regards to Impurities test.
2.	**Tablet Ascard 75 mg** Each Enteric Coated Tablet contains: Aspirin 75 mg (Reg # 016600)	AR049L	M/s Atco Laboratories Limited, B-18 S.I.T.E Karachi. (DML # 000188)	The samples have been declared Sub-standard with regards to Test for Related substances (Impurity C: Salicylic Acid).
4.	**Tablet CENEX 10 mg** Cetirizine dihydrochloride 10mg (Reg # 032103)	422	M/s Dr. Raza Pharma. Road B-4 P.No 44-C Indus: Estate Jamrud Road Peshawar. (DML # 000387)	The sample is declared as "Sub-Standard" on the basis of test for Impurities i.e. Organic Impurities.
5.	**Tablet Valron-P** Each Sugar Coated Tablet contains: Diclofenac Sodium …. 50 mg (Reg # 030760)	T-03624	M/s Venus Pharma. 23 Km Multan Road Lahore. (DML # 000300)	The sample is declared as "Sub-Standard" on the basis of Disintegration and Dissolution Test.

Risk Statement:

The presence of **excessive impurities, toxic contaminants, and performance failures** in **Megadip (amlodipine), Ascard (aspirin), Entagyl suspension (metronidazole), Cenex (cetirizine), and Valron-P (diclofenac)** poses a **significant risk to patient safety**. Elevated levels of impurities, including **salicylic acid, organic impurities, and ethylene glycol**, may lead to **toxicity, organ damage, allergic reactions, and gastrointestinal or neurological**

complications, while poor **disintegration and dissolution** can cause **treatment failure or unpredictable dosing**. The **public most likely to be affected** includes **patients with heart disease, hypertension, infections, allergies, and chronic pain**, particularly **elderly patients, children, and those with kidney, liver, or cardiovascular disorders**, where compromised medicine quality may result in **serious and potentially life-threatening outcomes**.

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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