MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/01-25-16

SUBSTANDARD PRODUCTS DECLARED BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 07th January, 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 (DDC) Punjab has informed DRAP that samples below product has been reported substandard due to presence of impurities by Drug Testing Laboratory (DTL) Lahore:

S#	Product Name	Batch No.	Manufactured by	Test Results
1	AMLOShine 10mg (Amlodipine 10mg)	7180	Sunshine Pharmaceuticals, Khan Payara, Near Saim Nala, Eimanabad road, Gujranwala	Substandard
2	Bytec tablet (Cetrizine 2HCl 10mg)	E088	Batala Pharmaceuticals, 23/B Small Industrial Estate #2, Gujranwala	Substandard

Risk Statement:

Use of substandard products can lead to therapy failure which can increase chances of complications in susceptible users including immunocompromised patients, pediatric and geriatric population.

Action initiated:

The regulatory field force of DRAP and Provincial Drug Control departments have been requested to immediately conduct market surveys for detection and removal of these products from the market.

Advice for Healthcare Professionals:

DRAP urges heightened vigilance in affected supply chains and requests reporting of adverse reactions or quality issues to the National Pharmacovigilance Centre (NPC), DRAP via the Adverse Event Reporting Form or online via this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers / general public:

Consumers with the affected batches should report to the Drug Regulatory Authority of Pakistan (DRAP) and consult their healthcare provider if they experience any issues related to the drug.

Drug Regulatory Authority of Pakistan
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