



MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/05-25-45

PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 02nd June, 2025

Target Audience:

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

Alert Summary:

The Directorate of Drug Control (DDC) Punjab, has informed Drug Regulatory Authority of Pakistan (DRAP) that the samples of below mentioned products have been reported as '**Substandard**'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	AMLOshine Tablet Each tablet contains: Amlodipine as besylate.....5mg Reg. No. 062420	7840	M/s. Sunshine Pharmaceuticals, Khan Payara, Near Saim Nala, Emanabad Gujranwala - Pakistan.	' Substandard ' on the basis of Impurities test.
2.	AMLOshine Tablet Each tablet contains: Amlodipine as besylate.....5mg Reg. No. 062420	7623	M/s. Sunshine Pharmaceuticals, Khan Payara, Near Saim Nala, Emanabad Gujranwala - Pakistan.	' Substandard ' on the basis of Impurities test.
3.	AMLOshine Tablet Each tablet contains: Amlodipine as besylate.....10mg Reg. No. 062419	7361	M/s. Sunshine Pharmaceuticals, Khan Payara, Near Saim Nala, Emanabad Gujranwala - Pakistan.	' Substandard ' on the basis of Impurities test.



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4.	FLAZOL Infusion 100mL Each 100ml vial contains: Metronidazole....500mg Reg. No. 070611	F250028	M/s Bosch Pharmaceuticals (Pvt) Ltd., 209, Sector 23, Korangi Industrial Area, Karachi.	‘Substandard’ on the basis of Bacterial Endotoxin Test.
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Risk Statement:

The use of substandard products can result in therapy failure, increasing the risk of complications, particularly in vulnerable groups such as immunocompromised individuals, as well as pediatric and geriatric population.

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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