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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/09-25-80

Immediate Withdrawal of all batches of AMLOshine Tablet 5mg (Reg # 062420) & Tablet AMLOshine 10 mg (Reg. # 062419) manufactured by M/s Sunshine Pharmaceuticals

Date: 26th September, 2025

Target Audience:

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

Alert Summary:

In continuation to **DRAP Alert No. NºII/S/05-25-45** dated 2nd June 2025, wherein three batches (7840, 7623, 7361) of **Tablet AMLOshine 5mg** [contains Amlodipine (as Beysalte) 5mg] bearing Reg. # 62420, and manufactured by **M/s Sunshine Pharmaceuticals. Emanabad, G.T. Road, Gujranwala (DML # 000662)** declared **'substandard'** by Provincial Drug Testing Laboratory on the basis of impurities testing.

The panel of inspectors of DRAP accordingly conducted inspection at manufacturing unit of **M/s. Sunshine Pharmaceuticals, Khan Payara, Near Saim Nala, Emanabad, Gujranwala**, revealed multiple critical non-compliances with Good Manufacturing Practices (GMP). These included the absence of vendor qualification, failure to perform impurities testing and analytical method validation, unjustified use of API overages, lack of process validation, failure to investigate assay deviations observed in stability data, and the non-availability of impurity reference standards. **The panel advised firm to initiate an immediate recall of** all batches of AMLOshine Tablet 5mg (Reg # 062420) & Tablet AMLOshine 10 mg (Reg. # 062419)**.**

Registration of Tablet AMLOshine 5 mg (Reg. #062420) and Tablet AMLOshine 10 mg (Reg. # 062419) are under suspension proceedings.

Risk Statement:

The presence of impurities, lack of validated testing, and failure to investigate assay deviations in AMLOshine Tablets may compromise product quality, leading to reduced therapeutic efficacy and potential treatment failure in patients requiring amlodipine for hypertension and cardiovascular conditions. Such deficiencies may also expose patients to unpredictable adverse effects, particularly among the elderly, long-term users, and those with comorbidities. In view of the nature of defect and potential health risks, the issue is classified as a **Class II Recall**, as the defect may cause illness or treatment failure but is not considered immediately life-threatening.

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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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