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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/03-26-16

DRUG PRODUCT DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.

Date: 11th March, 2026

Target Audience:

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

Alert Summary:

Central Drugs Laboratory Karachi informed that the samples of below mentioned drug product has been declared as '***Substandard***'.

S#	Product Name	Batch	Manufacturers	Remarks
1.	**Santochlor ophthalmic Solution** Chloramphenicol 5mg/ml (Reg # 021605)	D-330	M/s Sante (Pvt) Ltd. A/97 S.I.T.E Super Highway Karachi. (DML # 000702)	The sample has been declared **"substandard"** on the basis of assay test.
2.	**Ciprozat Tablet** Ciprofloxacin 500mg/ per tablet (Reg # 031221)	2421	M/s Hizat Pharmaceutical Industry. 170 Industrial Estate Jamrud Road Peshawar. (DML # 000315)	The sample has been declared **"substandard"** on the basis of dissolution test.

Risk Statement:

The above-mentioned batches of Santochlor Ophthalmic Solution (Chloramphenicol 5mg/ml) and Ciprozat Tablet (Ciprofloxacin 500mg) have been declared Substandard based on failure of assay and dissolution tests respectively. Substandard ophthalmic chloramphenicol may result in inadequate treatment of bacterial eye infections, leading to prolonged infection, worsening inflammation, or potential complications affecting vision. Substandard ciprofloxacin tablets may cause reduced therapeutic response in bacterial infections, increasing the risk of treatment failure, antimicrobial resistance, and disease progression.

The most likely affected population includes patients suffering from eye infections and individuals being treated for bacterial infections, particularly those requiring timely and effective antibiotic therapy. Healthcare professionals are advised to discontinue use of the affected batches and ensure availability of quality-assured alternatives.

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

محفوظ، موثر اور معیاری اشیائے علاج