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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/01-26-134

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUG LABORATORY KARACHI.

Date: 21st January, 2026

Target Audience:

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

Alert Summary:

Central Drug Laboratory Karachi informed that the sample of below mentioned drug products has been declared as '***Substandard***'.

S#	Product Name	Batch	Manufacturers	Remarks
1.	**Henafim Paediatric Suspension** Each 5ml contains: Paracetamol …. 120mg Chlorphineramine Maleate …. 1mg **(Reg. # 078545)**	558	M/s Wisdom Pharmaceutical Industry. (DML # 000780) 78-A Industrial Estate Hayatabad Peshawar.	The samples have been declared "Sub-Standard" on the basis of assay test of Paracetamol (71%) & Chlorpheniramine Maleate (81%).

Risk Statement:

The use of **Henafim Paediatric Suspension, Batch No. 558**, poses a **potential risk to public health**, particularly affecting **infants and children**, who are the primary users of this product for the management of fever, pain, and allergic symptoms. The product has been declared **sub-standard due to low assay results of Paracetamol (71%) and Chlorpheniramine Maleate (81%)**, which may lead to **inadequate therapeutic response**, resulting in **poor fever control, persistent discomfort, and unresolved allergic symptoms**. This may prompt caregivers to administer **repeated or higher doses**, increasing the risk of **medication misuse**. Although not adulterated, the reduced potency of this paediatric formulation may compromise effective treatment in a **vulnerable population**, warranting regulatory attention and appropriate risk management.

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.

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk

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