



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

### MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/01-26-133

**DRUG PRODUCT DECLARED SUBSTANDARD & ADULTERATED BY DRUG TESTING LABORATORIES, PUNJAB.**

**Date:** 21<sup>st</sup> January, 2026

#### Target Audience:

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

#### Alert Summary:

Drug Testing Laboratories of Punjab Province informed that the samples of below mentioned drug products have been declared as '*Substandard & Adulterated*'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	<b>Tablet. BP-NORM</b> Atenolol ... 50mg (Reg. # 071447)	5968P485	M/s Neutro Pharma (Pvt) Ltd. 9.5-Km Sheikhpura Road Lahore. (DML # 000576)	The sample has been declared <b>Substandard</b> on the basis of <b>failed assay of Atenolol, &amp; Adulterated</b> as per Section 3 (a) (v) of The Drugs Act 1976 ( <i>confirmed presence of an undeclared active ingredient i.e. Ciprofloxacin HCl</i> )

#### Risk Statement:

The use of **BP-NORM (Atenolol 50 mg)**, **Batch No. 5968P485**, presents a **serious risk to public health**, particularly for **patients with cardiovascular diseases** such as hypertension, ischemic heart disease, arrhythmias, and the elderly who depend on consistent atenolol therapy. The product is **substandard due to failed assay of atenolol**, which may result in **loss of therapeutic control**, and is **adulterated by the confirmed presence of an undeclared active ingredient, Ciprofloxacin HCl**. This may expose patients to **unintended antibiotic intake**, leading to **adverse reactions, drug interactions, and development of antimicrobial resistance**, especially in vulnerable patients. Continued use of this batch may therefore cause **significant harm**, warranting immediate risk mitigation.

#### 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.



## DRUG REGULATORY AUTHORITY OF PAKISTAN

### DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

#### 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



DRAP, Islamabad



+92 051 9255969



gsms@dra.gov.pk