



DRUG REGULATORY AUTHORITY OF PAKISTAN

Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: N° I/S/06-26-33

SPURIOUS DRUG PRODUCTS (NOVIDAT 500MG Tablets and TONOFLEX-P Tablets)

Date: 03rd June, 2026

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

The Drug Regulatory Authority of Pakistan (DRAP) has received test and analysis reports from the Provincial Drug Testing Laboratory, Punjab, regarding the following drug products sampled from the market. The laboratory has declared the products **Spurious** under Section 3(zb)(i) of the Drugs Act, 1976. Further investigation conducted by the manufacturer, SAMI Pharmaceuticals (Pvt.) Ltd., confirmed that the products were **not manufactured by the company** and are falsified/spurious.

S#	Product Name	Batch	Manufacturer	Remarks
1	NOVIDAT 500mg Tablets Ciprofloxacin HCl equivalent to Ciprofloxacin 500mg (Reg. No. 011837)	139N086	<i>Purportedly manufactured under license of SAMI Pharmaceuticals (Pvt.) Ltd., Karachi</i>	Spurious. Assay result showed 0.00 mg/tablet against the stated strength of 500 mg/tablet.
2	TONOFLEX-P Tablets Tramadol HCl 37.5mg + Paracetamol 325mg (Reg # 067163)	248N105		Spurious. Assay results showed 0.00 mg/tablet for both active ingredients against the stated strengths of 37.5 mg and 325 mg, respectively.

Risk Statement:

The presence of spurious medicines containing no detectable active pharmaceutical ingredients poses a serious risk to public health due to treatment failure, disease progression, and potential harm to patients relying on these products. Healthcare professionals and supply chain stakeholders are advised to remain vigilant and immediately report any information regarding the availability or distribution of the above-mentioned batches.

Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.



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Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using [Adverse Event Reporting Form](#) or online through this [link](#). Further information on reporting problems to DRAP is available on this [link](#).

Advice for Consumers:

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre. All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.



Drug Regulatory Authority of Pakistan

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