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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-26-66

Substandard Tycin-D Ophthalmic Suspension by Welmed Pharmaceutical Industries (Pvt) Ltd., Swabi

Date: 27th November, 2026

Target Audience:

- National Regulatory Field Force
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Drugs Testing Laboratory (DTL) Punjab, Faisalabad has declared the below-mentioned product as "Substandard" on the basis of sterility testing.

Following are the details:

S#	Product Name	Batch	Manufacturer	Remarks
1.	Tycin-D Ophthalmic Suspension Each mL of suspension contains: Tobramycin……3mg Dexamethason……1mg	809E	**Mfg by:** Winthrox Laboratories (pvt) Ltd., K-219/A SITE Super Highway Phase II Karachi **Mfg for:** Welmed Pharmaceutical Industries (Pvt) Ltd., Plot No. 108, R-2, Industrial Estate Gadoon, Swabi.	The product is declared as "Substandard" on the basis of sterility testing.

Risk Statement:

Administration of a non-sterile product may expose patients to serious adverse health consequences, including localized infections, systemic infections, sepsis, and other potentially complications, particularly in vulnerable or immunocompromised individuals.

Action initiated: -

The Provincial Drug Control departments have been asked to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Manufacturer has been directed to initiate recall of the affected batches in accordance with applicable regulatory requirements.

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).

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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