

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Eugia US LLC (f/k/a AuroMedics Pharma LLC) has initiated a recall to the Retailer level for the product **Tobramycin for Injection USP, 1.2g/vial** from the US market.

Considering the Out of Specification (OOS) received for product Tobramycin for Injection USP, 1.2g/vial, 50ml vial, Batch. No.: 3TB23001,3TB23002 USA Market 06 Month(s) long term condition stability (25°C/60% RH, Invert) for the test" Water determination ( $\frac{3}{4}$ w/w, by KF)", the obtained result is 2.30 % w/w which is not complying with specification limit NMT 2.0 %.

Tobramycin is indicated for the treatment of serious bacterial infections caused by susceptible strains of the designated microorganisms in the diseases.

Tobramycin sulfate, a water-soluble antibiotic of the aminoglycoside group, is derived from the actinomycete *Streptomyces tenebrarius*. Tobramycin for injection, USP is supplied as a sterile white to off-white lyophilized powder or cake and is intended for reconstitution with 30 mL of Sterile Water for Injection, USP. Sulfuric acid and/ or sodium hydroxide may have been added during manufacture to adjust the pH between 6.0 and 8.0. Each vial contains tobramycin sulfate equivalent to 1,200 mg of tobramycin, USP. After reconstitution, the solution will contain 40 mg of tobramycin, USP per mL. The product contains no preservative or sodium bisulfite.

Eugia US LLC (f/k/a AuroMedics Pharma LLC) began shipping this batch to customers nationwide July 18, 2023.

## **NDC 55150-470-06 (For Eugia US LLC f/k/a AuroMedics Pharma LLC)**

<b>Sr.No.</b>	<b>Batch number</b>	<b>Expiry date</b>
1.	3TB23001	04/2025
2.	3TB23002	04/2025

**\* NDC 55150-470-06 contains 6 vials of NDC 55150-470-01**