

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 Wholesale level for the product Gentamicin Injection USP 20mg/2ml (10mg/ml) (Single Dose Vial)- from the USA market due to OOS (Out of specification results) in the commercial stability, at long term condition ((25°C ±2°C/60%RH ± 5% Invert), during 12 Month(s) sample analysis in the batch no's: 3GT23006, 3GT23007 and 3GT23008 in the test Color Absorbance (AU at 430 nm) is not complying with specification (NMT 0.05)(Reference OOS: E3OOS250005).

Gentamicin sulfate, USP, a water-soluble antibiotic of the aminoglycoside group, is derived from Micromonospora purpurea, an actinomycete. Gentamicin injection, USP is a sterile, nonpyrogenic, aqueous solution for parenteral administration. Each mL of the preservative free product contains: Gentamicin sulfate, USP equivalent to gentamicin 10 mg; water for injection q.s. sulfuric acid and/or sodium hydroxide may have been added for pH adjustment (3 to 5.5).

Injecting Gentamicin injection with degradation products may reduce the drug's efficacy and potential adverse health effects.

PRODUCT NAME: Gentamicin Injection USP
20mg/2ml (10mg/ml) (Single Dose Vial)

NDC NUMBER: 55150-401-25(Carton) &
NDC 55150-401-01(Vial Label)

3GT23006

BATCH
NUMBERS:

3GT23007

3GT23008

EXPIRATION
DATE:

NOVEMBER
2025