

*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 **Dexamethasone sodium phosphate injection USP 120mg/30mL (MDV)** from the US market due to OOS (Out of specification results) for commercial stability at (25°C ± 2°C/60% RH± 5% RH, 436 Day(s) Invert) analysis of “Dexamethasone Sodium Phosphate Injection USP 120 mg/30 mL (4 mg/mL) [Multiple Dose Vial] Batch No: 3DS23001, 3DS23009 and 3DS23011 for the test 'Sulfonic acid adduct of Dexamethasone phosphate', the obtained result (6.134%, 5.883% & 6.234%) found not meeting with the specification limit (NMT 5.5%) as per OOS No. E3OOS240071 & E3OOS240077.

As an impact assessment for the subject OOS (OOS No. E3OOS240071 & E3OOS240077), marketed batches of above 14 months age sample analysis was performed and results for 3DS23004 (17 months) is close to the specification limit i.e. 5.457 % for Sulfonic acid adduct of Dexamethasone phosphate (Limit: NMT 5.5%) (Shelf life of the product is 18 months). Hence as an abundant precaution, batch number 3DS23004 is also subjected for recall.

Dexamethasone sodium phosphate injection USP is a sterile, clear, colorless solution, free from visible particles and a water-soluble inorganic ester of dexamethasone which produces a rapid response even when injected intramuscularly.

It occurs as a white to practically white powder, is exceedingly hygroscopic, is soluble in water and its

solutions have a pH between 7.0 and 8.5. Each mL of dexamethasone sodium phosphate injection USP, 4 mg/mL, contains 4.37 mg of dexamethasone sodium phosphate, USP equivalent to 4 mg dexamethasone phosphate; 1 mg sodium sulfite; 10 mg benzyl alcohol (preservative). Made isotonic with sodium citrate. pH adjusted with citric acid or sodium hydroxide. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Eugia US LLC (f/k:/a AuroMedics Pharma LLC) began shipping this batch to customers nationwide 24Feb2023.

<b>Sr.No.</b>	<b>Batch number</b>	<b>Expiry date</b>
1.	3DS23001	JUN 2024
2.	3DS23004	JUN 2024
3.	3DS23009	JUL 2024

4. 3DS23011

JUL 2024