

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.

Aurobindo Pharma USA, Inc. has initiated a voluntary Drug Recall at the Retail Level for the product **Clorazepate Dipotassium Tablets USP 3.75 mg and Clorazepate Dipotassium Tablets USP 7.5 mg** from USA market due to confirmed consumer complaint received with the observation “dotted and yellowish color spots on tablets”.

Clorazepate Dipotassium Tablets USP are indicated for management of anxiety disorder or for the short-term relief of symptoms of anxiety. Clorazepate dipotassium tablets are also indicated as adjunctive therapy in the management of partial seizures. To date, Aurobindo has not received any reports of adverse drug events that are confirmed with this recall.

As per the product information leaflet, **Clorazepate Dipotassium Tablets USP 3.75 mg** are “Mottled blue colored, round, flat face tablets, debossed with “CL” and “11” separated by score-line on one side and plain on other side and **Clorazepate Dipotassium Tablets USP 7.5 mg** are “Mottled peach colored, round flat face tablets, debossed with “CL” and “14” separated by score-line on one side and plain on other side”.

Aurobindo USA began shipping of impacted batches from 02/29/2024 to 04/16/2024.

Product Name: Clorazepate Dipotassium Tablets USP 3.75 mg

Sr. No	Pack Size	NDC No	Batch No	Exp Date
1.	500's Count HDPE Bottle	13107-282-05	CZA124001A	Dec-2025
2.	100's Count HDPE Bottle	13107-282-01	CZA124001B	Dec-2025
3.	100's Count HDPE Bottle	13107-282-01	CZA124002B	Dec-2025
4.	500's Count HDPE Bottle	13107-282-05	CZA124003A	Dec-2025
5.	100's Count HDPE Bottle	13107-282-01	CZA124003B	Dec-2025

Product Name: Clorazepate Dipotassium Tablets USP 7.5 mg

Sr. No	Pack Size	NDC No	Batch No	Exp Date
1.	500's Count HDPE Bottle	13107-283-05	CZB124001A	Dec-2025
2.	100's Counts HDPE Bottle	13107-283-01	CZB124001B	Dec-2025
3.	100's Count HDPE Bottle	13107-283-01	CZB124002B	Dec-2025
4.	500's Count HDPE Bottle	13107-283-05	CZB124003A	Dec-2025
5.	100's Count HDPE Bottle	13107-283-01	CZB124003B	Dec-2025