

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.

This is to inform you that Glenmark is initiating a Market Withdrawal at the Retail level involving Atomoxetine Capsules USP 10 mg.

Out-of-trend (OOT) results were reported in Atomoxetine Capsules USP 10mg for batch# 19243299 (Expiry-July 2026), 19243300 (Expiry - July 2026), and 19243324 (Expiry - July 2026) at long term (25°C/60% RH) 18 month time interval, wherein the N-Nitroso Atomoxetine impurity results observed above the OOT criteria of not more than 0.5 ppm (Internal OOT limit is Not More than 50% of Specification). The results for N-Nitroso Atomoxetine impurity comply with the registered specification of NMT 1.0 ppm. The shelf life of these batches is 24 months.

The statistical predictive analysis was performed for N-Nitroso Atomoxetine impurity of the abovementioned OOT batches, and it is observed that the N-Nitroso Atomoxetine impurity results at the terminal time point (Expiry) of 24 months are likely to be towards the higher side of the specification or Out of Specification (OOS), though meeting the specification currently. Hence, as an abundance of caution, Glenmark is initiating a market withdrawal of all four (4) within-shelf-life batches of Atomoxetine Capsules USP 10 mg manufactured with 24-month shelf life. There has been no failure observed as of today for these 4 batches. For Atomoxetine Capsules USP 10 mg, Glenmark filed CBE-30 for reduction in shelf life from 24 months to 18 months. Subsequently, the CBE-30 was approved on February 18, 2025, and the change was made effective from March 1, 2025. Further, Atomoxetine Capsules USP 10 mg commercial batches are manufactured with an 18-month shelf life. As of today, a total of four (4) batches of Atomoxetine Capsules USP 10 mg have been manufactured with 24-month shelf life before the shelf-life reduction to 18 months, which are within shelf life and proposed for market withdrawal.

Glenmark Pharmaceuticals Inc., USA, initiated shipment of this product on October 17, 2024.

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
1	68462-265-30	19243299	30 Capsules in Container Pack	July 2026
2	68462-265-30	19243300	30 Capsules in Container Pack	July 2026

3	68462-265-30	19244394	30 Capsules in Container Pack	October 2026
4	68462-265-30	19244395	30 Capsules in Container Pack	October 2026