

*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 recall at the Retail level involving Theophylline Extended-Release Tablets 400 mg (100's Tablets).

The recall to the retail level of the below-identified Theophylline Extended-Release Tablets 400 mg batches have been initiated due to failure results were reported for the Dissolution (By UV) test for commercial annual stability batch #19230553 of Theophylline Extended-Release Tablets 400mg at the long-term (25°C/60% RH) shelf life stability interval, wherein the dissolution results do not comply with L3 stage dissolution criteria.

As part of impact assessment testing, Theophylline Extended-Release Tablets 400mg batches within the shelf life were tested for dissolution. During this testing, failure results are reported for batch # 19243193, 19243215, 19243231, 19243248, 19243283, 19244561, 19244530, and 19250178.

Since the failure results in dissolution test are observed in 8 out of 27 batches of Theophylline Extended-Release Tablets 400mg, a recall is proposed for these eight (8) batches of Theophylline Extended-Release Tablets 400mg that are within shelf life. To date, Glenmark has not received any reports of adverse events related to this recall. The Health hazard assessment concluded that the observed OOS results in dissolution testing for the concerned batches of Theophylline Extended-Release Tablets 400mg are not expected to pose a clinically significant risk to patient health and safety.

Theophylline Extended-Release Tablets 400 mg (100's Tablets)

<b>Sr. No.</b>	<b>NDC Code</b>	<b>Batch</b>	<b>Pack Size</b>	<b>Expiry Date</b>
1	68462-380-01	19243193	100's Tablets	Jul-2026
2	68462-380-01	19243215	100's Tablets	Jul-2026
3	68462-380-01	19243231	100's Tablets	Jul-2026
4	68462-380-01	19243248	100's Tablets	Jul-2026
5	68462-380-01	19243283	100's Tablets	Jul-2026
6	68462-380-01	19244530	100's Tablets	Oct-2026
7	68462-380-01	19244561	100's Tablets	Oct-2026

8

68462-380-01

19250178

100's Tablets

Dec-2026