

*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.*

Glenmark is initiating a market withdrawal at the **Retail level** for the below-identified batches of Theophylline Extended-Release Tablets 400 mg 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. The batch already expired in January 2025; hence no market action is warranted.

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 in 8 out of 27 batches of Theophylline Extended-Release Tablets 400mg. A voluntary recall is being initiated for these eight (8) batches that are within shelf life. As an abundance of caution, Glenmark is initiating market withdrawal of the remaining below mentioned 19 batches of Theophylline Extended-Release Tablets 400mg that are within shelf life wherein the Dissolution test results are complying with the Dissolution specification criteria when tested as part of impact assessment.

To date, Glenmark has not received any reports of adverse events related to this market withdrawal. The Health hazard assessment (HHA) 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 USP 400 mg (100's Tablets)**

<b>Sr.No.</b>	<b>NDC Code</b>	<b>Batch No.</b>	<b>Pack Size</b>	<b>Exp. Date</b>
1	68462-380-01	19233993	100's Tablets	Sep-2025
2	68462-380-01	19234027	100's Tablets	Sep-2025
3	68462-380-01	19234047	100's Tablets	Sep-2025
4	68462-380-01	19234070	100's Tablets	Sep-2025
5	68462-380-01	19234079	100's Tablets	Sep-2025

6	68462-380-01	19234093	100's Tablets	Sep-2025
7	68462-380-01	19234114	100's Tablets	Sep-2025
8	68462-380-01	19234385	100's Tablets	Oct-2025
9	68462-380-01	19234427	100's Tablets	Oct-2025
10	68462-380-01	19234459	100's Tablets	Oct-2025
11	68462-380-01	19234462	100's Tablets	Oct-2025
12	68462-380-01	19240385	100's Tablets	Dec-2025
13	68462-380-01	19240437	100's Tablets	Jan-2026
<b>14</b>	68462-380-01	19241185	100's Tablets	Feb-2026
15	68462-380-01	19241197	100's Tablets	Feb-2026
16	68462-380-01	19241220	100's Tablets	Feb-2026
17	68462-380-01	19241238	100's Tablets	Feb-2026
18	68462-380-01	19244538	100's Tablets	Oct-2026
19	68462-380-01	19250174	100's Tablets	Dec-2026