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 Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Viorele) due to failure results reported for the Related Substances (By HPLC) test for commercial annual stability batch# 20230733 at the long-term (25°C/60% RH) 18 month time stability interval. Recall is being initiated for batch# 20230733 separately.

Glenmark filed Prior Approval Supplement (PAS) and received the approval on April 25, 2024, to change the drug product formula to control the degradation of 'Impurity D' and 'Total impurities' since the product is sensitive to peroxide degradation (Oxygen). The revised manufacturing formulation is implemented from July 2024. All the batches manufactured post July 2024 are manufactured using the revised formulation.

As of today, three (3) batches of Viorele tablets are in the market and within shelf life that have been manufactured before the implementation of the revised formulation. Out of these 3 batches, subject OOS batch# 20230733 was charged as the annual stability batch for the year 2023. As part of the impact assessment, reserve sample of the other two (2) batches were tested for Related Substances (By HPLC), and the results comply as per the specification.

Hence, as an abundance of caution, Glenmark is initiating a market withdrawal of both these batches# 20240086 (Expiry - January 2026) and# 20240128 (Expiry - February 2026) that are within shelf life, and manufactured before the implementation of the revised formulation.

To date, Glenmark has not received any reports of adverse events related to this subjected batches. The health hazard assessment concluded that the observed OOS results in related substance test are not considered a clinically significant risk to patient health and safety.

Sr. No.	NDC	Batch Number	Pack Size	Expiry Date
1	68462-318-29	20240086	3 X 28 tablet pack	January 2026
2	68462-318-29	20240128	3 X 28 tablet pack	February 2026