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 voluntary recall at the Retail level involving Norethindrone and Ethinyl Estradiol tablets USP 0.5mg/0.035mg, 0.75mg/0.035mg and 1.0mg/0.035 mg (Brand Name - Alyacen 7/7/7).

The recall to the retail level of the below-identified Norethindrone and Ethinyl Estradiol tablets USP 0.5mg/0.035mg, 0.75mg/0.035mg and 1.0mg/0.035 mg (Brand Name - Alyacen 7/7/7) batches is being initiated due to Out-of-specification results were reported for the Related Substances test (By HPLC) for commercial stability batch # 20240411 at long term (25°C/60% RH) 18-month time interval (age of the batch is 21 months), for middle strength 0.75mg/0.035 mg, the total impurity result is observed as 5.31% against the specification limit of not more than 5.0%. The product is packed in three strengths: 0.5mg/0.035mg, 0.75mg/0.035mg, and 1.0mg/0.035mg, and the results of 0.5mg/0.035mg and 1.0mg/0.035mg are within the specification limit. The shelf life of the batch is 24 months.

As of today, two batches of Alyacen 7/7/7, batch # 20240411 (Expiry - June 2026) and Batch # 20250252 (March 2027), are within shelf life. Batch # 20250252 is also charged on stability, and total impurities test results up to the last tested interval of 9 months are complying with the specification. The stability sample pulled out at 10 months is tested as part of the impact assessment, results complied with the specification. No failure is reported for this batch. However, as an abundance of caution, the Batch # 20250252 is proposed for the recall.

Based on the overall investigation, no assignable root cause was identified for the OOS results; however, the retest and reserve sample results indicate that the batch complies with the specification. Although the control sample results and the retest results performed in 7 replicates for OOS Batch # 20240411 complied with the specification, the trend of total impurities is on the higher side as compared with other batches. Hence, in accordance with the FDA communication, it is proposed to initiate market recall for the batch # 20240411 and batch # 20250252.

Health hazard assessment concluded that the observed OOS result in the Total Impurities test for Alyacen 7/7/7 Tablets (0.75 mg/0.035 mg) is not considered to pose any risk to the consumer health and safety.

Norethindrone and Ethinyl Estradiol tablets USP 0.5mg/0.035mg, 0.75mg/0.035mg and 1.0mg/0.035 mg (Brand Name - Alyacen 7/7/7)

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
1	68462-556-29	20240411	28 tablet blister pack	June 2026

2	68462-556-29	20250252	28 tablet blister pack	March 2027