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.

Macleods Pharmaceuticals Limited is initiating a Retail/Pharmacy level Recall of Olmesartan Medoxomil, Amlodipine, and Hydrochlorothiazide Tablets (40 mg / 10 mg / 12.5 mg). This recall is being conducted with the knowledge of the United States Food and Drug Administration.

This recall is based upon an Out-of-Specification result identified during 9-month stability testing (25°C/60%RH) of Batch # 12251163B, Exp: 05/2027, 90's container pack. The dissolution result for Olmesartan Medoxomil did not meet the S3 stage acceptance criteria. The mean of 24 units was 79% against the requirement of not less than 80% (Q), while all individual units met the unit-level S3 criteria (minimum 76%; no unit below Q−15%).

Macleods Pharmaceuticals Limited conducted a Health Hazard Assessment which identified no adverse event reports or spontaneous safety reports for batch # 12251163B. Assay, related substances and the dissolution of Amlodipine and Hydrochlorothiazide complied with specifications, and the Olmesartan Medoxomil dissolution was marginal low (mean 79% against Q of 80%). Use of the affected product may result in reduced or delayed absorption of Olmesartan Medoxomil, potentially leading to a temporary and medically reversible reduction in blood pressure control. The probability of serious adverse health consequences is considered remote. Based on the available information, the affected product is not expected to pose a risk to consumer safety under the labeled conditions.

Accordingly, as a precautionary measure, Macleods Pharmaceuticals Limited is initiating a recall at the 'Retail/Pharmacy Level' for bulk Batch # 12251163, packed in 30's container pack (Batch # 12251163A) and 90's container pack (Batch # 12251163B).

The batch was distributed during the period of November 21, 2025 & April 27, 2026.

Product Name	**NDC(s)**	**Lot/Batch**	**Expiry date**
Olmesartan Medoxomil, Amlodipine, and Hydrochlorothiazide Tablets (40 mg / 10 mg / 12.5 mg)	33342-246-07	12251163A	05/2027
	33342-246-10	12251163B	05/2027