

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.

Ajanta Pharma USA, Inc. is recalling the following lot of Ranolazine Extended-Release Tablets 1000 mg. The recalled lot was distributed between 7/09/2025 and 7/30/2025 to wholesalers, distributors, and drug chain stores nationwide. This recall should be carried out to the **Retail level.**

This recall has been initiated as a precautionary measure due to marginal failure results in the dissolution test during 18-month long-term stability testing of Ranolazine Extended-Release Tablets 1000 mg (Batch DJ25134). The 12-hour mean dissolution result was 59%, which is below the required specification [Mean: Between 60% and 80%].

The **HHE** report concluded that the observed OOS results pose a low risk to patient safety and represent a quality-related compliance issue rather than a clinically meaningful health hazard.

PRODUCT: Ranolazine Extended-Release Tablets 1000 mg

NDC NUMBER: 27241-126-02

BATCH NUMBER: DJ25134

MANUFACTURER DATE: 12/2024

EXPIRATION DATE: 11/2028