

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 lots of Fluphenazine Hydrochloride Tablets, USP, 1 mg. The recalled lots were distributed nationwide to wholesalers, distributors, and chain drugstores from April 1, 2025, through April 28, 2026. This recall must be carried out to the **retail level**.

During ongoing long-term stability testing, lot DJ23254 produced a result for organic impurity A that was slightly above the established specification limit. Lot DJ10205 met the applicable specifications but is also being recalled as a precaution based on the stability finding for lot DJ23254.

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

Sr. No.	Product Name	Batch No.	NDC No.	Mfg. Date	Exp. Date	Pack Size
1	Fluphenazine Hydrochloride Tablets, USP 1 mg	DJ23254	27241-255-01	Dec-24	Nov-26	100's
2	Fluphenazine Hydrochloride Tablets, USP 1 mg	DJ10205	27241-255-01	May-25	Apr-27	100's