

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.

Amneal Pharmaceuticals LLC is initiating a recall for Ropivacaine Hydrochloride Injection, USP 500mg/100ml in an abundance of caution as there may be potential for a fiber to be present in the IV infusion bag. This recall is being issued to the Hospital level.

An extraneous fiber was initially observed in some infusion bags of Ropivacaine Hydrochloride Injection, USP 5 mg/ml (500 mg/100 ml), 0.5%. All infusion bags were visually inspected prior to the release of the finished product with no fibers observed; however in an abundance of caution Amneal is recalling these batches.

Available medical literature indicates that the clinical risk associated with small amounts of inert particulate matter is minimal, and no documented patient harm has been reported. Additionally, no adverse events or product quality complaints have been identified, supporting a favorable benefit-risk profile. A recall of the impacted batches has been initiated out of an abundance of caution, commensurate with current Good Manufacturing Practices (cGMP).

This recall is being conducted with the knowledge of the U.S. Food & Drug Administration.

NDC number	Lot number	Expiration Date	1st Ship Date	Last Ship Date
70121-1734-3	AL240003	01/2026	04/23/2024	11/8/2024
70121-1734-3	AL240004	01/2026	04/23/2024	11/8/2024