

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.

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a recall of lot M200498, Expiry: June 2024 of Penicillamine Tablets USP 250 mg to the retail level.

This lot is being recalled due to an out of specification (“OOS”) result observed in dissolution test at stability study whereas all other Quality attributes including assay met the acceptance. Further, dissolution test met acceptance criteria during retesting (as part of investigation) and subsequent interim stability time point.

Dissolution testing determines the active drug content release under specified conditions and lower dissolution, over a period of time may result in decreased bioavailability and therapeutic effectiveness, however as outlined above that dissolution test met the acceptance criteria during retesting (as part of investigation) and subsequent interim stability time point, there is a less likelihood of such occurrences.

Product: Penicillamine Tablets USP 250 mg

NDC Number: 70748-153-01

Lot Number: M200498

Expiration Date: June 2024

Distribution Dates: 8/26/22 - 12/22/22