

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.

This recall is to the **RETAIL LEVEL**.

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP (Twice-a-day Dosage) Nitrofurantoin Capsules USP (Monohydrate/Macrocrystals), 100 mg, 100 Capsules NDC#: 68084-446-01 (Individual Dose NDC: 68084-446-11)	1003829	01/31/2023	06/04/2021 to 11/04/2021
REASON	This recall is being initiated due to dissolution testing failure at 0-time of the repackaged lot. Dissolution testing at the initial time point failed to meet stage 2 specifications (80% -100%) at the 3 hour time point with an average (n=24) of 101%.		
HEALTH HAZARD EVALUATION	Nitrofurantoin capsules USP (monohydrate/macrocrystals) are indicated only for the treatment of acute uncomplicated urinary tract infections (acute cystitis) caused by susceptible strains of Escherichia coli or Staphylococcus saprophyticus.		