

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.

Rising Pharma Holdings, Inc is initiating a recall at the Consumer Level for Cetirizine Hydrochloride Tablets USP 5 mg, manufactured by Unique Pharmaceutical Laboratories for Batch No's. GY825029, GY825030, GY825031 and GY825032, 100's count Bottle pack due to cross contamination with Ranitidine.

As a part of investigation, Finish product retain samples testing for four batches (Batch No. GY825029, GY825030, GY825031, and GY825032) have been carried out and two batches (GY825030 and GY825031) failed to comply in Related substances (By HPLC) (Unspecified degradation products & Total degradation products). In an abundance of caution and in accordance with our commitment to product quality and patient safety, a recall has been initiated for all four batches.

After the failure of two batches in Related substances (By HPLC) test for unspecified impurities, LCMS has been carried out to find out the mass of unknown impurity peak and it was identified that the failure is attributed due to presence of traces of Ranitidine (Approximately< 0.5 %), a product also manufactured at Unique Pharmaceutical Laboratories (A Division of J. B. Chemicals & Pharmaceuticals Ltd.). Based on the levels at which ranitidine was detected, no adverse impact on patient health and safety is anticipated as provided in HHE.

Further investigative activities are ongoing to confirm the root cause and to implement appropriate corrective measures.

This product was shipped between April 2026 to June 2026.

This recall is being conducted at a consumer level with the knowledge of the U.S. Food and Drug Administration.

Product Name	NDC(s)	Lot(s) / Exp. date	Distribution dates
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825029 Exp.: 10/2028	April 2026 to May 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825030 Exp.: 10/2028	May 2026

Cetirizine Hydrochloride
Tablets USP 5 mg

16571-
401-10

GY825031
Exp.: 10/2028

May 2026 to
June 2026

Cetirizine Hydrochloride
Tablets USP 5 mg

16571-
401-10

GY825032
Exp.: 10/2028

May 2026 to
June 2026