

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 Retail 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. This recall is based on a product quality complaint received from pharmacy, wherein an appearance of red dots was observed on Cetirizine Hydrochloride Tablets USP 5 mg.

Based on investigation, retain sample testing of 4 impacted batches (Batch No. GY825029 to GY825032) has been performed and out of four batches, two batches (Batch No. GY825030 and GY825031) failed to comply in Related substances (By HPLC) test for unspecified impurities. This 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. In an abundance of caution, and in accordance with our commitment to product quality and patient safety, a recall is being initiated for all impacted batches.

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 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	April 2026 to May 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825030	May 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825031	May 2026 to June 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825032	May 2026 to June 2026