

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 this recall of **Tramadol Hydrochloride Tablets, USP 50 mg (NDC 60219-2348-5)** due to the presence of Nitrosamine Drug Substance Related Impurity (NDSRI), (N-nitroso-desmethyl-tramadol impurity) slightly above the FDA recommended intake (AI) limit.

This impurity may increase the risk of cancer if people are exposed over long periods of time. To date, there have been no reports of adverse events that have been assessed to be related to this recall.

Tramadol HCL Tablets, 50 mg, is a prescription CIV medication commonly used for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Only the lot numbers listed in the table below are being recalled.

This recall is being carried out to the Retail Level.

NDC Code	Lot number	Expiration Date	Bottle Size	1st Ship Date	Last Ship Date
60219-2348-5	AM230987	05/2026	500-count	11/06/2023	01/02/2024
60219-2348-5	AR232387	12/2026	500-count	3/20/2025	11/26/2025