

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 Health LLC has initiated a drug product recall for the product Duloxetine DR Capsules USP 30 mg from USA market due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Duloxetine above the interim acceptable intake limit of 5ppm as stipulated by the FDA. Based on the health hazard evaluation, long term exposure to nitrosamines above regulatory limits may increase the risk of cancer. This product was shipped between the dates of 06/13/2024 – 06/26/2024.

The product description is a Blue Opaque / White opaque, size '3' hard gelatin capsule filled with white to off white pellets and imprinted with "X" on Blue opaque cap and "02" on White opaque body with black ink.

PRODUCT: Duloxetine DR Capsules USP 30 mg - 1000's HDPE Bottle

NDC NUMBER: 57237-018-99

LOT NUMBER: DTB23111A

EXPIRATION DATE: Aug-2025