

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.

Macleods Pharmaceuticals Limited is initiating a voluntary Retail/ Pharmacy level Recall of **Olanzapine tablets USP 2.5 mg**.

This recall is based upon the Out-of-Specification results observed in the Organic Impurities test for Olanzapine Tablets USP 2.5 mg; batch number BOB12318A, at the 12-month, 25°C/60% RH (long-term stability condition). The level of an individual unspecified impurity was observed at 0.269%, exceeding the specification limit of NMT 0.20% for individual unspecified impurities.

Macleods conducted an analysis resulting in the classification of this as an Olanzapine related impurity. However, total impurities, dissolution, and assay results were found complying with the specification. Therefore, it is less likely to affect the therapeutic efficacy of Olanzapine Tablets 2.5mg and less likely to pose risk on consumer safety. Hence, as an additional precautionary measure, the subject batch is proposed to a voluntary recall from the market at a class II (Retail level).

The batch was distributed during the period of 30th November 2023 & 7th December 2023.

Product Name	NDC(s)	Lot/Batch	Exp
Olanzapine Tablets USP 2.5 mg	33342-067-07	BOB12318A	07/2027