

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.

This notice is to inform you of a product recall involving **Carbamazepine 200 mg Tablets, 1000ct** by Sun Pharmaceutical Industries, Inc. **(This is a marketed product under the Taro Pharmaceutical label)**. This recall is being reissued to change the depth of the recall to the **retail level**.

This recall has been initiated in response to a quality complaint report from private label customer/repackager that they observed 12 tablets with black specks out of the 500-sample size during repackaging operations of the Carbamazepine 200 mg Tablets. The laboratory findings, the examined particulates were identified as a carbon-rich material containing localized iron-rich regions, elementally consistent with the tablet matrix.

Based on the Health Hazard Evaluation, *"The black specks observed on the tablet surface are clearly visible to the naked eye, therefore, inadvertent consumption is unlikely and there would be no patient exposure. Furthermore, analytical investigations confirmed that the black specks identified on the tablet surface is composed predominantly of tablet excipient material (cellulose and carbon). The specks were smaller in size, and no hard, embedded, or metallic contaminants were detected. There is no evidence of heavy metal contamination and microbial growth. Therefore, a clinically significant risk to patients is not anticipated"*

The lot complied with all of the established product specifications at the time the product was released for distribution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product between October 2, 2025 and December 4, 2025.

PRODUCT: Carbamazepine 200 mg Tablets, 1000 count bottle

NDC NUMBER: 51672-4005-3

LOT NUMBER: AD94033

EXPIRATION DATE: 5/31/2028