

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 is to inform you of a product recall by Cipla USA, Inc. for 4 lots (Nilotinib Capsules 150 mg- Lot # 5GJ0220, 5GJ0221 and 5GJ0222 and Nilotinib Capsules 200 mg- 5GJ0223).

The product is labeled for and marketed by Cipla USA, Inc., bearing the NDC Numbers (69097-031-74 - Outer carton; 69097-031-56 - Inner carton; 69097-031-17-Blister) and for Nilotinib capsules 200 mg (69097- 032-74 - Outer carton; 69097-032-56 - Inner carton; 69097-032-17-Blister).

This recall has been initiated due to Out-of-specification results that were observed for description of capsule.

Health Hazard evaluation concluded that the results of the critical quality attributes of the batch were within the proposed stability limits and comparable to the initial batch data. Hence the exposure to the product with observed OOS results is not likely to cause adverse health consequences.

Sr. No.	Product Name	NDC No.	FG Batch No.	Dates distributed
1.	Nilotinib Capsules 150 mg		5GJ0220	June 26, 2025, to July 24, 2025
2.	Nilotinib Capsules 150 mg	69097-031-74 - Outer carton, 69097-031-56 - Inner carton 69097-031-17-Blister	5GJ0221	July 24, 2025, to July 25, 2025
3.	Nilotinib Capsules 150 mg		5GJ0222	July 25, 2025, to Nov 21, 2025
4.	Nilotinib Capsules 200 mg	69097-032-74 - Outer carton, 69097-032-56 - Inner carton 69097-032-17-Blister	5GJ0223	June 26, 2025, to Nov 21, 2025