

*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 to inform you that Slate Run Pharmaceuticals is voluntarily recalling Cinacalcet Hydrochloride Tablets as listed below. We are working with Piramal Pharma Solutions, Pithampur, our manufacturing partner, to complete this recall.

This recall is being initiated due to the presence of a nitrosamine impurity, N-nitroso-cinacalcet, at or above the acceptable daily intake (ADI) limits established by regulatory authorities. During testing, the presence of N-nitroso-cinacalcet above ADI limits was detected, a type of nitrosamine impurity in certain batches of Cinacalcet Hydrochloride Tablets. Nitrosamines are classified as probable human carcinogens based on laboratory studies and long-term exposure above the ADI may increase the risk of cancer. As patient safety is its highest priority, Slate Run Pharmaceuticals is taking immediate action to recall the affected product batches. To date, Slate Run Pharmaceuticals has not received any reports of adverse events related to the presence of a nitrosamine impurity in the medicine.

<b>Product</b>	<b>Lot Numbers</b>	<b>NOC Number</b>	<b>Expiry</b>
Cinacalcet Hydrochloride Tablets, 30mg, 30 Tablets	07711	70436-007-04	07/2025
Cinacalcet Hydrochloride Tablets, 30mg, 30 Tablets	08900	70436-007-04	09/2026
Cinacalcet Hydrochloride Tablets, 30mg, 30 Tablets	08899	70436-007-04	09/2026
Cinacalcet Hydrochloride Tablets, 60mg, 30 Tablets	109797	70436-008-04	11/2026