Aurobindo – Recall of quinapril/hydrochlorothiazide

- On October 25, 2022, the FDA announced a consumer level recall of two lots of Aurobindo's quinapril/hydrochlorothiazide (HCTZ) 20 mg/12.5 mg tablets due to the presence of nitrosamine drug substance related impurity (NDSRI), N-Nitroso-Quinapril, above the proposed interim limit.

- This recalled lots were distributed May 2021.

Product Description	NDC#	Lot# (Expiration Date)
Quinapril/HCTZ 20 mg/12.5 mg tablets, 90 count bottle	65862-162-90	QE2021005-A (1/2023); QE2021010-A (1/2023)

- Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

- To date, Aurobindo has not received any reports of adverse events related to this recall.

- Quinapril/HCTZ Tablets are indicated for the treatment of hypertension.

- Patients who have the recalled quinapril/HCTZ should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled product.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

- Contact Aurobindo by phone at **1-866-850-2876** or by email at **pvg@aurobindousa.com** for more information.