



Drug Recall

DATE OF RECALL: December 20, 2018

DRUG NAME: Losartan Potassium

RECALLING FIRM: Torrent Pharmaceuticals LTD

REASON FOR RECALL: This recall was issued due to a detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA).

FDA LINK: <https://www.fda.gov/Safety/Recalls/ucm628966.htm>

OTHER DETAILS: See FDA link.

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Losartan potassium 100mg tablets 30 count bottles	13668-0115-30	BO31C016	04/2019
Losartan potassium 100mg tablets 90 count bottles	13668-0115-90	BO31C016	04/2019
Losartan potassium 100mg tablets 1,000 count bottles	13668-0115-10	4DK3C005	04/2019