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APO-AMITRIPTYLINE 10mg (2021-04-13)

Report a Concern (http://www.healthycan adians.gc.ca/reportsignalez/indexeng.php)

Type of communication: Drug Recall Subcategory: Drugs Hazard classification: Type I Source of recall: Health Canada
Hazard classification: Type I
Source of recally Health Canada
Issue: Product Safety
Audience: General Public, Healthcare Professionals, Hospitals
Identification number: RA-75397

Last updated: 2021-04-14

Summary

- Product: APO-AMITRIPTYLINE 10mg
- Reason

Depth of distribution

Affected products

Reason

Presence of higher than accepted levels of a nitrosamine impurity known as N-nitrosodimethylamine (NDMA) in the affected lot.

Depth of distribution

Retailers, Wholesalers, Healthcare Establishments

Affected products

APO-AMITRIPTYLINE

DIN, NPN, DIN-HIM

DIN 02403137

Dosage form

Tablet

Strength

AMITRIPTYLINE HYDROCHLORIDE 10mg

Lot or serial number

RF0410

Companies

Recalling Firm	Apotex Inc. 150 Signet Drive Toronto M9L 1T9 Ontario CANADA
Marketing Authorization Holder	Apotex Inc. 150 Signet Drive Toronto M9L 1T9 Ontario CANADA