

Concerned about nitrosamine recalls?

In October 2024, 7,000 bottles of duloxetine were recalled due to the presence of the impurity N-nitroso duloxetine (a nitrosamine drug substance-related impurity or NDSRI) above recommended limits. More recently, more than 200,000 bottles of duloxetine produced by a different manufacturer were recalled.

USP's Pharmaceutical Analytical Impurity (PAI) reference materials for more than 65 small-molecule nitrosamine and NDSRIs such as N-nitroso duloxetine are now available at Labmix24.

Identify, detect, and quantify nitrosamines with confidence

To confirm the presence and formation of NDSRIs in your drug product, it's essential to develop suitable analytical methods using authentic, well-characterized NDSRI reference materials.

Reference material quality and reliability are crucial for confidently identifying, detecting and quantifying nitrosamines at trace levels (ppb) across various formulations. For a dependable source of NDSRI and small-molecule nitrosamine reference materials, turn to USP.

Solutions from USP

Each USP Nitrosamine PAI is supplied with a detailed lot-specific product information sheet which includes key analytical data on identification, purity and assay value to support testing and profiling nitrosamines throughout your product's drug lifecycle.

Advance your method development and NDSRI risk assessment strategy for duloxetine and other drug products with USP PAIs and Reference Standards for nitrosamines.



Authorized Distributor

CODE NO.	PRODUCT DESCRIPTION
USP-1A04000	N-Nitroso Duloxetine Solution
COMING SOON	N-Nitroso Ritonavir
USP-1A04360	N-Nitroso Sitagliptin Amine
USP-1A04030	N-Nitroso Rasagiline Solution
USP-1A05420	Deutero N-Nitrosodibutylamine Solution
USP-1A03930	N-Nitrosodipropylamine Solution
USP-1A04390	N-Nitroso Tamsulosin

CODE NO.	PRODUCT DESCRIPTION
USP-1A04200	N-Nitroso Metoprolol Solution
USP-1A04230	N-Nitroso Propranolol Solution
USP-1A04250	N-Nitroso Bisoprolol Solution
USP-1175800	Deutero N-Nitrosodimethylamine (NDMA-d6)
USP-1466641	N-Nitrosodibutylamine (NDBA)
USP-1466652	N-Nitrosodiethylamine (NDEA)
USP-1466663	N-Nitrosodiisopropylamine (NDIPA)
USP-1A08890	N-Nitroso Cinacalcet Solution
USP-1A04020	1-Methyl-4-Nitrosopiperazine Solution
USP-1A03960	N-Nitroso Sitagliptin Amine Solution
USP-1A05410	Deutero N-Nitrosodiethylamine Solution
USP-1A04380	N-Nitroso Dabigatran Etxilate
USP-1A03940	N-Nitrosomethylphenidate Solution
USP-1A03950	N-Nitrosopiperidine Solution
USP-1A04240	N-Nitroso Labetalol Solution
USP-1A04220	N-Nitroso Atenolol Solution
USP-1A03920	N-Nitroso Varenicline Solution
USP-1466607	N-Nitrosomethylphenylamine (NMPA)
USP-1466674	N-Nitrosodimethylamine (NDMA)
USP-1466685	N-Nitrosoethylisopropylamine (NEIPA)
USP-1466696	N-Nitrosomethylaminobutyric Acid (NMBA)

Need support finding pharmaceutical reference standards? Call or e-mail us today!