



Stable Isotope Labelled NDSRIs

Daicel's Solution to
Overcome Matrix
Effects in LC-MS/MS
Quantification of
NDSRIs

Regulatory expectations for N-nitrosamine drug substance-related impurities (NDSRIs) emphasize proactive risk management, robust analytical capabilities, and stringent quality control measures to safeguard patient health and maintain regulatory compliance across global markets. LC-MS/MS is a powerful analytical technique that plays a crucial role in the comprehensive assessment and control of NDSRIs in pharmaceutical drug substances and drug products, ensuring compliance with stringent regulatory expectations and enhancing drug safety and quality assurance efforts.

Matrix effects in LC-MS/MS can indeed pose significant challenges when quantifying NDSRIs. Such effects, often resulting from co-eluting substances that either enhance or suppress ionization, can lead to inaccuracies in quantification. Using stable isotope-labeled standards (SILS) is a highly effective strategy to mitigate these matrix effects. SILS are chemically identical to the target analytes except for the incorporation of stable isotopes (such as ^{13}C , ^{15}N , or ^2H). These standards co-elute with the analytes of interest and undergo similar ionization efficiencies, thereby correcting for matrix effects and improving recovery rates.

Key benefits of using SILS include:

1. **Compensation for Ion Suppression/Enhancement:** Since the SILS and the target analyte have nearly identical chemical properties, they experience similar ion suppression or enhancement effects, allowing for more accurate quantification.
2. **Improved Accuracy and Precision:** SILS can correct for variations in sample preparation, extraction efficiency, and instrument performance, leading to more reliable and reproducible results.
3. **Calibration and Quantification:** They facilitate accurate calibration by compensating for any variability during sample injection and analysis, providing a consistent internal standard for quantification.
4. **Recovery Studies:** SILS can be used to perform spike-and-recovery experiments to assess and improve recovery rates of the target analytes from complex matrices.

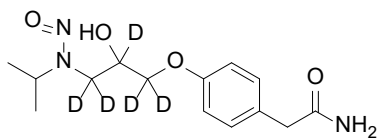
Overall, incorporating stable isotope-labeled standards in your LC-MS methodology can significantly enhance the accuracy and reliability of NDSRI quantification, effectively addressing matrix effects and ensuring better data quality in meeting the regulatory expectations.

Daicel offers both high-quality NDSRI standards and labelled NDSRI standards. We specialise in custom synthesis of NDSRIs and Labelled NDSRIs. Further, Daicel brings extensive expertise in developing and validating NDSRI methods, as well as conducting batch analyses. These services are provided from our state-of-the-art facility in Hyderabad, India, that has undergone successful inspections by the US FDA multiple times.

Please contact us at chiral@chiral.daicel.com for NDSRIs services and standards.

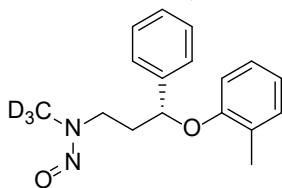


N-Nitroso Atenolol-D5



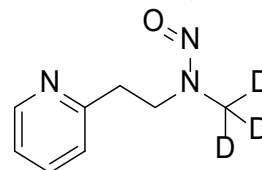
DCTI-A-321

N-Nitroso Atomoxetine-D3
(Mixture of Isomers)



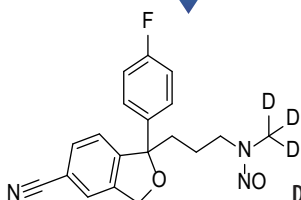
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N-Nitroso Betahistine D3
(Mixture of Isomers)



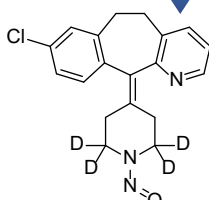
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N-Nitroso Desmethyl Citalopram D3



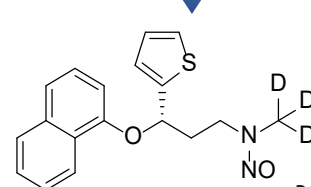
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N-Nitroso Desloratadine-D4



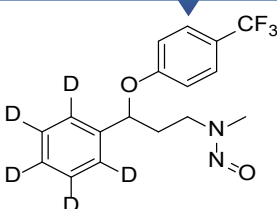
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N-Nitroso Duloxetine-D3



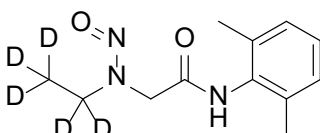
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N-Nitroso Fluoxetine-D5



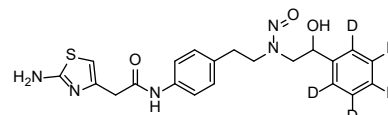
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N-Nitroso-Desethyl Lidocaine-D5



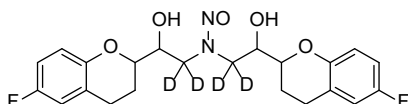
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N-Nitroso Mirabegron D5



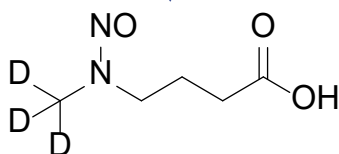
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Nitroso Nebivolol D4



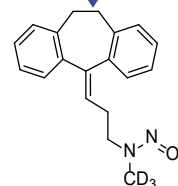
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N-Nitroso-N-methyl-4-Aminobutyric Acid-D3



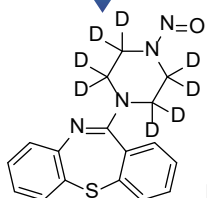
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N-Nitroso Nortriptyline-D3



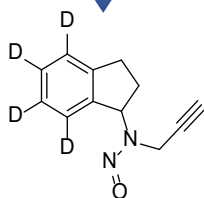
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Nitroso aryl piperazine-D8



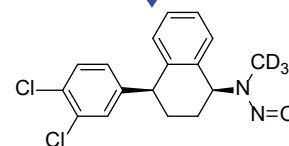
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N-Nitroso Rasagiline-D4



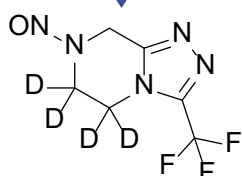
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N-Nitroso Sertraline-D3



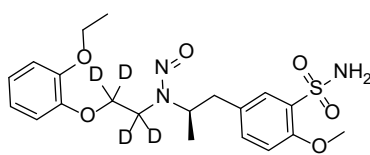
and enantiomer DCTI-A-395

Sitagliptin Nitroso Impurity-D4



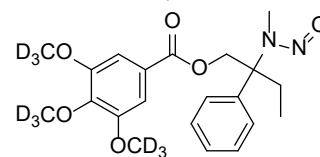
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N-Nitroso-Tamsulosin D4 Impurity
(Mixture of Isomers)



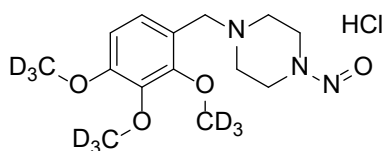
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N-Desmethyl Nitroso
Trimebutine D9



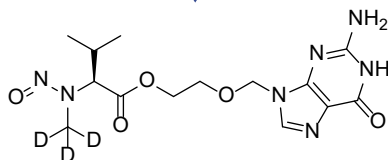
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Trimetazidine Nitroso D9 Impurity



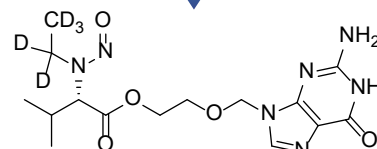
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N-nitroso-N-methyl-Valacyclovir-D3



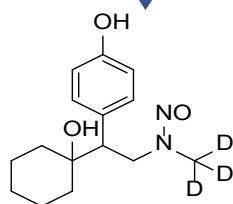
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Valaciclovir-N-Nitroso-N-ethyl -D5-Impurity



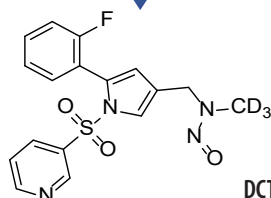
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N-Nitroso-N-Desmethyl-Desvenlafaxine-D3



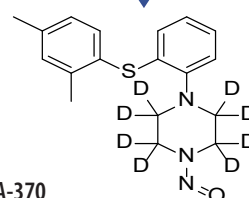
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N-Nitroso Vonoprazan-D3



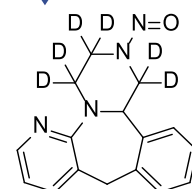
DCTI-A-341

N-Nitroso Vortioxetine-D8



DCTI-A-370

N-Nitroso mirtazapine-d6



DCTI-A-416



DAICEL CHIRAL TECHNOLOGIES
(INDIA) PRIVATE LIMITED

📍 Survey No: 542/2, IKP Knowledge Park,
Koltur Village, Shamirpet Mandal,
Medchal-Malkajgiri District,
Hyderabad-500101, Telangana, India.

☎ +91-8418-660-700

✉ chiral@chiral.daicel.com

🌐 <https://chiraltch.com>



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