

Stable Isotope Labelled NDSRIs and 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 (SIL-NDSRIs) 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 SIL-NDSRIs 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.

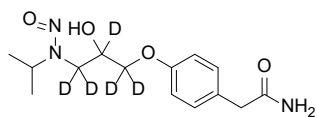
Daicel offers both high-quality NDSRI standards and labelled NDSRI standards. We specialise in custom synthesis of NDSRIs and SIL-NDSRIs.

Please contact us for NDSRIs services and standards.

E-mail id: chiral@chiral.daicel.com

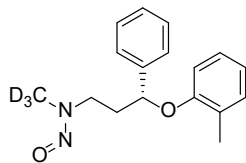
Stable Isotope Labelled NDSRIs

N-Nitroso Atenolol-D5



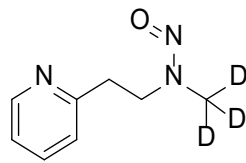
DCTI-A-321

N-Nitroso Atomoxetine-D3
(Mixture of Isomers)



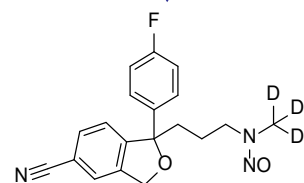
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N-Nitroso Betahistine-D3
(Mixture of Isomers)



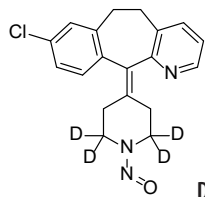
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N-Nitroso Desmethyl
Citalopram-D3



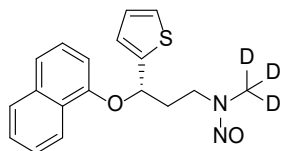
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N-Nitroso Desloratadine-D4



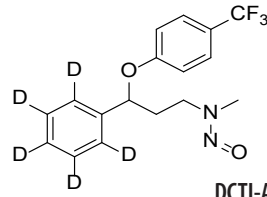
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N-Nitroso Duloxetine-D3



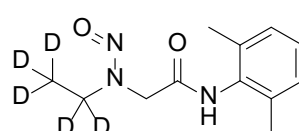
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N-Nitroso Fluoxetine-D5



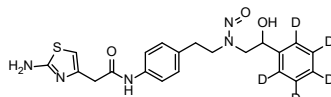
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N-Nitroso-Desethyl
Lidocaine-D5



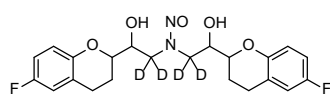
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N-Nitroso Mirabegron-D5



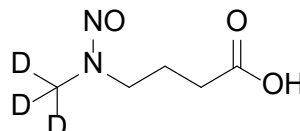
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Nitroso Nebivolol-D4



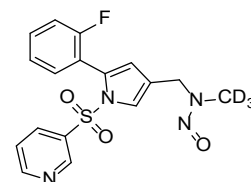
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N-Nitroso-N-methyl-4-
Aminobutyric Acid-D3



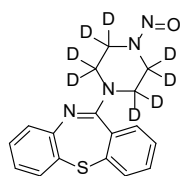
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N-Nitroso Vonoprazan-D3



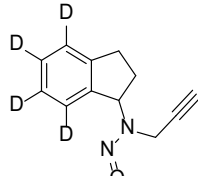
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Nitroso aryl piperazine-D8



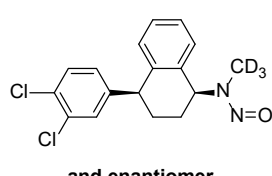
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N-Nitroso Rasagiline-D4



DCTI-A-274

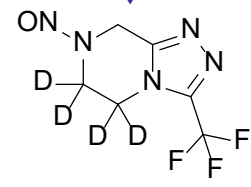
N-Nitroso Sertraline-D3



and enantiomer

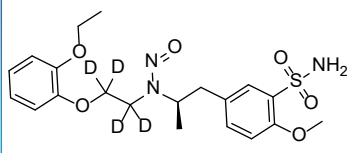
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Sitagliptin Nitroso Impurity-D4



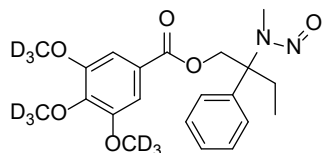
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N-Nitroso-Tamsulosin-D4 Impurity
(Mixture of Isomers)



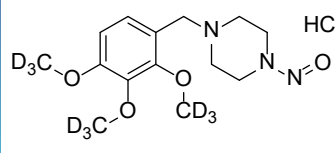
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N-Desmethyl Nitroso
Trimebutine-D9



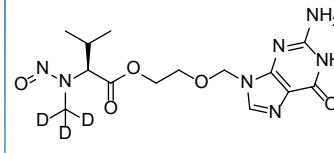
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Trimetazidine Nitroso-D9
Impurity



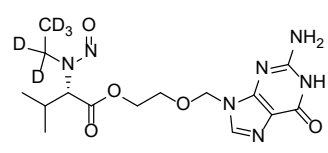
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N-nitroso-N-methyl-
Valacyclovir-D3



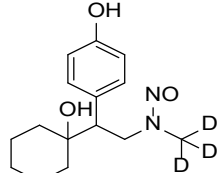
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Valaciclovir-N-Nitroso-
N-ethyl-D5-Impurity



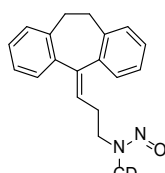
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N-Nitroso-N-Desmethyl-
Desvenlafaxine-D3



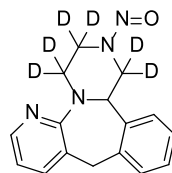
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N-Nitroso
Nortriptyline-D3



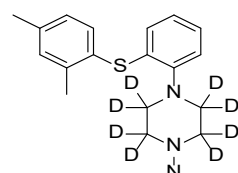
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N-Nitroso
mirtazapine-D6



DCTI-A-416

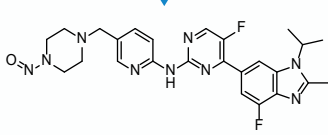
N-Nitroso
Vortioxetine-D8



DCTI-A-370

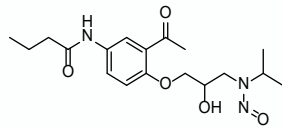
NDSRIs

N-Nitroso Desethyl Abemaciclib



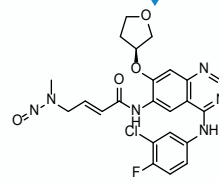
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N-Nitroso-Acebutolol



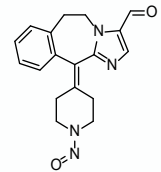
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N-desmethyl-N-nitroso Afatinib



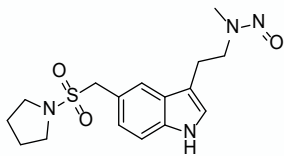
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Alcaftadine Nitroso Impurity



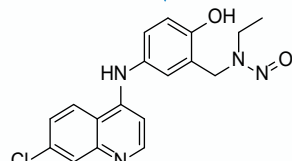
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N-nitroso-Desmethyl-Almotriptan



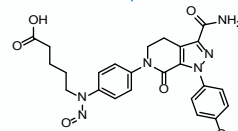
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N-Nitroso N-Desethyl Amodiaquine



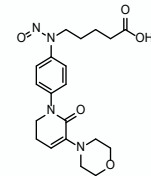
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N-Nitroso Apixaban Aminoacid Impurity



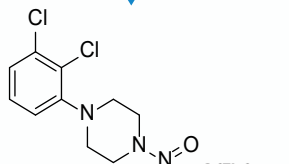
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5-((4-(5-morpholino-6-oxo-3,6-dihydropyridin-1(2H)-yl)phenyl)(nitroso)amino)pentanoic acid



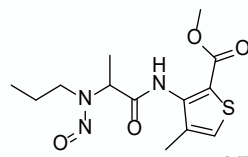
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1-(2,3-dichlorophenyl)-4-Nitropiperazine



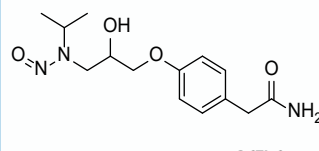
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N-Nitroso-Articaie



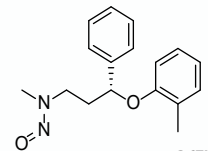
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N-Nitroso Atenolol Impurity



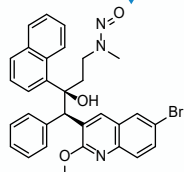
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N-Nitroso atomoxetine

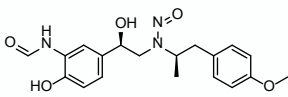


DCTI-C-3420

N-Nitroso-N-Desmethyl Bedaquiline

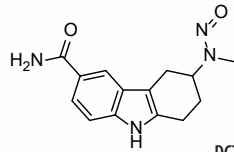


Arformoterol Nitroso Impurity



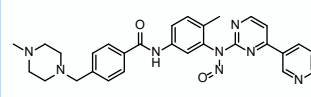
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Frovatriptan Nitroso Impurity



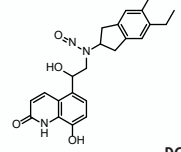
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N-Nitroso Imatinib



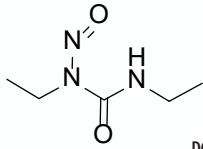
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N-Nitroso Indacaterol



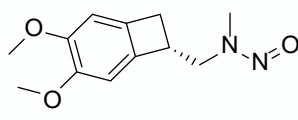
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Istradefylline Impurity



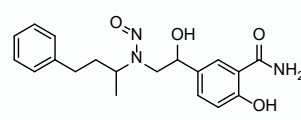
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Ivabradine intermediate nitroso impurity



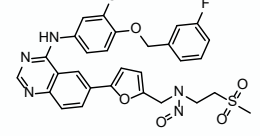
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Labelalol Nitroso Impurity



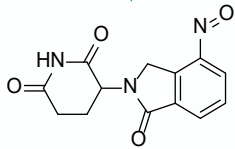
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Lapatinib Nitroso impurity



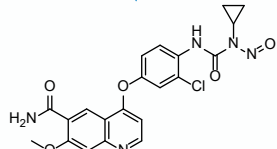
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3-(4-nitroso-1-oxoisindolin-2-yl) piperidine-2,6-dione



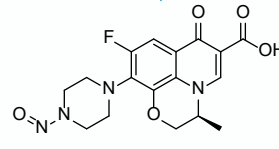
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Lenvatinib N-Nitroso impurity-2



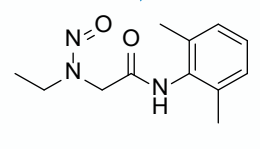
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N-Nitroso Levofloxacin



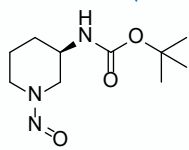
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N-Nitroso-desethyl lidocaine (Mixture of isomers)



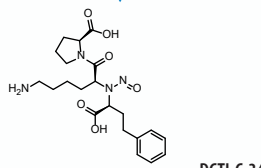
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tert-butyl (R)-(1-nitrosopiperidin-3-yl) carbamate



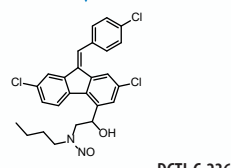
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N-Nitroso Lisinopril



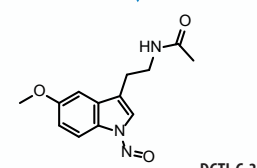
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N-Nitroso Lumefantrine Impurity



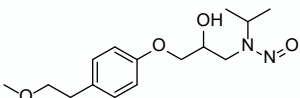
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N-Nitroso Melatonin



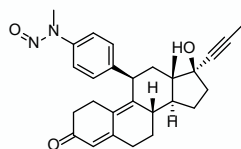
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N-Nitrosometoprolol



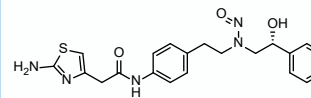
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N-Nitroso N-Desmethyl Mifepristone



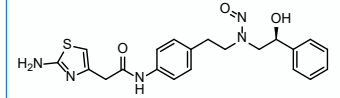
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N-Nitroso Mirabegron



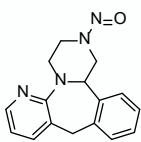
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N-Nitroso Mirabegron S Isomer



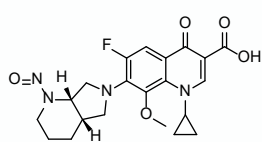
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Mirtazapine Nitroso Impurity



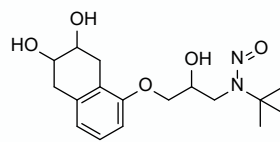
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N-Nitroso Moxifloxacin



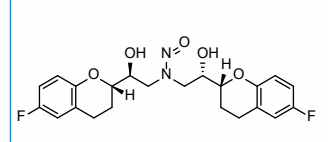
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N-Nitroso-Nadolol



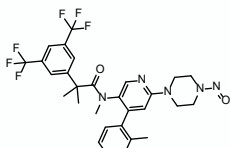
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Nebivolol Nitroso impurity



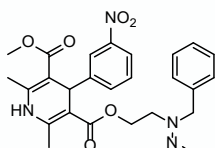
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N-desmethyl-N-nitroso Netupitant



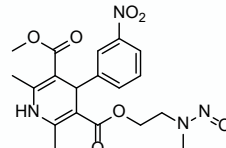
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N-Nitroso-N-Desmethyl Nicardipine Impurity (Mixture of isomers)



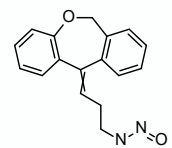
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N-Nitroso N-Desbenzyl Nicardipine Impurity



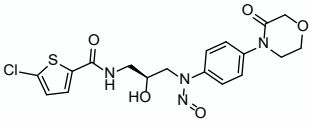
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N-Nitroso Nordoxepin



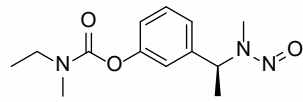
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Rivaroxaban Nitroso Impurity 2



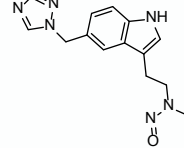
DCTI-C-2472

N-Nitroso-N-desmethyl rivastigmine



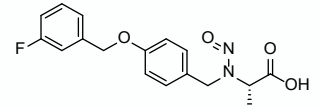
DCTI-C-3830

N-Nitroso Desmethyl Rizatriptan



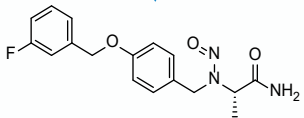
DCTI-C-3787

N-(4-((3-fluorobenzyl)oxy)benzyl)-N-nitroso-L-alanine



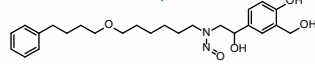
DCTI-C-3297

N-Nitroso-Safinamide



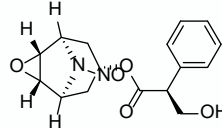
DCTI-C-3711

N-Nitroso Salmeterol



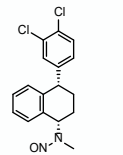
DCTI-C-3802

N-Nitroso Scopolamine



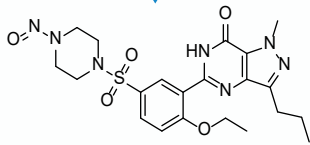
DCTI-C-3209

N-Nitroso Sertraline



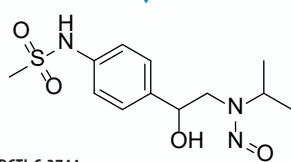
DCTI-C-2364

N-Nitroso sildenafil impurity 2



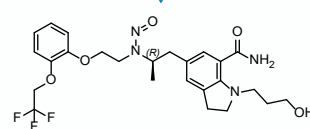
DCTI-C-3692

N-Nitroso-Sotalol



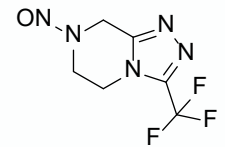
DCTI-C-3744

N-Nitroso Silodosin



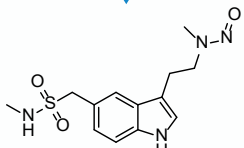
DCTI-C-3096

7-Nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyridine



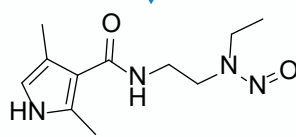
DCTI-C-2432

N-Nitroso-Desmethyl-Sumatriptan Impurity



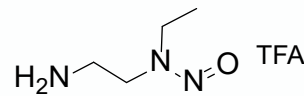
DCTI-C-3367

N-(2-(ethyl(nitroso)amino)ethyl)-2,4-dimethyl-1H-pyrrole-3-carboxamide



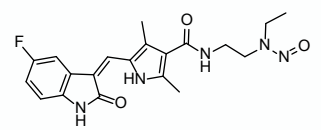
DCTI-C-2593

N-(2-aminoethyl)-N-ethylnitrous amide



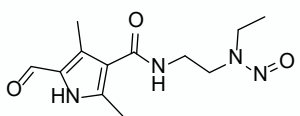
DCTI-C-2586

(Z)-N-(2-(ethyl(nitroso)amino)ethyl)-5-(5-fluoro-2-oxindolin-3-ylidene)methyl)-2,4-dimethyl-1H-pyrrole-3-carboxamide



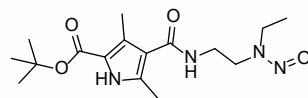
DCTI-C-2467

N-(2-(ethyl(nitroso)amino)ethyl)-5-formyl-2,4-dimethyl-1H-pyrrole-3-carboxamide



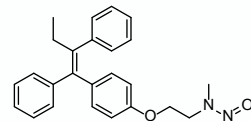
DCTI-C-2468

tert-butyl 4-((2-(ethyl(nitroso)amino)ethyl)carbamoyl)-3,5-dimethyl-1H-pyrrole-2-carboxylate



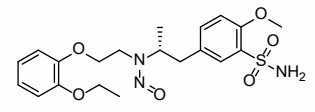
DCTI-C-2469

N-Nitroso Desmethyl Tamoxifen (Mixture of isomers)



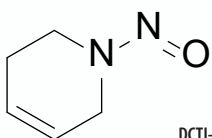
DCTI-C-3556

N-Nitroso Tamsulosin Impurity



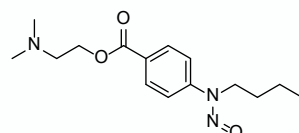
DCTI-C-2704

1-nitroso-1,2,3,6-tetrahydropyridine



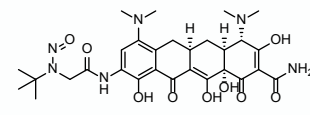
DCTI-C-2489

N-Nitroso-tetracaine



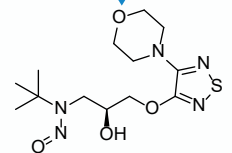
DCTI-C-3786

N-Nitroso Tigecycline



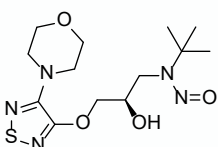
DCTI-C-2106

N-Nitroso Timolol



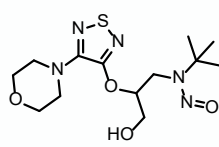
DCTI-C-3715

N-Nitroso (R)-Timolol



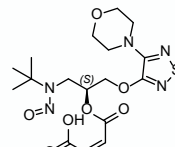
DCTI-C-3671

NDSRI of Timolol Impurity B



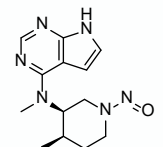
DCTI-C-3678

NDSRI of Timolol Related Compound E



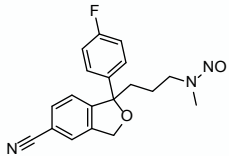
DCTI-C-3679

Tofacitinib Nitrosoamine Impurity-1



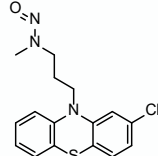
DCTI-C-3112

N-Nitroso Citalopram



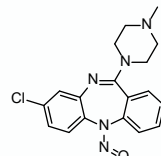
DCTI-C-3196

N-Nitroso Desmethyl Chlorpromazine



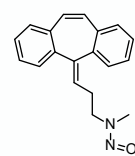
DCTI-C-3825

N-Nitroso Clozapine



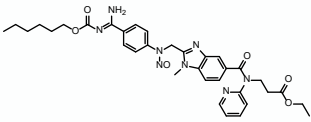
DCTI-C-3726

N-Nitroso Cyclobenzaprine



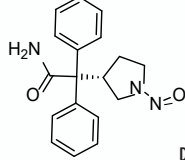
DCTI-C-3780

N-Nitroso Dabigatran etexilate



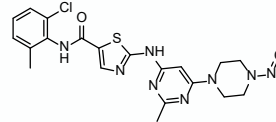
DCTI-C-2361

Darifenacin Nitroso Impurity



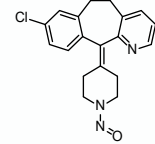
DCTI-C-3703

N-(2-chloro-6-methylphenyl)-2-((2-methyl-6-(4-nitrosopiperazin-1-yl) pyrimidin-4-yl) amino) thiazole-5-carboxamide



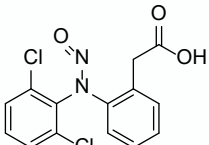
DCTI-C-3428

N-Nitroso-Desloratadine



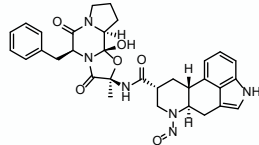
DCTI-C-3304

N-Nitroso Diclofenac



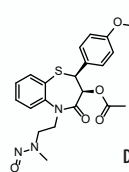
DCTI-C-3794

N-Nitroso Dihydroergotamine impurity B



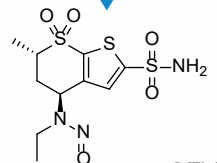
DCTI-C-3913

N-Nitroso Desmethyl Diltiazem



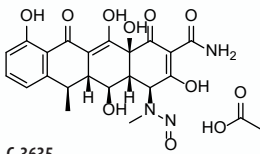
DCTI-C-3746

N-Nitroso Dorzolamide



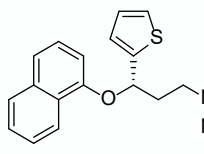
DCTI-C-3793

N-Nitroso-desmethyldoxycycline Acetate



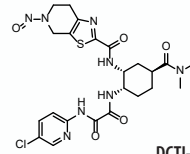
DCTI-C-3635

N-Nitroso Duloxetine



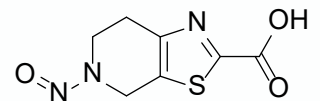
DCTI-C-3090

Edoxaban nitroso impurity



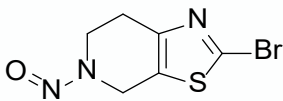
DCTI-C-3128

5-Nitroso-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridine-2-carboxylic acid



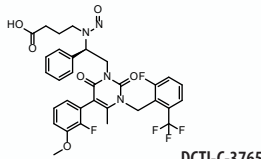
DCTI-C-3238

2-bromo-5-nitroso-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridine



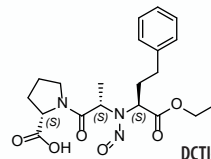
DCTI-C-3400

Elagolix Nitroso impurity



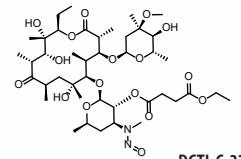
DCTI-C-3765

N-Nitroso-Enalapril



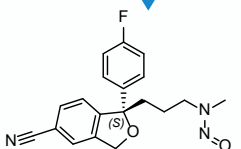
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N-Nitroso-Desmethyl Erythromycin ethyl succinate



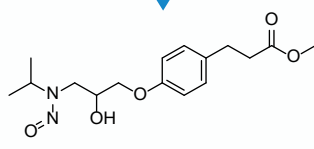
DCTI-C-3784

Nitroso Desmethyl Escitalopram



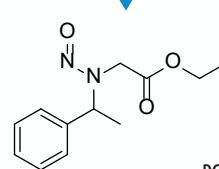
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N-Nitroso-Esmolol



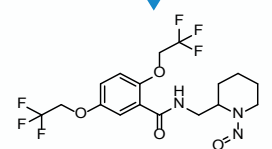
DCTI-C-3796

Etomidate intermediate Nitroso impurity



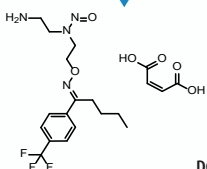
DCTI-C-1476

N-Nitroso Flecainide



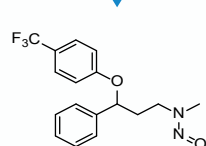
DCTI-C-3695

N-Nitroso Fluvoxamine Impurity K



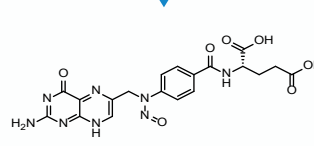
DCTI-C-3790

N-Nitroso Fluoxetine



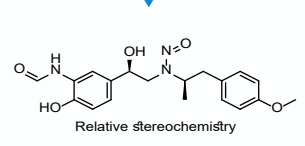
DCTI-C-3541

N-Nitroso-Folic acid



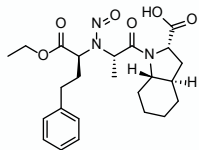
DCTI-C-3697

Formoterol Nitroso Impurity



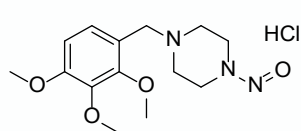
DCTI-C-3651

N-Nitroso-trandolapril



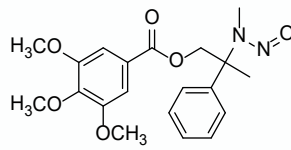
DCTI-C-3781

N-Nitrosamine Trimetazidine.HCl



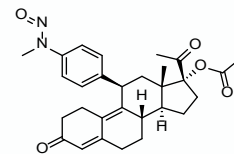
DCTI-C-2238

N-Desmethyl Nitroso Trimebutine



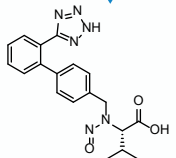
DCTI-C-3563

N-Nitroso N-Desmethyl Ulipristal acetate



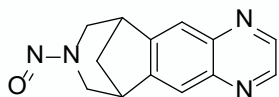
DCTI-C-3767

Desvaleryl Valsartan N-Nitroso Impurity



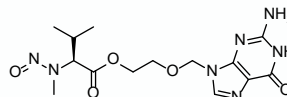
DCTI-C-2218

N-Nitroso Varenicline



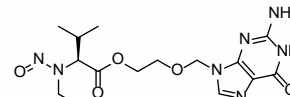
DCTI-C-2488

N-nitroso-N-methyl-valacyclovir



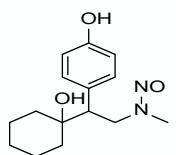
DCTI-C-3614

N-Nitroso-N-ethyl-valacyclovir (Mixture of isomers)



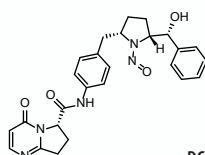
DCTI-C-3627

N-Nitroso-N-Desmethyl-Desvenlafaxine



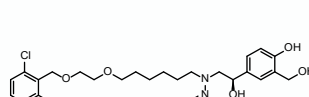
DCTI-C-3579

Vibegron Nitroso impurity (Mixture of isomers)



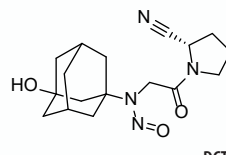
DCTI-C-3140

N-Nitroso Vilanterol



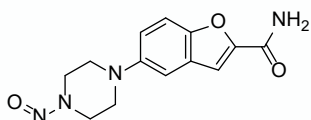
DCTI-C-3737

Vildagliptin Nitroso impurity



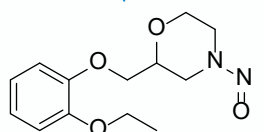
DCTI-C-1843

5-(4-nitrosopiperazin-1-yl) benzofuran-2-carboxamide



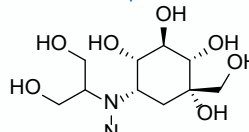
DCTI-C-3143

N-Nitroso Viloxazine



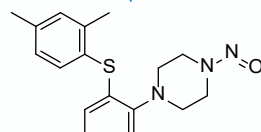
DCTI-C-3735

N-Nitroso Voglibose impurity



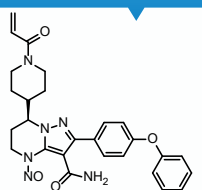
DCTI-C-3916

N-Nitroso-Vortioxetine



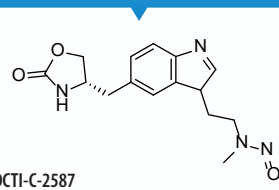
DCTI-C-3417

N-Nitroso Zanubrutinib



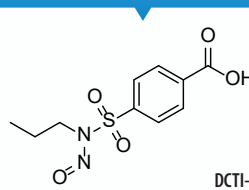
DCTI-C-2412

N-Nitroso N-Desmethyl Zolmitriptan



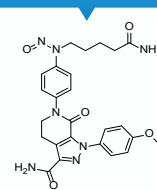
DCTI-C-2587

4-(N-nitroso-N-propylsulfamoyl) benzoic acid



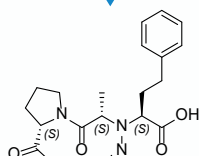
DCTI-C-3666

N-Nitroso Apixaban Open Ring Amide



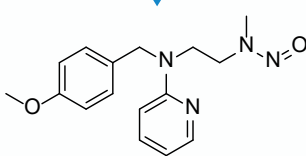
DCTI-C-3441

N-Nitroso-Enalaprilat



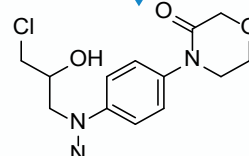
DCTI-C-3864

N-nitroso-Desmethyl Pyrilamine impurity



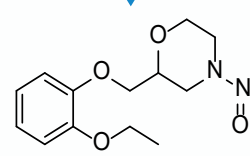
DCTI-C-3861

Rivaroxaban Nitroso Impurity 5



DCTI-C-3859

N-Nitroso Viloxazine



DCTI-C-3735



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