

Established acceptable intake for nitrosamines in medicines

Last updated

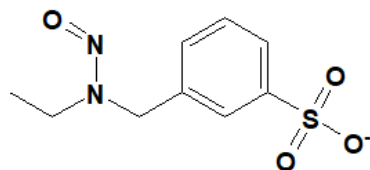
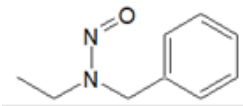
29 January 2026

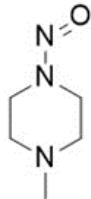
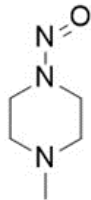
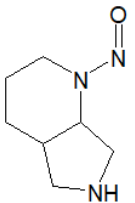
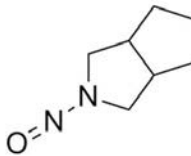
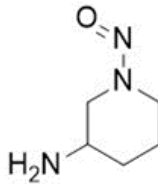
Below is a list of established AI limits for some nitrosamine impurities. These apply for all routes of administration.

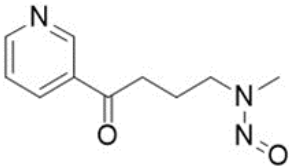
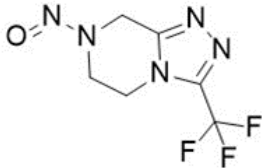
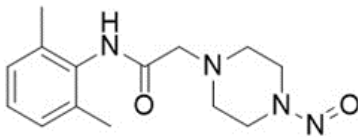
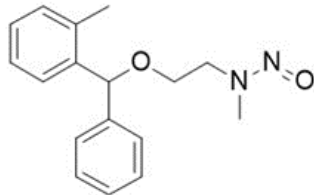
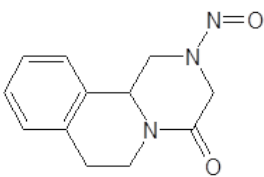
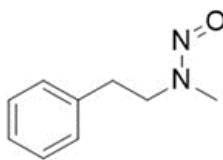
Established AI limits for some other *N*-nitroso-structures. *N*-Nitroso-structures that include *N*-nitrosoguanidines, *N*-nitroso-indoles and *N*-nitrosoureas impurities are listed [separately](#).

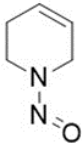
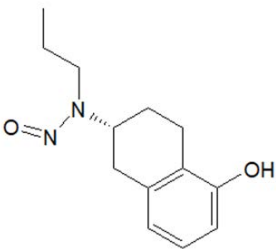
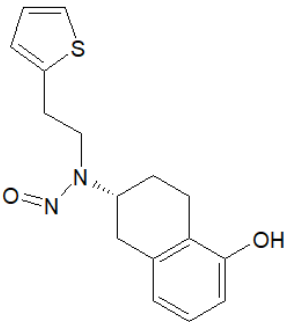
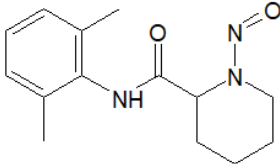
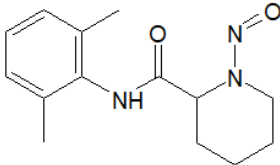
A revision table listing updates to the AI limit information for nitrosamines and other *N*-nitroso-structures is available [separately](#).

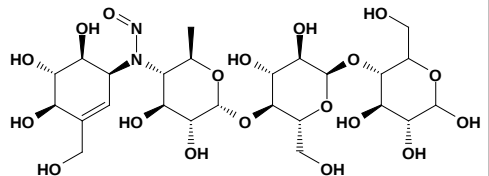
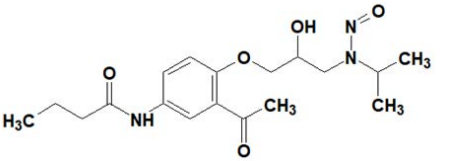
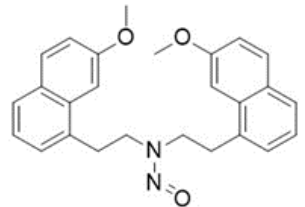
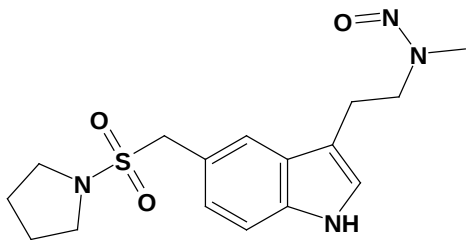
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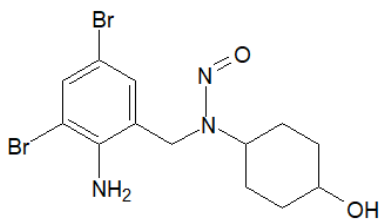
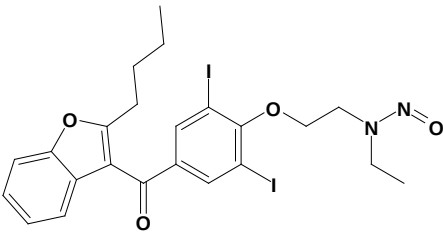
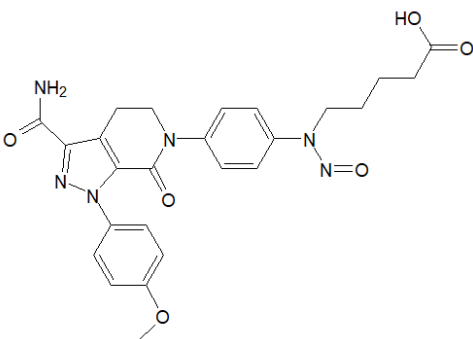
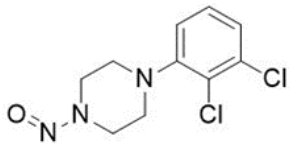
Nitrosamine (CAS number, Abbreviation)	Source ²	Nitrosamine structure	AI limit (ng/day) ¹	CPA Potency category	First published
Default class specific threshold of toxicological concern TTC	-		18.0	Default limit	-
3-((Ethyl(nitroso)amino)methyl) benzenesulfonate (N-M8)	Dextromethorphan		18	1	29 July 2024
<i>N</i> -Nitroso- <i>N</i> -ethyl-benzylamine / <i>N</i> -benzyl- <i>N</i> -ethylnitrous amide (20689-96-7, NBEA)	-		18	1	29 July 2024

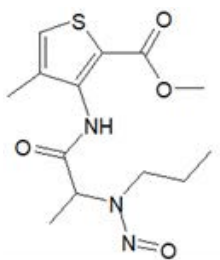
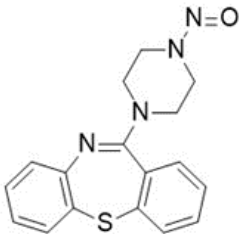
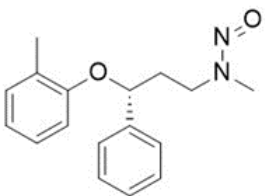
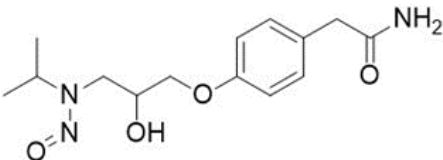
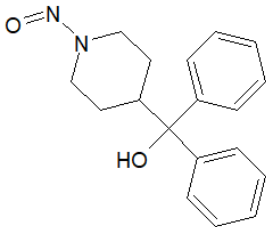
1-Methyl-4-nitrosopiperazine (16339-07-4, MeNP/MNP)	Rifampicin		400	3	20 July 2022 Updated 24 August 2023
1-Methyl-4-nitrosopiperazine (16339-07-4, MeNP/MNP)	Sildenafil		400	3	3 November 2025
1-Nitroso-pyrroloperidine	-		1500	4	24 August 2023
2-Nitroso-octahydrocyclopenta(c)pyrrole (54786-86-6)	Gliclazide		1700		24 August 2023
3-Amino-N-nitrosopiperidine (2819242-71-0)	Alogliptin		400	3	16 October 2023

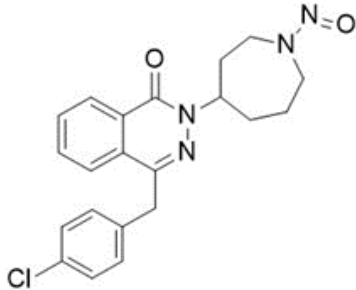
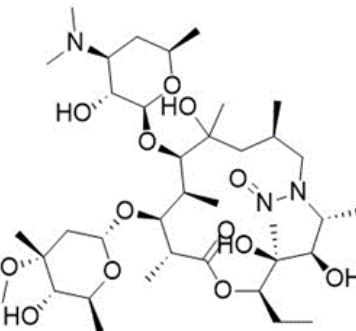
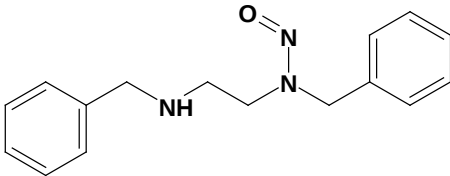
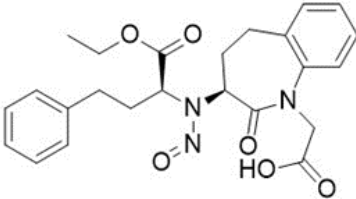
4-(Methylnitrosoamino)-1-(3-pyridinyl)-1-butanone (64091-91-4, NNK)	-		100		5 January 2023
7-Nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo-[4,3-a]pyrazine (2892260-32-9, NTPP)	Sitagliptin		100	2	20 July 2022 Updated 29 July 2024
Nitroso impurity C'' [N-(2,6-dimethylphenyl)-2-(4-nitrosopiperazin-1-yl)acetamide]	Ranolazine		400	3	24 August 2023
N-Nitroso-orphenadrine (NMOA)	Orphenadrine		18	1	24 August 2023
N-Nitroso-praziquanamine / [2-nitroso-2,3,6,7-tetrahydro-1H-pyrazino[2,1-a]isoquinolin-4(11bH)-one] (115822-46-3)	Arpraziquantel		1500	4	24 August 2023
N-Methyl-N-nitrosophenethylamine (13256-11-6, NMPEA)	-		8.0		5 January 2023

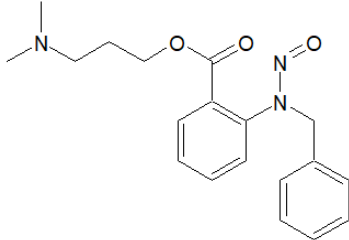
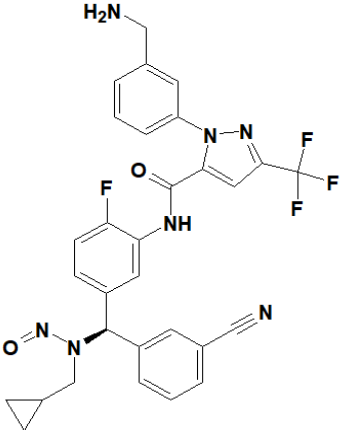
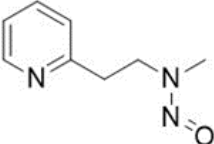
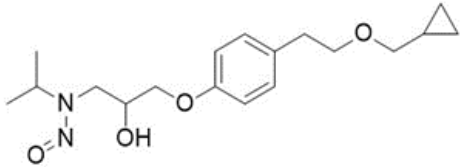
<i>N</i> -Nitroso-1,2,3,6-tetrahydropyridine (55556-92-8, NTHP)	-		37.0		20 July 2022
<i>N</i> -Nitroso derivative of rotigotine impurity B / <i>N</i> -(5-hydroxy-1,2,3,4-tetrahydronaphthalen-2-yl)- <i>N</i> -propylnitrous amide	Rotigotine		400	3	16 October 2023
<i>N</i> -Nitroso derivative of rotigotine impurity C / <i>N</i> -(5-hydroxy-1,2,3,4-tetrahydronaphthalen-2-yl)- <i>N</i> -(2-(thiophen-2-yl)ethyl)nitrous amide	Rotigotine		1500	4	16 October 2023
<i>N</i> -Nitroso-2,6-pipecoloxilidide / desbutyl bupivacaine nitroso impurity (3035512-94-5)	Ropivacaine		1500	4	24 August 2023
<i>N</i> -Nitroso-2,6-pipecoloxilidide / desbutyl bupivacaine nitroso impurity (3035512-94-5)	Bupivacaine		1500	4	3 November 2025

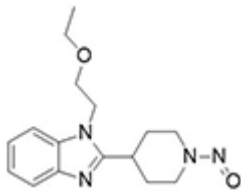
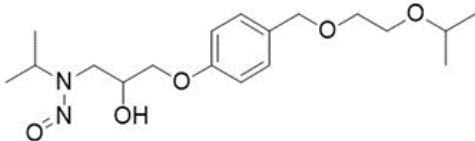
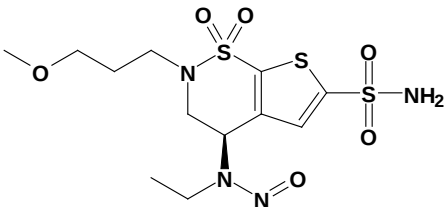
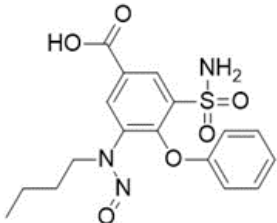
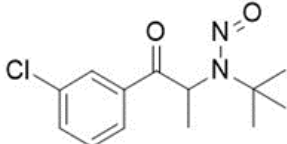
<i>N</i> -Nitroso-acarbose / <i>N</i> -nitroso-4,6-dideoxy-4-[(1 <i>S</i> ,2 <i>S</i> ,3 <i>R</i> ,4 <i>S</i> ,5 <i>S</i>)- 3,4,5-trihydroxy-2- (hydroxymethyl)cyclohexyl]- α - <i>D</i> - glucopyranosyl-(1 $\rightarrow$ 4)- α - <i>D</i> - glucopyranosyl-(1 $\rightarrow$ 4)- α - <i>D</i> - glucopyranosyl-(1 $\rightarrow$ 4)- <i>D</i> -glucopyranose	Acarbose		1500	5	31 July 2025
<i>N</i> -Nitroso-acebutolol	Acebutolol		1500	4	15 October 2024
<i>N</i> -Nitroso-2-(7-methoxy-1-naphthyl)- <i>N</i> - [2-(7-methoxy-1- naphthyl)ethyl]ethylamine	Agomelatine		100	2	29 July 2024
<i>N</i> -Nitroso-desmethyl-almotriptan	Almotriptan		18	1	3 November 2025

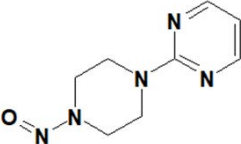
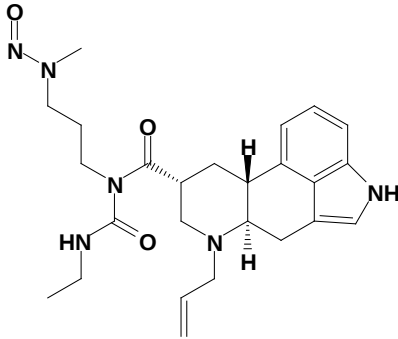
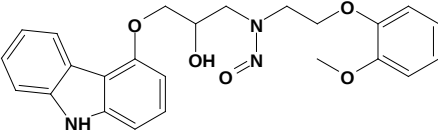
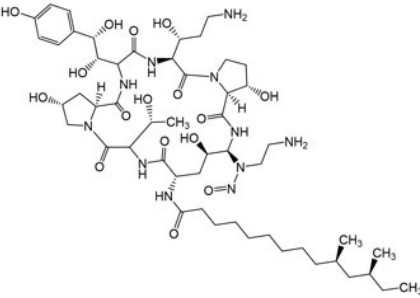
<i>N</i> -Nitroso-ambroxol	Ambroxol		1500		24 August 2023 Updated 31 January 2024
<i>N</i> -Nitroso- <i>N</i> -desethyl-amiodarone (678982-38-2)	Amiodarone		18	1	3 November 2025
<i>N</i> -Nitroso-apixaban impurity B / 5-[4-[3-carbamoyl-1-(4-methoxyphenyl)- 7-oxo-4,5-dihydropyrazolo[3,4- <i>c</i>]pyridin- 6-yl]- <i>N</i> -nitrosoanilino]pentanoic acid	Apixaban		1500	4	24 April 2024
1-(2,3-Dichlorophenyl)-4-nitrosopiperazine (2221987-86-4)	Aripiprazole		400	3	31 January 2024

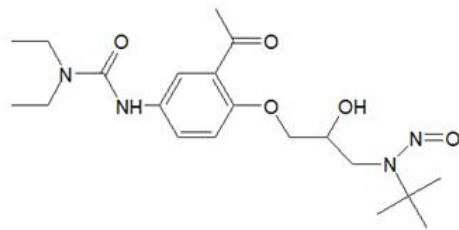
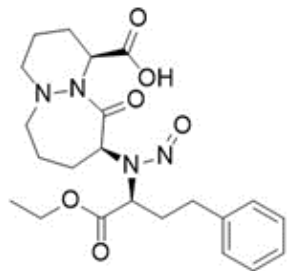
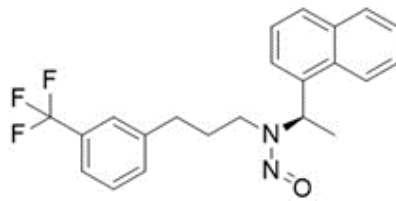
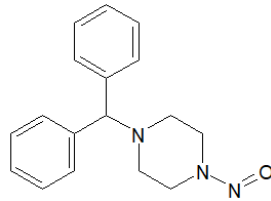
<i>N</i> -Nitroso-articaine / methyl 4-methyl-3-(2-(nitroso(propyl)amino)propanamido)thiophene-2-carboxylate	Articaine		1500	4	29 July 2024
<i>N</i> -Nitroso-aryl piperazine / <i>N</i> -nitroso-desalkylquetiapine (NDAQ)	Quetiapine		400	3	24 August 2023
<i>N</i> -Nitroso-atomoxetine	Atomoxetine		100		24 August 2023
<i>N</i> -Nitroso-atenolol (134720-04-0)	Atenolol		1500	4	24 August 2023
<i>N</i> -Nitroso-azacyclonol (1038-06-8)	Azacyclonol		400	3	31 January 2024

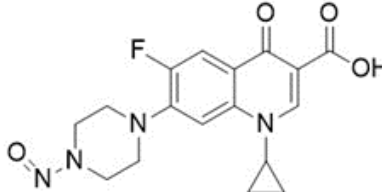
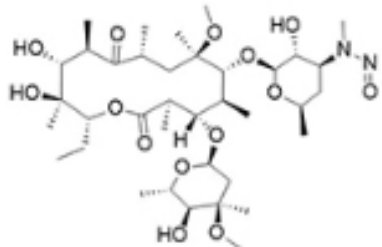
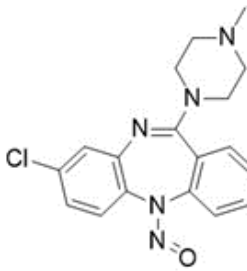
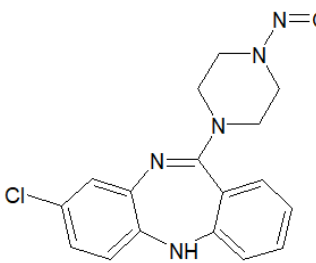
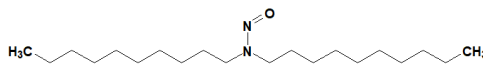
<i>N</i> -Nitroso-desmethyl-azelastine	Azelastine		100	2	31 January 2024
<i>N</i> -Nitroso-azithromycin	Azithromycin		NMI		24 August 2023
<i>N</i> -Nitroso-benzathine / <i>N</i> -nitroso- <i>N,N'</i> -dibenzylethanediamine / <i>N</i> -benzyl- <i>N</i> -(2-(benzylamino)ethyl)nitrous amide (NNB)	Benzathine		18	1	31 July 2025
<i>N</i> -Nitroso-benazepril	Benazepril		1500	5	24 August 2023

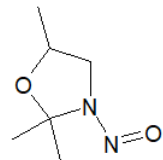
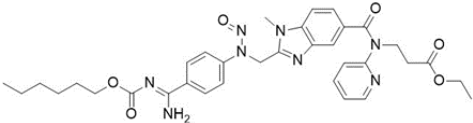
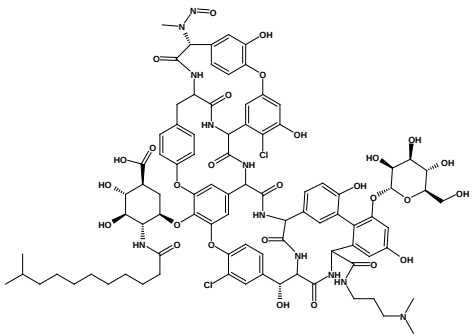
3-(Dimethylamino)propyl 2-[benzyl(nitroso)amino]benzoate	Benzydamine		400	3	29 July 2024
<i>N</i> -Nitroso-berotralstat / (<i>R</i>)-1-(3-(aminomethyl)phenyl)- <i>N</i> -(5-((3-cyanophenyl)((cyclopropylmethyl)(nitroso)amino)methyl)-2-fluorophenyl)-3-(trifluoromethyl)-1 <i>H</i> -pyrazole-5-carboxamide	Berotralstat		1500		3 November 2025 Updated 29 January 2026
<i>N</i> -Nitroso-betahistine (32635-81-7)	Betahistine		18	1	24 August 2023
<i>N</i> -Nitroso-betaxolol	Betaxolol		1500	4	31 January 2024

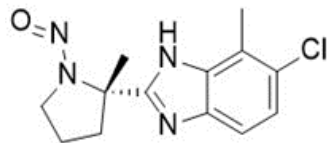
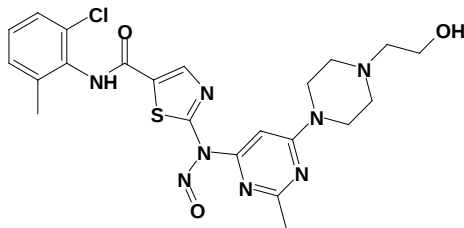
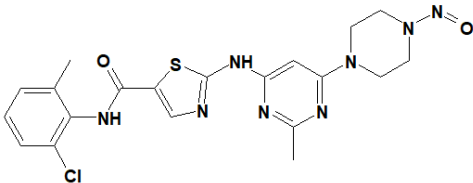
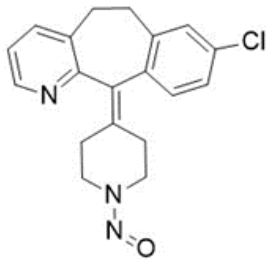
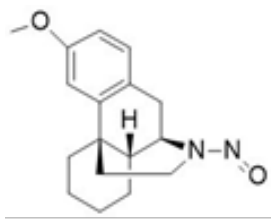
<i>N</i> -Nitroso-bilastine impurity 2 / 1-(2-ethoxyethyl)-2-(1-nitrosopiperidin-4-yl)-1 <i>H</i> -benzo[d]imidazole	Bilastine		400	3	29 July 2024
<i>N</i> -Nitroso-bisoprolol (2820170-76-9, NBP)	Bisoprolol		1500	4	24 August 2023
<i>N</i> -Nitroso-brinzolamide / (<i>R</i>)-4-(ethyl(nitroso)amino)-2-(3-methoxypropyl)-3,4-dihydro-2 <i>H</i> -thieno[3,2- <i>e</i>][1,2]thiazine-6-sulfonamide 1,1-dioxide	Brinzolamide		100	2	31 July 2025
<i>N</i> -Nitroso-bumetanide (2490432-02-3, NNB)	Bumetanide		1500		24 August 2023 Updated 29 January 2026
<i>N</i> -Nitroso-bupropion / <i>N</i> - <i>tert</i> -butyl- <i>N</i> -[1-(3-chlorophenyl)-1-oxopropan-2-yl]nitrous amide (2763780-10-3)	Bupropion		NMI		24 August 2023 Updated 4 February 2025

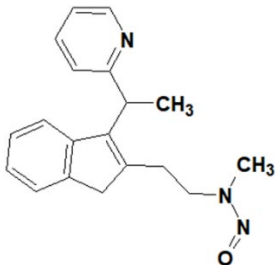
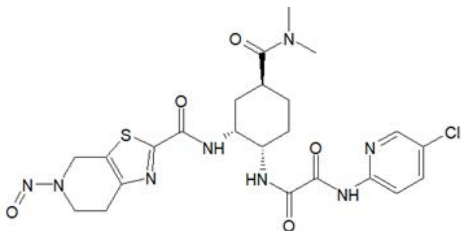
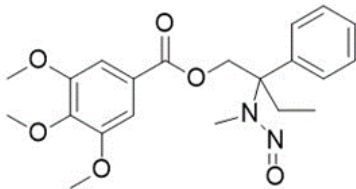
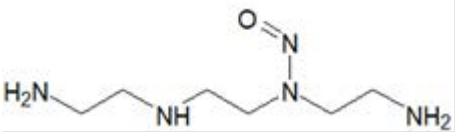
<i>N</i> -Nitroso-buspirone Impurity 1 / 2-(4-nitrosopiperazine-1-yl)-pyrimidine (872826-80-7)	Buspirone		400	3	15 October 2024
<i>N</i> -Nitroso-desmethyl-cabergoline / (6 <i>aR</i> ,9 <i>R</i> ,10 <i>aR</i>)-7-allyl- <i>N</i> -(ethylcarbamoyl)- <i>N</i> -(3-(methyl(nitroso)amino)propyl)- 4,6,6 <i>a</i> ,7,8,9,10,10 <i>a</i> -octahydroindolo[4,3- fg]quinoline-9-carboxamide	Cabergoline		18	1	30 April 2025
<i>N</i> -Nitroso-carvedilol / <i>N</i> -(3-((9 <i>H</i> -carbazol-4-yl)oxy)-2- hydroxypropyl)- <i>N</i> -(2-(2- methoxyphenoxy)ethyl)nitrous amide (2248746-67-8)	Carvedilol		400	3	31 July 2025
<i>N</i> -Nitroso-caspofungin / (10 <i>R</i> ,12 <i>S</i>)- <i>N</i> - ((2 <i>R</i> ,9 <i>S</i> ,11 <i>R</i> ,12 <i>S</i> ,14 <i>aS</i> ,15 <i>S</i> ,20 <i>S</i> ,25 <i>aS</i>)-20- ((<i>R</i>)-3-amino-1-hydroxypropyl)-12-((2- aminoethyl)(nitroso)amino)-23-((1 <i>S</i> ,2 <i>S</i>)- 1,2-dihydroxy-2-(4-hydroxyphenyl)ethyl)- 2,11,15-trihydroxy-6-((<i>R</i>)-1-hydroxyethyl)- 5,8,14,19,22,25-hexaoxotetracosahydro- 1 <i>H</i> -dipyrrolo[2,1- <i>c</i> :2',1'- l][1,4,7,10,13,16]hexaazacyclohenicosin-9-	Caspofungin		1500	4	29 July 2024

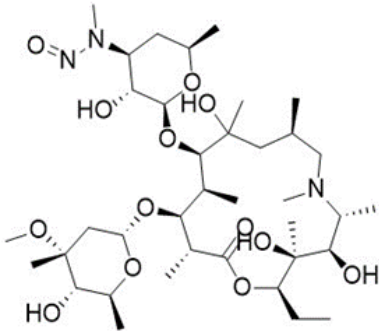
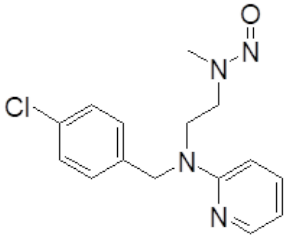
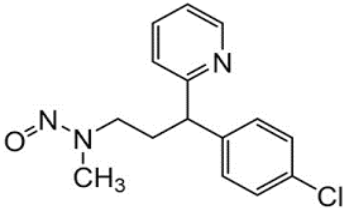
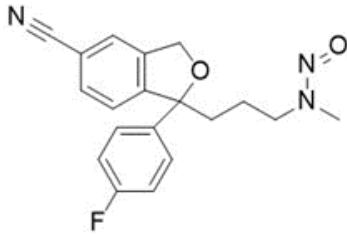
yl)-10,12-dimethyltetradecanamide					
<i>N</i> -Nitroso-celiprolol	Celiprolol		1500	5	31 January 2024
<i>N</i> -Nitroso-cilazapril (1053740-92-3)	Cilazapril		1500	5	24 August 2023
<i>N</i> -Nitroso-cinacalcet	Cinacalcet		400	3	31 January 2024
1-(Diphenylmethyl)-4-nitrosopiperazine / 1-benzhydryl-4-nitrosopiperazine (1698-25-5)	Cinnarizine		400	3	29 July 2024

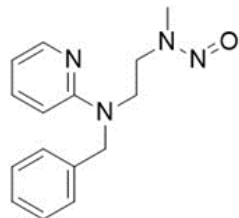
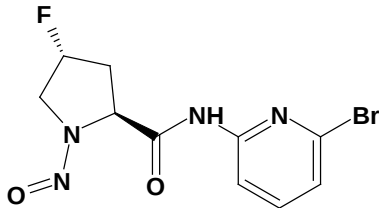
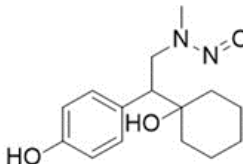
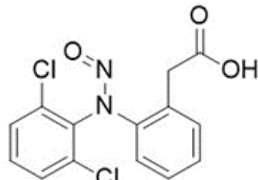
<i>N</i> -Nitroso-ciprofloxacin (864443-44-7)	Ciprofloxacin		NMI		24 August 2023 Updated 15 October 2024
<i>N</i> -Nitroso- <i>N</i> -desmethyl-clarithromycin / <i>N</i> -[(2 <i>S</i> ,3 <i>R</i> ,4 <i>S</i> ,6 <i>R</i>)-2-[[[(3 <i>R</i> ,4 <i>S</i> ,5 <i>S</i> ,6 <i>R</i> ,7 <i>R</i> ,9 <i>R</i> ,11 <i>R</i> ,12 <i>R</i> ,13 <i>S</i> ,14 <i>R</i>)-14-ethyl-12,13-dihydroxy-4-[(2 <i>R</i> ,4 <i>R</i> ,5 <i>S</i> ,6 <i>S</i>)-5-hydroxy-4-methoxy-4,6-dimethyloxan-2-yl]oxy-7-methoxy-3,5,7,9,11,13-hexamethyl-2,10-dioxo-oxacyclotetradec-6-yl]oxy]-3-hydroxy-6-methyloxan-4-yl]- <i>N</i> -methylnitrous amide	Clarithromycin		NMI		29 July 2024
<i>N</i> -Nitroso-clozapine / 8-chloro-11-(4-methylpiperazin-1-yl)-5-nitroso-5 <i>H</i> -dibenzo[<i>b,e</i>][1,4]diazepine (156632-03-0)	Clozapine		1500	5	24 April 2024
<i>N</i> -Nitroso-clozapine EP Impurity C / 8-chloro-11-(4-nitrosopiperazin-1-yl)-5 <i>H</i> -dibenzo[<i>b, e</i>][1, 4]diazepine	Clozapine		400	3	24 April 2024
<i>N</i> -Nitroso-didecylamine	Colesevelam		100	2	4 February 2025

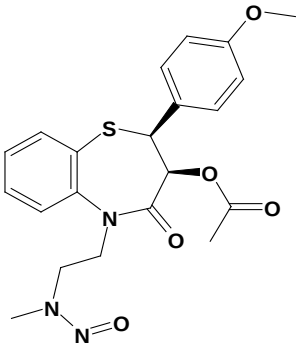
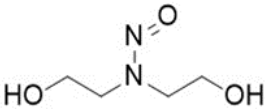
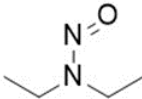
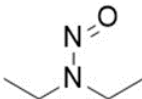
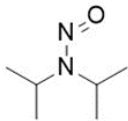
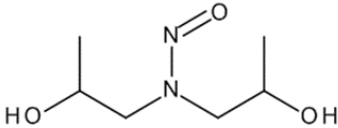
2,2,5-Trimethyl-3-nitroso-1,3-oxazolidine (77400-46-5, TMNO)	Cyanocobalamine		1500	4	24 April 2024
N-Nitroso-dabigatran etexilate (NDAB)	Dabigatran etexilate		1500		5 January 2023 Updated 24 August 2023 Updated 24 April 2024
N-Nitroso-dalbavancin / (2 <i>S</i> ,3 <i>S</i> ,4 <i>R</i> ,5 <i>R</i> ,6 <i>S</i>)-6- [[[(1 <i>S</i> ,2 <i>R</i> ,19 <i>R</i> ,22 <i>R</i> ,34 <i>S</i> ,37 <i>R</i> ,40 <i>R</i> ,52 <i>R</i>)-5,32- dichloro-52-[3- (dimethylamino)propylcarbamoyl]- 2,26,31,44,49-pentahydroxy-22- [methyl(nitroso)amino]-21,35,38,54,56,59- hexa-oxo-47-[(2 <i>R</i> ,3 <i>S</i> ,4 <i>S</i> ,5 <i>S</i> ,6 <i>R</i>)-3,4,5- trihydroxy-6-(hydroxymethyl)oxan-2- yl]oxy-7,13,28-trioxa-20,36,39,53,55,58- hexazaundecacyclo[38.14.2.23,6.214,17.21 9,34.18,12.123,27.129,33.141,45.010,37.04 6,51]hexahexaconta- 3,5,8,10,12(64),14(63),15,17(62),23(61),24,2 6,29(60),30,32,41(57),42,44,46(51),47,49,65 -henicosan-64-yl]oxy]-3,4-dihydroxy-5- (10-methylundecanoylamino)oxane-2- carboxylic acid	Dalbavancin		1500	4	30 April 2025

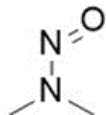
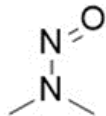
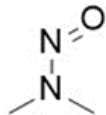
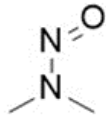
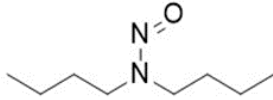
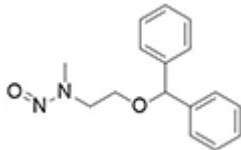
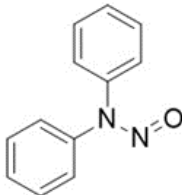
5-Chloro-4-methyl-2-[(2 <i>S</i>)-2-methyl-1-nitrosopyrrolidin-2-yl]-1 <i>H</i> -benzimidazole (IDOR-1135-8758)	Daridorexant		1500	5	31 January 2024
<i>N</i> -Nitroso-dasatinib / <i>N</i> -(2-chloro-6-methylphenyl)-2-((6-(4-(2-hydroxyethyl)piperazin-1-yl)-2-methylpyrimidin-4-yl)(nitroso)amino)thiazole-5-carboxamide	Dasatinib		1500	5	30 April 2025
<i>N</i> -Nitroso- <i>N</i> -deshydroxyethyl-dasatinib / <i>N</i> -(2-chloro-6-methylphenyl)-2-((2-methyl-6-(4-nitrosopiperazin-1-yl)pyrimidin-4-yl)amino)thiazole-5-carboxamide (2135905-86-9)	Dasatinib		400	3	4 February 2025
<i>N</i> -Nitroso-desloratadine (1246819-22-6)	Desloratadine		400	3	24 August 2023
<i>N</i> -Nitroso- <i>N</i> -desmethyl dextromethorphan / (4 <i>bS</i> ,8 <i>aS</i> ,9 <i>S</i>)-3-methoxy-11-nitroso-6,7,8,8 <i>a</i> ,9,10-hexahydro-5 <i>H</i> -9,4 <i>b</i> -(epiminoethano)phenanthrene	Dextromethorphan		1500	4	29 July 2024

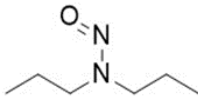
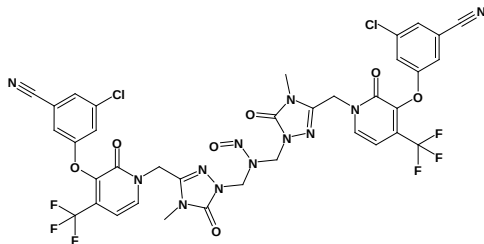
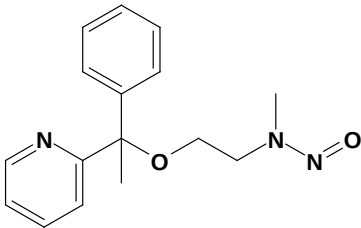
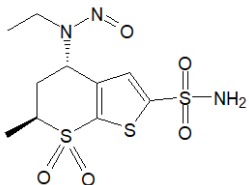
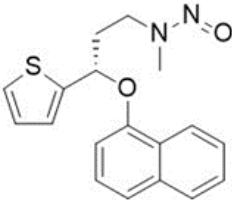
(N-DEX)					
<i>N</i> -Nitroso-desmethyl-dimetindene / <i>N</i> -methyl- <i>N</i> -(2-(3-(1-(pyridin-2-yl)ethyl)-1 <i>H</i> -inden-2-yl)ethyl)nitrous amide (NO-DDMT)	Dimetindene		18	1	15 October 2024
<i>N</i> -Nitroso-desmethyl-edoxaban / <i>N</i> -1-(5-chloropyridin-2-yl)- <i>N</i> 2-((1 <i>S</i> ,2 <i>R</i> ,4 <i>S</i>)-4-(dimethylcarbamoyl)-2-(5-nitroso-4,5,6,7-tetrahydrothiazolo[5,4- <i>c</i>]pyridine-2-carboxamido)cyclohexyl)oxalamide 4-methylbenzenesulfonate	Edoxaban		100	2	29 July 2024
<i>N</i> -Nitroso-desmethyl trimebutine	Trimebutine		1500	5	24 August 2023
<i>N</i> -Nitroso-trientine Impurity 1 / <i>N</i> -(2-aminoethyl)- <i>N</i> -(2-((2-aminoethyl)amino)ethyl)nitrous amide (2817316-41-7)	Trientine		18	1	29 July 2024

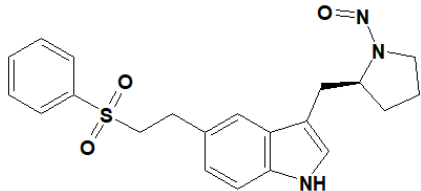
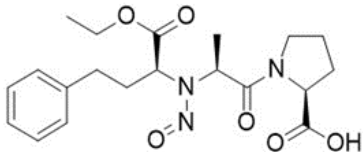
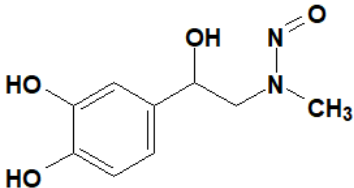
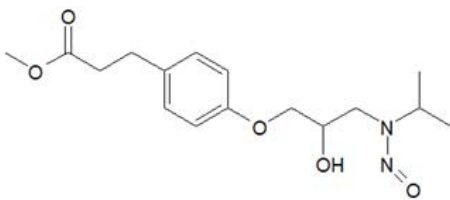
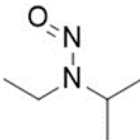
<i>N</i> -Nitroso-desmethylazithromycin	Azithromycin		NMI		24 August 2023
<i>N</i> -Nitroso-desmethyl-chloropyramine (N-DMCP)	Chloropyramine		18	1	24 August 2023
<i>N</i> -Nitroso-desmethyl-chlorphenamine / <i>N</i> -(3-(4-chlorophenyl)-3-(pyridin-2-yl)propyl)- <i>N</i> -methylnitrous amide	Chlorphenamine		18	1	4 February 2025
<i>N</i> -Nitroso-desmethyl-citalopram / <i>N</i> -(3-(5-cyano-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-1-yl)propyl)- <i>N</i> -methylnitrous amide	Citalopram		100		31 January 2024 Updated 29 July 2024

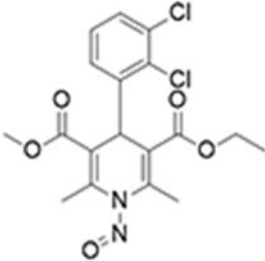
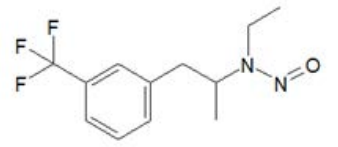
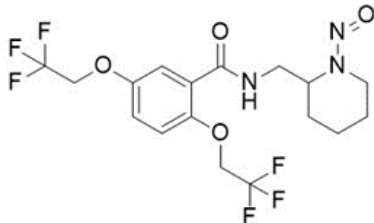
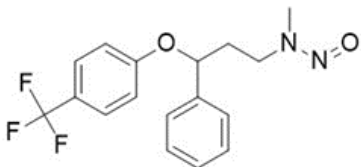
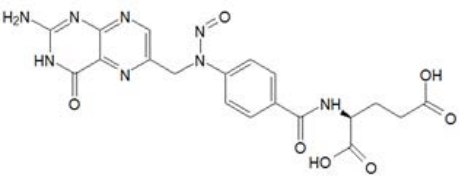
<i>N</i> -Nitroso-desmethyl-tripelennamine	Tripelennamine		18	1	24 August 2023
(2 <i>S</i> ,4 <i>R</i>)- <i>N</i> -(6-Bromopyridin-2-yl)-4-fluoro-1-nitrosopyrrolidine-2-carboxamide	Danicopan		1500	4	3 November 2025
<i>N</i> -Nitroso-desvenlafaxine	Desvenlafaxine		18	1	31 January 2024
<i>N</i> -Nitroso-diclofenac (66505-80-4)	Diclofenac		78000		24 August 2023 Updated 15 October 2024

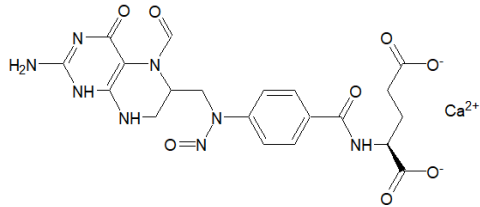
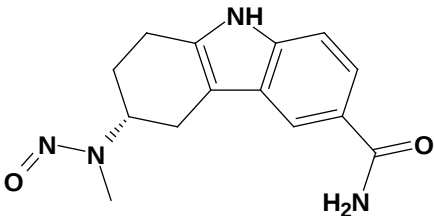
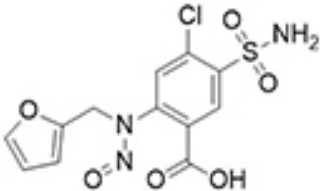
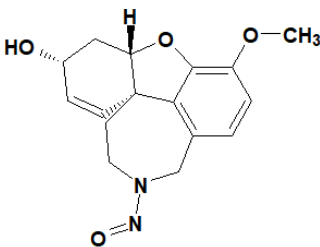
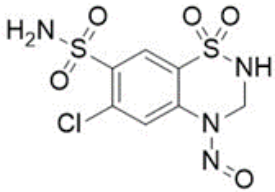
<i>N</i> -Nitroso- <i>N</i> -desmethyl-diltiazem (3036581-85-5)	Diltiazem		100		3 November 2025
<i>N</i> -Nitroso-diethanolamine (1116-54-7, NDELA)	-		1900		5 January 2023
<i>N</i> -Nitroso-diethylamine (55-18-5, NDEA)	-		26.5		15 September 2019
<i>N</i> -Nitroso-diethylamine (55-18-5, NDEA)	Entacapone		26.5		3 November 2025
<i>N</i> -Nitroso-diisopropylamine / <i>N,N</i> -di(propan-2-yl)nitrous amide (601-77-4, DIPNA/NDIPA)	-		1500	5	15 September 2019 Updated 29 July 2024
<i>N</i> -Nitrosodiisopropanolamine / 1, 1'-(nitrosoimino)bis-2-propanol (53609-64-6)	-		400	3	24 April 2024

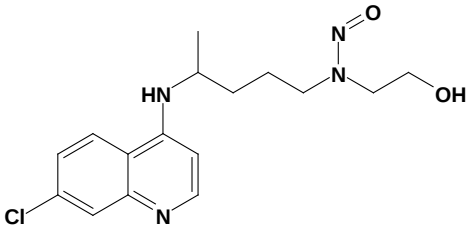
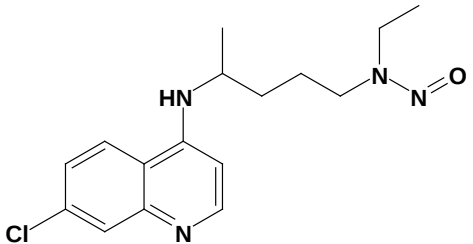
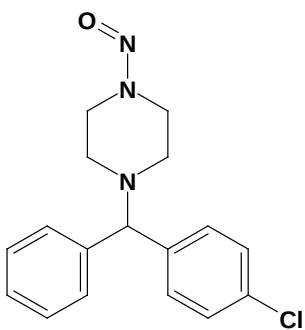
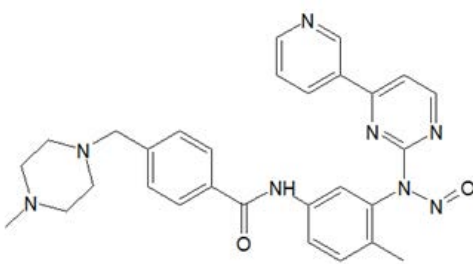
<i>N</i> -Nitroso-dimethylamine (62-75-9, NDMA)	-		96.0		15 September 2019
<i>N</i> -Nitroso-dimethylamine (62-75-9, NDMA)	Ranitidine		96.0		15 September 2019
<i>N</i> -Nitroso-dimethylamine (62-75-9, NDMA)	Nizatidine		96.0		15 September 2019
<i>N</i> -Nitroso-dimethylamine (62-75-9, NDMA)	Metformin		96.0		15 September 2019
<i>N</i> -Nitroso-di- <i>n</i> -butylamine (924-16-3, NDBA)	-		26.5		20 July 2022
<i>N</i> -Nitroso- <i>N</i> -desmethyl- diphenhydramine / <i>N</i> -(2-benzhydryloxyethyl)- <i>N</i> - methylnitrous amide (55855-43-1)	Diphenhydramine / Dimenhydrinate		100		29 July 2024 Updated 29 January 2026
<i>N</i> -Nitroso-diphenylamine (86-30-6, NDPh)	-		78000		5 January 2023

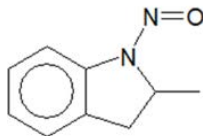
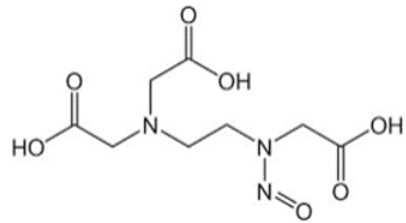
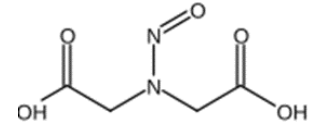
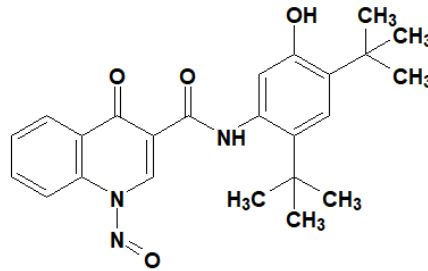
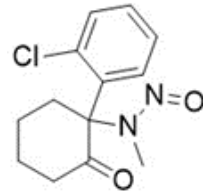
<i>N</i> -Nitroso-dipropylamine (621-64-7, NDPA)	-		26.5		20 July 2022
<i>N</i> -Nitroso-doravirine dimer (NDD)	Doravirine		1500		3 November 2025
<i>N</i> -Nitroso-desmethyl-doxylamine / <i>N</i> -methyl- <i>N</i> -(2-(1-phenyl-1-(pyridin-2-yl)ethoxy)ethyl)nitrous amide	Doxylamine		100		3 November 2025
<i>N</i> -Nitroso-dorzolamide	Dorzolamide		1500		31 January 2024
<i>N</i> -Nitroso-duloxetine (2680527-91-5, NDLX)	Duloxetine		100		20 July 2022

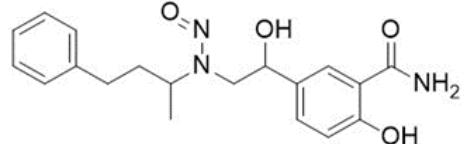
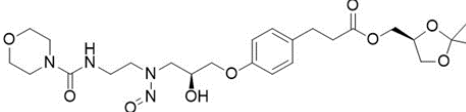
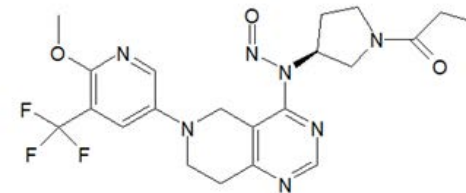
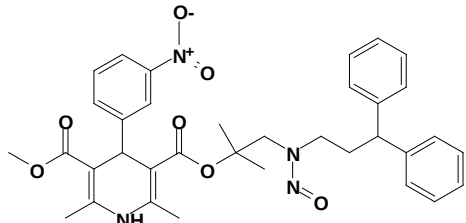
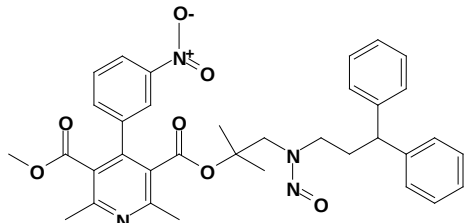
<i>N</i> -Nitroso-desmethyl-eletriptan / 5-[2-(benzenesulfonyl)ethyl]-3-[[<i>(2R)</i> -1-nitrosopyrrolidin-2-yl]methyl]-1 <i>H</i> -indole	Eletriptan		1500	4	4 February 2025
<i>N</i> -Nitroso-enalapril	Enalapril		1500	5	24 August 2023
<i>N</i> -Nitroso-epinephrine / <i>N</i> -nitroso-adrenaline	Epinephrine / Adrenaline		100	2	4 February 2025
<i>N</i> -Nitroso-esmolol	Esmolol		1500	4	31 January 2024
<i>N</i> -Nitroso-ethylisopropylamine / <i>N</i> -ethyl- <i>N</i> -propan-2-yl nitrous amide (16339-04-1, EIPNA/NEIPA)	-		400	3	15 September 2019 Updated 29 July 2024

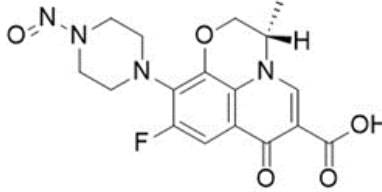
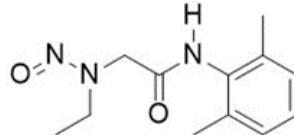
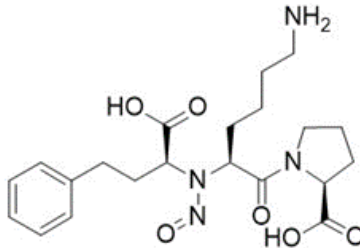
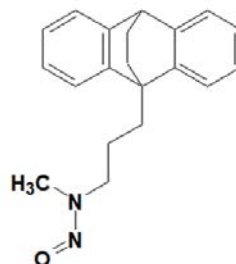
<i>N</i> -Nitroso-felodipine	Felodipine		1500	5	24 August 2023
<i>N</i> -Nitroso-fenfluramine / <i>N</i> -ethyl- <i>N</i> -[1-[3-(trifluoromethyl)phenyl]propan-2-yl]nitrous amide (19023-40-6)	Fenfluramine		400	3	29 July 2024
<i>N</i> -Nitroso-flecainide / <i>N</i> -((1-nitrosopiperidin-2-yl)methyl)-2, 5-bis(2, 2, 2-trifluoroethoxy)benzamide (2901109-58-6)	Flecainide		1500	4	24 April 2024
<i>N</i> -Nitrosofluoxetine (150494-06-7)	Fluoxetine		100		5 January 2023
<i>N</i> -Nitroso-folic acid / 2-[[4-[(2-amino-4-oxo-3 <i>H</i> -pteridin-6-yl)methyl-nitrosoamino]benzoyl]amino]pentanedioic acid (26360-21-4, NFA)	Folic acid		1500	4	24 August 2023 Updated 29 July 2024

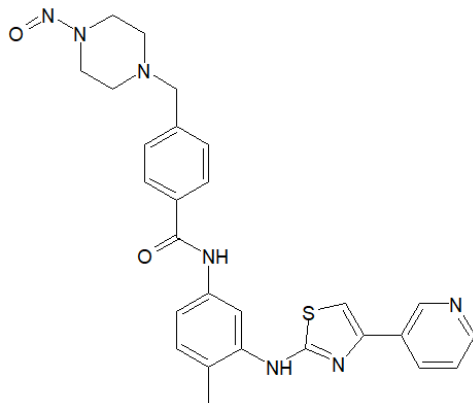
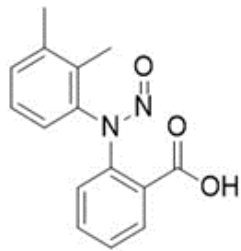
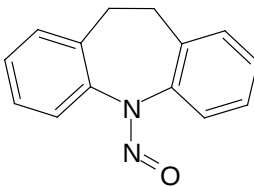
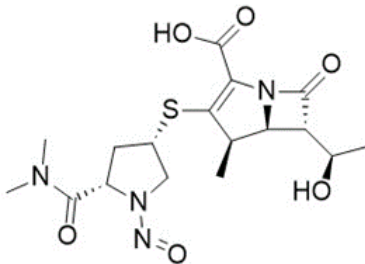
<i>N</i> -Nitroso-calcium folinate	Calcium folinate / Calcium levofolate		NMI		31 January 2024
<i>N</i> -Nitroso-frovatriptan / (6 <i>R</i>)-6-[methyl(nitroso)amino]-6,7,8,9- tetrahydro-5 <i>H</i> -carbazole-3-carboxamide	Frovatriptan		400	3	31 July 2025
<i>N</i> -Nitroso-furosemide / 4-chloro-2-[furan-2- ylmethyl(nitroso)amino]-5- sulfamoylbenzoic acid (2708280-93-5)	Furosemide		1500		29 July 2024
<i>N</i> -Nitroso-desmethyl-galantamine / (4 <i>aS</i> ,6 <i>R</i> ,8 <i>aS</i>)-3-methoxy-11-nitroso- 4 <i>a</i> ,5,9,10,11,12-hexahydro-6 <i>H</i> - benzo[2,3]benzofuro[4,3- <i>cd</i>]azepin-6-ol	Galantamine		18	1	4 February 2025
<i>N</i> -Nitroso-hydrochlorothiazide (63779-86-2, NHCTZ)	Hydrochlorothiazide		NMI		24 August 2023

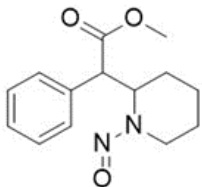
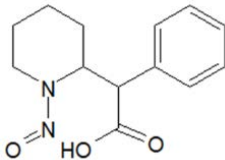
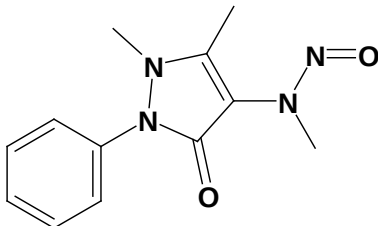
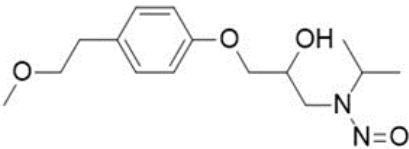
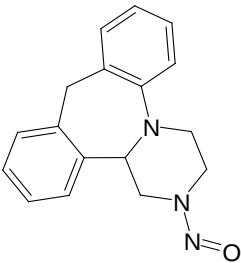
<i>N</i> -Nitroso hydroxychloroquine EP Impurity C / <i>N</i> -(4-((7-chloroquinolin-4-yl)amino)pentyl)- <i>N</i> -(2-hydroxyethyl)nitrous amide	Hydroxychloroquine		100	2	3 November 2025
<i>N</i> -Nitroso hydroxychloroquine EP Impurity D / <i>N</i> -(4-((7-chloroquinolin-4-yl)amino)pentyl)- <i>N</i> -ethylnitrous amide	Hydroxychloroquine		18	1	3 November 2025
<i>N</i> -Nitroso-hydroxyzine Impurity A / 1-((4-chlorophenyl)(phenyl)methyl)-4-nitrosopiperazine (2005-04-1)	Hydroxyzine		400	3	3 November 2025
<i>N</i> -Nitroso imatinib	Imatinib		1500	5	31 January 2024

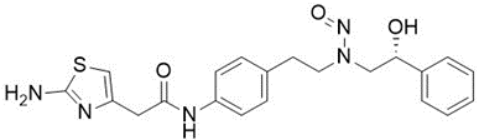
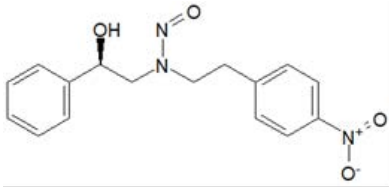
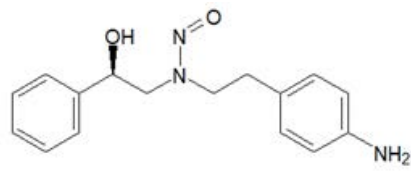
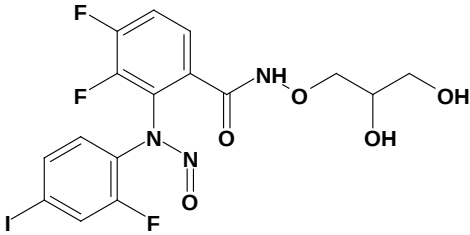
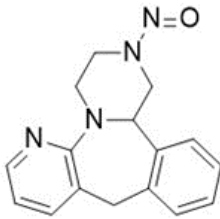
Indapamide impurity A / 2-methyl-1-nitroso-2,3-dihydroindole (85440-79-5)	Indapamide		1500	5	31 January 2024
<i>N</i> -Nitroso-ethylenediamine-triacetic acid (862542-34-5)	Isosorbide mononitrate		1500	4	31 January 2024
<i>N</i> -Nitroso-iminodiacetic acid (25081-31-6)	Isosorbide mononitrate		1500	4	31 January 2024
<i>N</i> -Nitroso-ivacaftor / <i>N</i> -(2,4-di- <i>tert</i> -butyl-5-hydroxyphenyl)-1-nitroso-4-oxo-1,4-dihydroquinoline-3-carboxamide	Ivacaftor		1500	5	4 February 2025
<i>N</i> -Nitroso-ketamine / <i>N</i> -[1-(2-chlorophenyl)-2-oxocyclohexyl]- <i>N</i> -methylnitrous amide (86144-35-6)	Ketamine		1500	5	24 August 2023

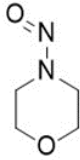
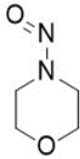
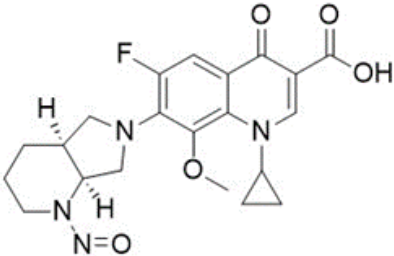
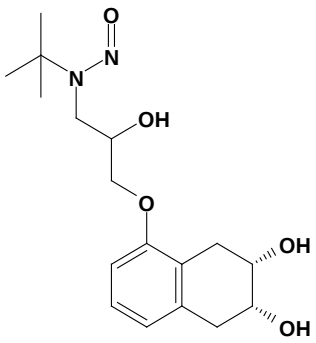
<i>N</i> -Nitroso-labetalol (2820170-74-7)	Labetalol		1500	4	24 August 2023
<i>N</i> -Nitroso-landiolol	Landiolol		400	3	24 August 2023
<i>N</i> -Nitroso-leniolisib	Leniolisib		1500	5	31 January 2024
<i>N</i> -Nitroso-desmethyl-lercanidipine / 3-(1-((3,3-diphenylpropyl)(nitroso)amino)- 2-methylpropan-2-yl) 5-methyl 2,6- dimethyl-4-(3-nitrophenyl)-1,4- dihydropyridine-3,5-dicarboxylate	Lercanidipine		100	2	30 April 2025
<i>N</i> -Nitroso-desmethyl-lercanidipine impurity C / 3-(1-((3,3-diphenylpropyl)(nitroso)amino)- 2-methylpropan-2-yl) 5-methyl 2,6- dimethyl-4-(3-nitrophenyl)pyridine-3,5- dicarboxylate	Lercanidipine		100	2	30 April 2025

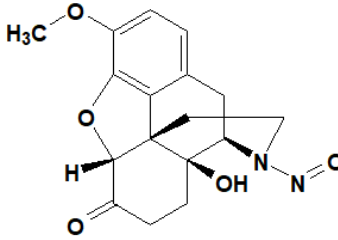
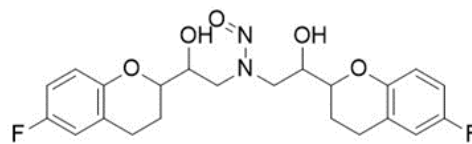
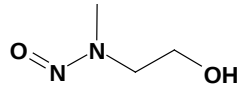
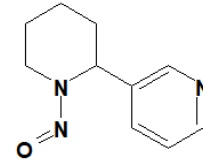
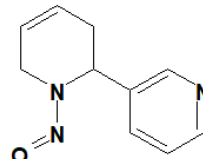
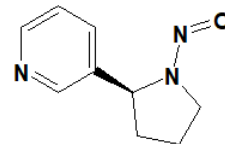
<i>N</i> -Nitroso-levofloxacin (1152314-62-9)	Levofloxacin		1500	4	24 August 2023
<i>N</i> -Nitroso-desethylidocaine	Lidocaine / Lignocaine		100	2	31 January 2024
<i>N</i> -Nitroso-lisinopril / <i>N</i> 2-((<i>S</i>)-1-carboxy-3-phenylpropyl)- <i>N</i> 2-nitroso- <i>L</i> -lysyl- <i>L</i> -proline (519175-80-5, NLP)	Lisinopril		NMI		24 August 2023 Updated 29 July 2024
<i>N</i> -Nitroso-maprotiline / <i>N</i> -(3-(9, 10-dihydro-9, 10-ethanoanthracen-9-yl)propyl)- <i>N</i> -methylnitrous amide (204268-61-1)	Maprotiline		18	1	15 October 2024

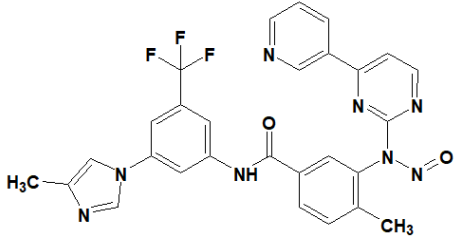
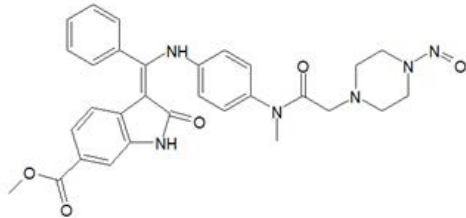
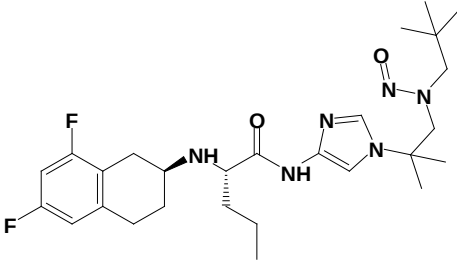
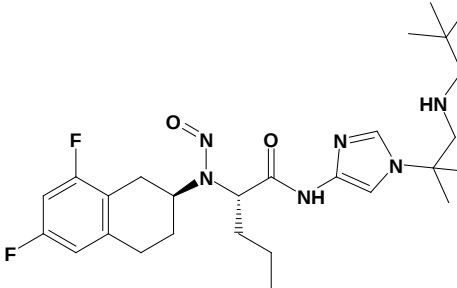
<i>N</i> -Nitroso-masitinib / 4-[(4-nitrosopiperazin-1-yl)methyl]- <i>N</i> -(4-methyl-3-{[4-(pyridin-3-yl)-1,3-thiazol-2-yl]amino}phenyl)benzamide	Masitinib		400	3	24 April 2024
<i>N</i> -Nitroso-mefenamic acid (2114-63-8)	Mefenamic acid		78000		5 January 2023
<i>N</i> -Nitroso-iminodibenzyl / 10,11-dihydro-5-nitroso-5 <i>H</i> - dibenz[b,f]azepine / 2-nitroso-2-azatricyclo[9.4.0.0 ^{3,8}] pentadeca-1(11),3(8),4,6,12,14-hexaene) (7458-08-4)	Melipramin (Imipramine)		78000		15 October 2024
<i>N</i> -Nitroso-meropenem / (4 <i>R</i> , 5 <i>S</i> , 6 <i>S</i>)-3-(((3 <i>S</i> , 5 <i>S</i>)-5-(dimethylcarbamoyl)-1-nitrosopyrrolidin- 3-yl)thio)-6-((<i>R</i>)-1-hydroxyethyl)-4- methyl-7-oxo-1-azabicyclo[3.2.0]hept-2- ene-2-carboxylic acid	Meropenem		1500	4	24 April 2024

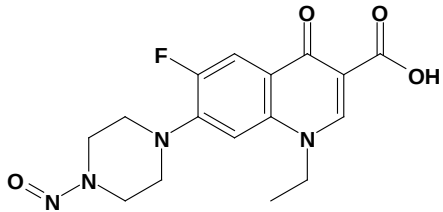
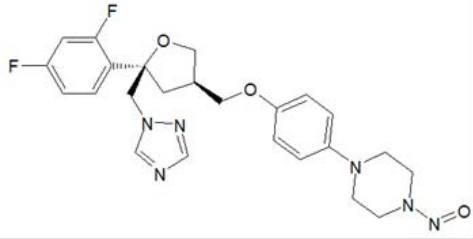
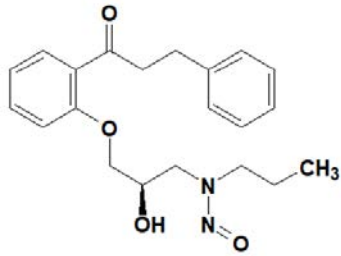
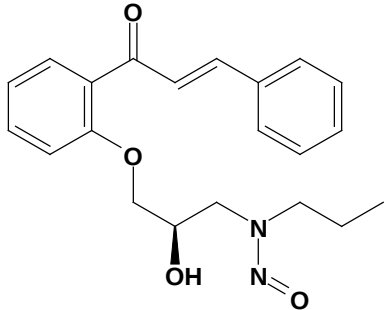
<i>N</i> -Nitroso-methylphenidate (55557-03-4, NMPH)	Methylphenidate		1300		20 July 2022
<i>N</i> -Nitroso-ritalinic acid / 2-(1-nitrosopiperidin-2-yl)-2-phenylacetic acid	Methylphenidate		1500	4	24 April 2024
<i>N</i> -Nitroso-methylaminoantipyrine / <i>N</i> -(1,5-dimethyl-3-oxo-2-phenylpyrazol- 4-yl)- <i>N</i> -methylnitrous amide (73829-38-6, NMAA)	Metamizole		100	2	3 November 2025
<i>N</i> -Nitroso-metoprolol (138768-62-4)	Metoprolol		1500	4	24 August 2023
<i>N</i> -Nitroso- <i>N</i> -desmethyl-mianserin / 2-nitroso-1,2,3,4,10,14b- hexahydrodibenzo[<i>c,f</i>]pyrazino[1,2- <i>a</i>]azepine	Mianserin		400	3	30 April 2025

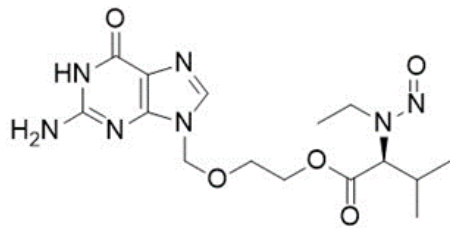
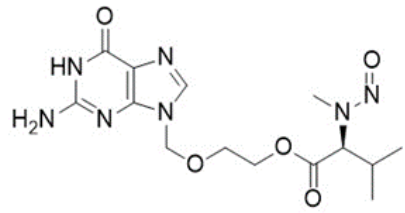
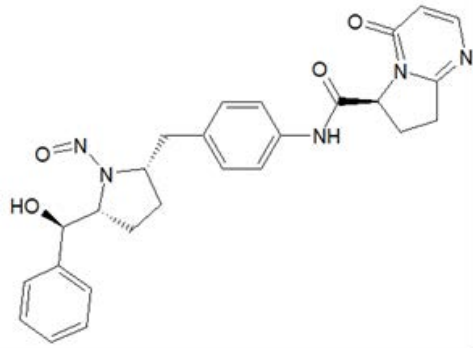
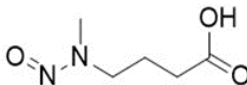
<i>N</i> -Nitroso-mirabegron	Mirabegron		400	3	24 August 2023
<i>N</i> -(2-Hydroxy-2-phenylethyl)- <i>N</i> -(4-nitrophenethyl)nitrous amide / (<i>R</i>)- <i>N</i> -(2-hydroxy-2-phenylethyl)- <i>N</i> -(4-nitrophenethyl)nitrous amide (MBL-2-NO)	Mirabegron		400	3	29 July 2024
<i>N</i> -(4-Aminophenethyl)- <i>N</i> -(2-hydroxy-2-phenylethyl)nitrous amide / (<i>R</i>)- <i>N</i> -(4-aminophenethyl)- <i>N</i> -(2-hydroxy-2-phenylethyl)nitrous amide (MBL-3-NO)	Mirabegron		400	3	29 July 2024
<i>N</i> -Nitroso-mirdametininib / <i>N</i> -(2,3-dihydroxypropoxy)-3,4-difluoro-2-((2-fluoro-4-iodophenyl)(nitroso)amino)benzamide	Mirdametininib		78000		3 November 2025
<i>N</i> -Nitroso-mirtazapine	Mirtazapine		400	3	31 January 2024

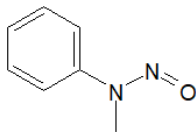
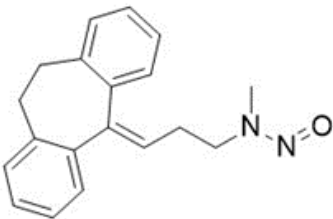
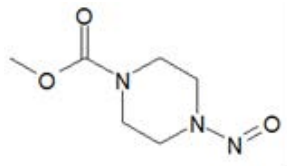
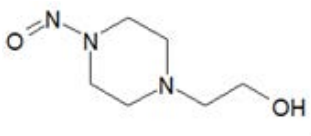
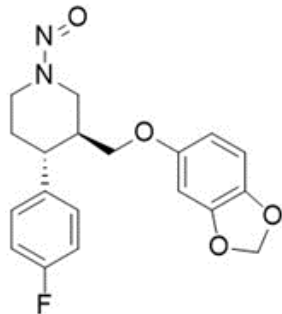
<i>N</i> -Nitroso-morpholine (59-89-2, NMOR)	-		127.0		20 July 2022
<i>N</i> -Nitroso-morpholine (59-89-2, NMOR)	Molsidomine		127.0		3 November 2025
<i>N</i> -Nitroso-moxifloxacin	Moxifloxacin		1500	4	24 August 2023
<i>N</i> -Nitroso-nadolol (134720-06-2)	Nadolol		1500	5	3 November 2025

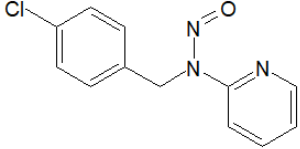
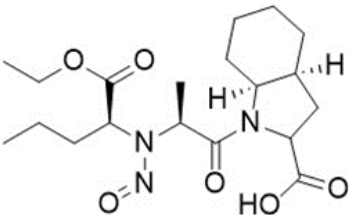
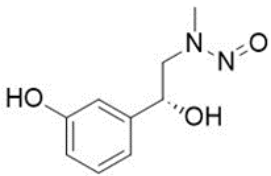
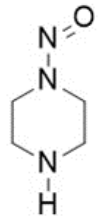
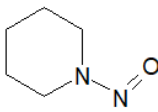
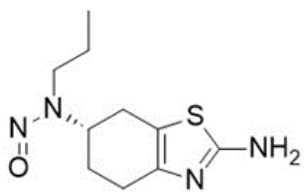
<i>N</i> -Nitroso-nor-oxycodone / (4 <i>R</i> ,4 <i>aS</i> ,7 <i>aS</i> ,12 <i>bS</i>)-4 <i>a</i> ,9-dihydroxy-3-nitroso-2,3,4,4 <i>a</i> ,5,6-hexahydro-1 <i>H</i> -4,12-methanobenzofuro[3,2- <i>e</i>]isoquinolin-7(7 <i>aH</i>)-one	Nalmefene		1500	4	4 February 2025
<i>N</i> -Nitroso-nebivolol (1391051-68-5, NNEB)	Nebivolol		NMI		24 August 2023 Updated 31 July 2025
<i>N</i> -Nitroso-methylethanolamine / <i>N</i> -(2-hydroxyethyl)- <i>N</i> -methylnitrous amide (26921-68-6, NMELA)	Nefopam		100	2	3 November 2025
<i>N</i> -Nitroso-anabasine / 3-(1-nitrosopiperidin-2-yl)pyridine (37620-20-5, NAB)	Nicotine		1500	4	4 February 2025
<i>N</i> -Nitroso-anatabine / 3-[(2 <i>S</i>)-1-nitroso-3,6-dihydro-2 <i>H</i> -pyridin-2-yl]pyridine (71267-22-6, NAT)	Nicotine		1500	4	4 February 2025
<i>N</i> -Nitroso-nornicotine / 3-[(2 <i>S</i>)-1-nitrosopyrrolidin-2-yl]pyridine (16543-55-8, NNN)	Nicotine		100		4 February 2025

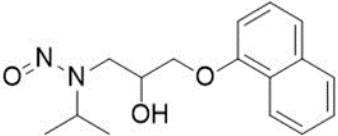
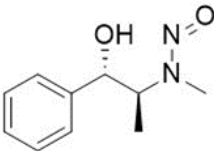
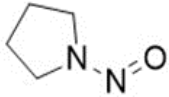
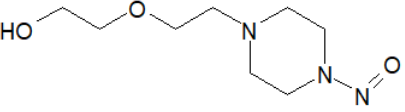
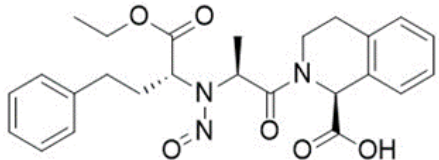
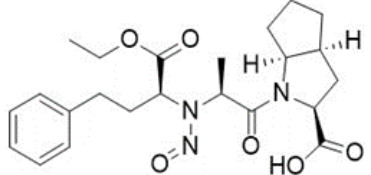
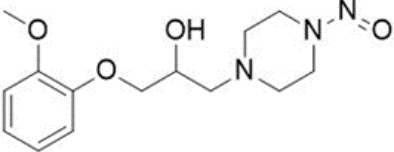
<i>N</i> -Nitroso-nilotinib / 4-methyl- <i>N</i> -(3-(4-methyl-1 <i>H</i> -imidazol-1-yl)-5-(trifluoromethyl)phenyl)-3-(nitroso(4-(pyridin-3-yl)pyrimidin-2-yl)amino)benzamide (2925306-68-7)	Nilotinib		1500	5	4 February 2025
<i>N</i> -Nitroso desmethyl nintedanib	Nintedanib		400	3	31 January 2024
<i>N</i> -Nitroso-nirogacestat / (<i>S</i>)-2-(((<i>S</i>)-6,8-difluoro-1,2,3,4-tetrahydronaphthalen-2-yl)amino)- <i>N</i> -(1-(2-methyl-1-(neopentyl(nitroso)amino)propan-2-yl)-1 <i>H</i> -imidazol-4-yl)pentanamide	Nirogacestat		1500		3 November 2025
<i>N</i> -Nitroso-nirogacestat impurity 1 / (<i>S</i>)-2-(((<i>S</i>)-6,8-difluoro-1,2,3,4-tetrahydronaphthalen-2-yl)(nitroso)amino)- <i>N</i> -(1-(2-methyl-1-(neopentylamino)propan-2-yl)-1 <i>H</i> -imidazol-4-yl)pentanamide	Nirogacestat		1500	5	3 November 2025

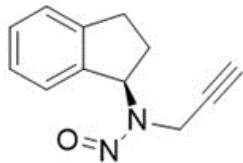
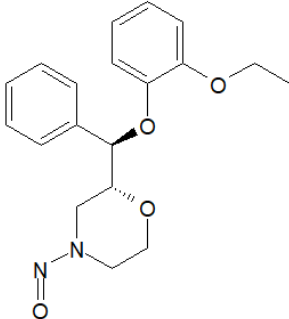
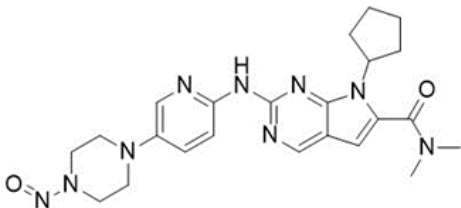
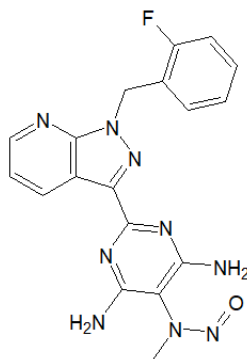
<i>N</i> -Nitroso-norfloxacin / 1-ethyl-6-fluoro-7-(4-nitrosopiperazin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid (74011-53-3)	Norfloxacin		NMI		31 July 2025
<i>N</i> -Nitroso-posaconazole Impurity 1 / 1-(4-(((3 <i>R</i> ,5 <i>R</i>)-5-((1 <i>H</i> -1,2,4-triazol-1-yl)methyl)-5-(2,4-difluorophenyl)tetrahydrofuran-3-yl)methoxy)phenyl)-4-nitrosopiperazine	Posaconazole		400	3	29 July 2024
<i>N</i> -Nitroso-propafenone / <i>N</i> -(2-hydroxy-3-(2-(3-phenylpropanoyl)phenoxy)propyl)- <i>N</i> -propylnitrous amide	Propafenone		100	2	15 October 2024
<i>N</i> -Nitroso-propafenone impurity B / (<i>R,E</i>)- <i>N</i> -(3-(2-cinnamoylphenoxy)-2-hydroxypropyl)- <i>N</i> -propylnitrous amide	Propafenone		100	2	3 November 2025

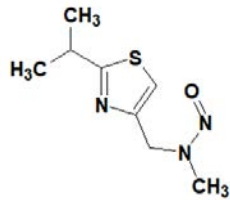
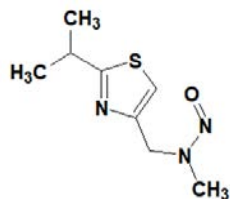
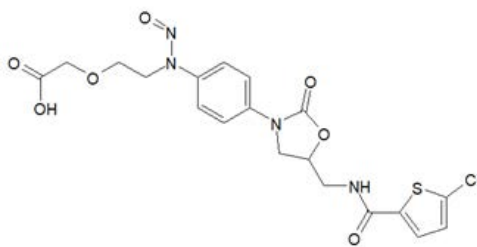
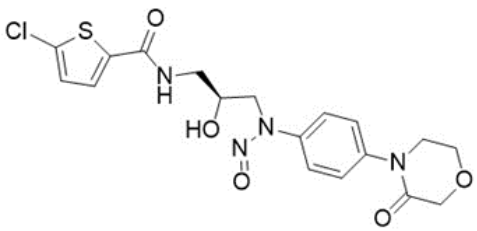
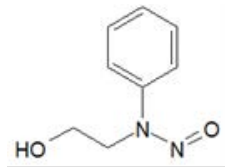
<i>N</i> -Nitroso- <i>N</i> -ethyl-valaciclovir	Valaciclovir		400	3	24 August 2023
<i>N</i> -Nitroso- <i>N</i> -methyl-valaciclovir	Valaciclovir		1500		24 April 2024 Updated 29 January 2026
<i>N</i> -Nitroso-vibegron (<i>S</i>)- <i>N</i> -(4-(((2 <i>R</i> ,5 <i>S</i>)-5-((<i>R</i>)-hydroxy(phenyl)methyl)-1-nitrosopyrrolidin-2-yl)methyl)phenyl)-4-oxo-4,6,7,8-tetrahydropyrrolo[1,2- <i>a</i>]pyrimidine-6-carboxamide	Vibegron		1500	5	29 July 2024
<i>N</i> -Nitroso- <i>N</i> -methyl-4-aminobutyric acid / 4-[methyl(nitroso)amino]butanoic acid (61445-55-4, NMBA)	-		1500	4	15 September 2019 Updated 29 July 2024

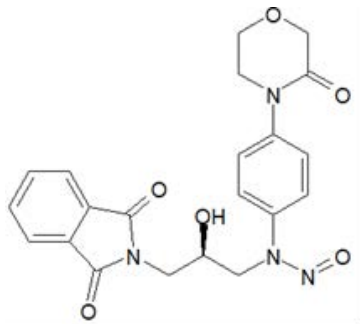
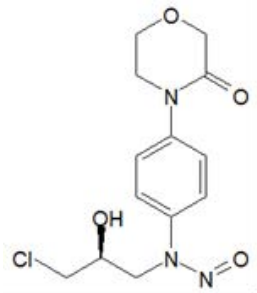
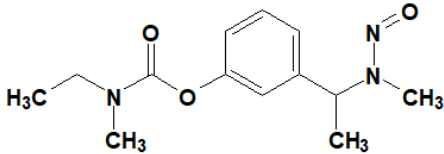
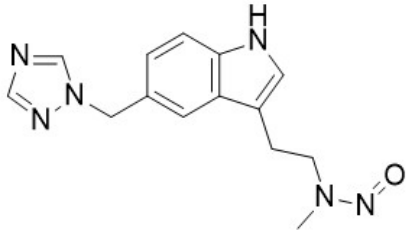
<i>N</i> -Nitroso- <i>N</i> -methylaniline / <i>N</i> -methyl- <i>N</i> -phenylnitrous amide (614-00-6, NMPA)	-		100	2	31 January 2024
<i>N</i> -Nitroso-nortriptyline (55855-42-0, NNORT)	Amitriptyline, Nortriptyline		18	1	20 July 2022 Updated 15 October 2024
4-Nitroso-methyl piperazine-1-carboxylate (<i>N</i> -nitroso PMEC)	Omecamtiv mecarbil		400	3	29 July 2024
2-(4-Nitrosopiperazin-1-yl)ethanol (48121-20-6)	Opipramol		400	3	29 July 2024
<i>N</i> -Nitroso-paroxetine (2361294-43-9)	Paroxetine		1300		5 January 2023

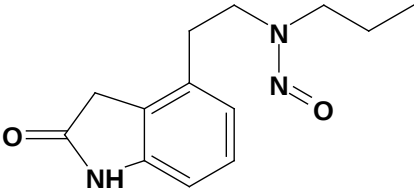
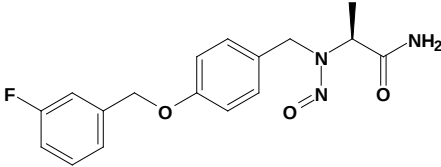
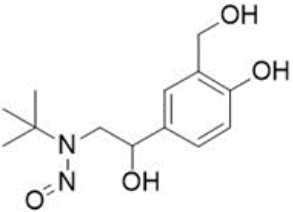
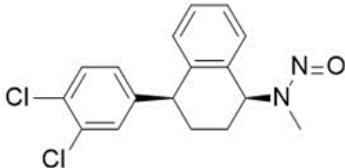
<i>N</i> -Nitroso- <i>p</i> -chloro-benzylamino-pyridine (N-CBAP)	Chloropyramine		100	2	24 August 2023
<i>N</i> -Nitroso-perindopril	Perindopril		NMI		24 August 2023 Updated 29 January 2026
<i>N</i> -Nitroso-phenylephrine (78658-64-7)	Phenylephrine		100	2	24 August 2023
<i>N</i> -Nitroso-piperazine (5632-47-3, NPZ)	-		400	3	24 August 2023
<i>N</i> -Nitroso-piperidine (100-75-4)	-		1300		20 July 2022
<i>N</i> -Nitroso-pramipexole	Pramipexole		400	3	24 August 2023

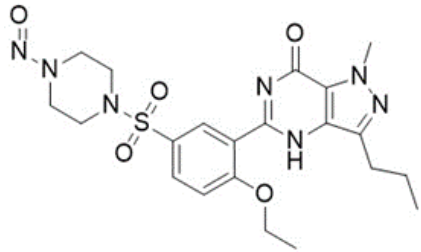
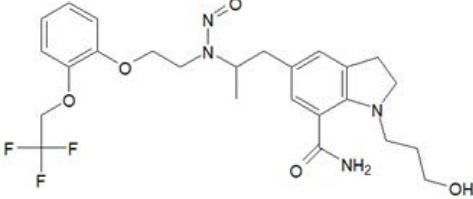
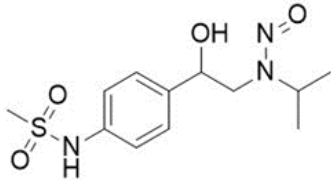
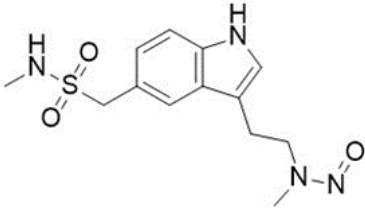
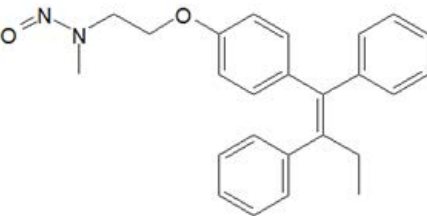
<i>N</i> -Nitroso-propranolol (84418-35-9)	Propranolol		1500	4	24 August 2023
<i>N</i> -Nitroso-pseudoephedrine (1850-88-0)	Pseudoephedrine		1500		24 August 2023 Updated 29 January 2026
<i>N</i> -Nitroso-pyrrolidine (930-55-2, NPYR)	-		1700		5 January 2023
<i>N</i> -Nitroso quetiapine HEEP impurity / 2-(2-(4-nitrosopiperazin-1-yl)ethoxy)ethan-1-ol (73486-81-4)	Quetiapine		1500		31 January 2024
<i>N</i> -Nitroso-quinapril	Quinapril		NMI		24 August 2023
<i>N</i> -Nitroso-ramipril	Ramipril		NMI		24 August 2023 Updated 29 January 2026
<i>N</i> -nitroso ranolazine impurity 1 / 1-(2-methoxyphenoxy)-3-(4-nitrosopiperazin-1-yl)propan-2-ol	Ranolazine		400	3	31 January 2024

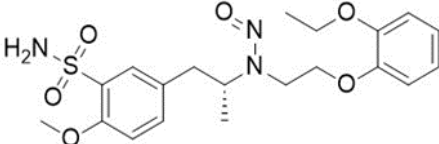
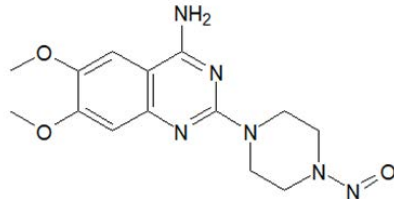
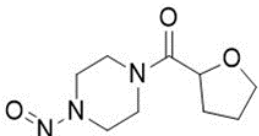
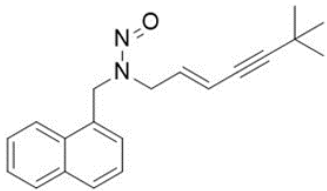
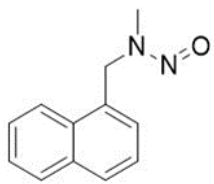
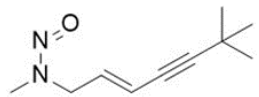
<i>N</i> -Nitroso-rasagiline (2470278-90-9)	Rasagiline		100	2	20 July 2022 Updated 24 August 2023
<i>N</i> -Nitroso-reboxetine	Reboxetine		127		24 August 2023
<i>N</i> -Nitroso-ribociclib impurity 1 / 7-cyclopentyl- <i>N,N</i> -dimethyl-2-((5-(4-nitrosopiperazin-1-yl)pyridine-2-yl)amino)-7 <i>H</i> -pyrrolo[2,3- <i>d</i>]pyrimidine-6-carboxamide	Ribociclib		400	3	31 January 2024
<i>N</i> -Nitroso-desformyl-riociguat / <i>N</i> -(4,6-diamino-2-(1-(2-fluorobenzyl)-1 <i>H</i> -pyrazolo[3,4- <i>b</i>]pyridin-3-yl)pyrimidin-5-yl)- <i>N</i> -methylnitrous	Riociguat		100	2	29 July 2024

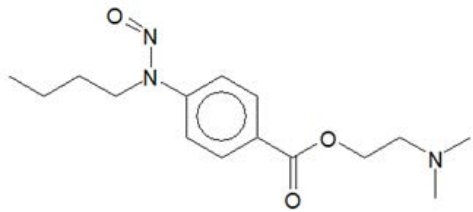
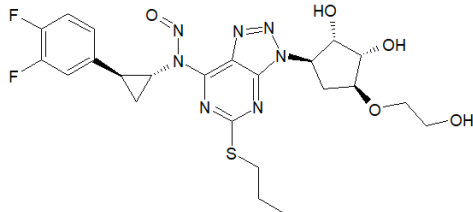
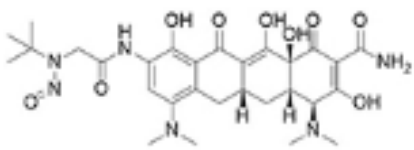
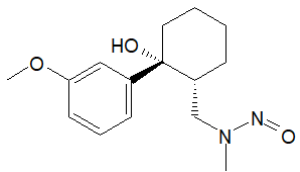
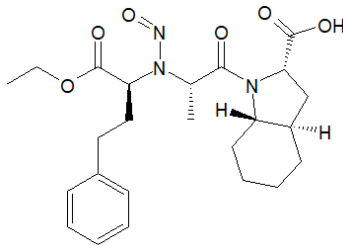
<i>N</i> -Nitroso-2,4-thiazole amine / <i>N</i> -((2-isopropylthiazol-4-yl)methyl)- <i>N</i> -methylnitrous amide (NNTA)	Ritonavir		18	1	15 October 2024
<i>N</i> -Nitroso-2,4-thiazole amine / <i>N</i> -((2-isopropylthiazol-4-yl)methyl)- <i>N</i> -methylnitrous amide (NNTA)	Cobicistat		18	1	3 November 2025
<i>N</i> -Nitroso-rivaroxaban open-ring acid / (<i>S</i>)-2-(2-((4-(5-((5-chlorothiophene-2-carboxamido)methyl)-2-oxooxazolidin-3-yl)phenyl)(nitroso)amino)ethoxy) acetic acid	Rivaroxaban		1500	4	31 January 2024
<i>N</i> -Nitroso-rivaroxaban amide / (<i>S</i>)-5-chloro- <i>N</i> -(2-hydroxy-3-(nitroso (4-(3-oxomorpholino)phenyl)amino)propyl)thiophene-2-carboxamide	Rivaroxaban		1500	4	31 January 2024
Rivaroxaban nitroso impurity 1 / <i>N</i> -(2-hydroxyethyl)- <i>N</i> -phenyl-nitrous amide (25413-76-7, <i>N</i> -Nitroso KCR-1)	Rivaroxaban		1500	4	29 July 2024

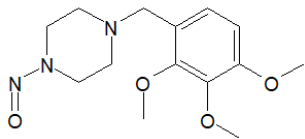
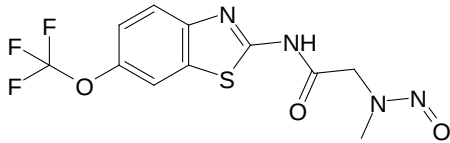
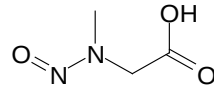
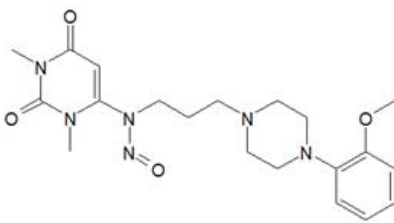
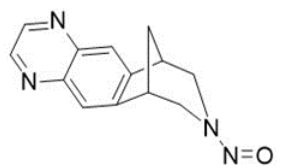
Rivaroxaban nitroso impurity 2 / <i>N</i> -(3-(1,3-dioxoisindolin-2-yl)-2-hydroxypropyl)- <i>N</i> -(4-(3-oxomorpholino)phenyl)nitrous amide	Rivaroxaban		1500	4	29 July 2024
Rivaroxaban nitroso impurity 5 / <i>N</i> -(3-chloro-2-hydroxypropyl)- <i>N</i> -(4-(3-oxomorpholino)phenyl)nitrous amide (<i>N</i> -Nitroso RVR-A)	Rivaroxaban		1500	4	29 July 2024
<i>N</i> -Nitroso-desmethyl-rivastigmine / [3-[(1 <i>S</i>)-1-[methyl(nitroso)amino]ethyl]phenyl] <i>N</i> -ethyl- <i>N</i> -methyl carbamate	Rivastigmine		100	2	15 October 2024
<i>N</i> -Nitroso- <i>N</i> -desmethyl-rizatriptan / <i>N</i> -(2-(5-((1 <i>H</i> -1,2,4-triazol-1-yl)methyl)-1 <i>H</i> -indol-3-yl)ethyl)- <i>N</i> -methylnitrous amide	Rizatriptan		18	1	15 October 2024

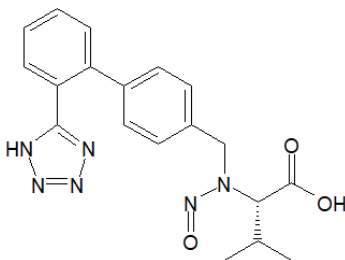
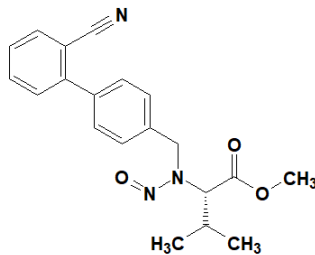
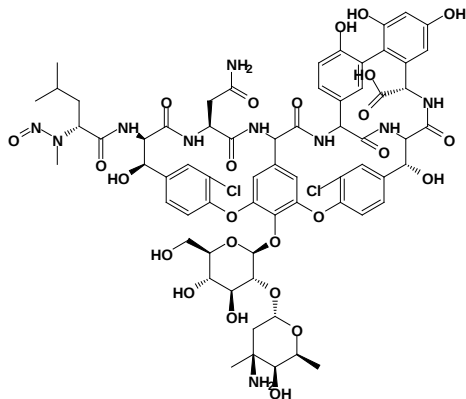
<i>N</i> -Nitroso-despropyl-ropinirole / <i>N</i> -(2-(2-oxoindolin-4-yl)ethyl)- <i>N</i> -propylnitrous amide	Ropinirole		18	1	31 July 2025
<i>N</i> -Nitroso-safinamide / (2 <i>S</i>)-2-[[4-[(3-fluorophenyl)methoxy]phenyl]methyl-nitrosoamino]propanamide (2657645-00-4)	Safinamide		400	3	31 July 2025
<i>N</i> -Nitroso-salbutamol (2919946-71-5)	Salbutamol		1500	5	24 August 2023
<i>N</i> -Nitroso-sertraline	Sertraline		100	2	24 August 2023 Updated 16 October 2023 Updated 15 October 2024

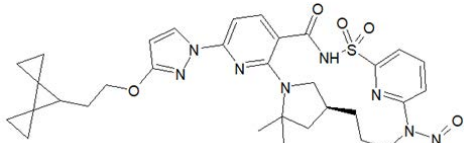
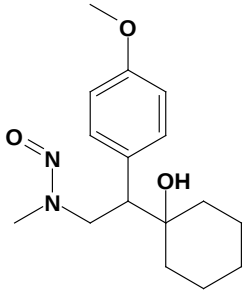
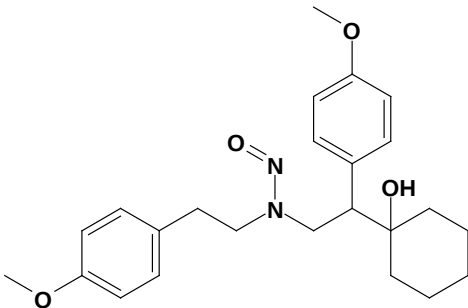
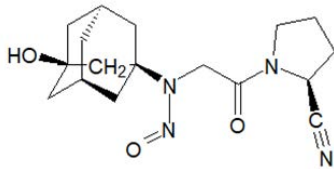
<i>N</i> -Nitroso-desmethyl-sildenafil	Sildenafil		400	3	31 January 2024
<i>N</i> -Nitroso-silodosin / 1-(3-hydroxypropyl)-5-[(2 <i>R</i>)-2-[nitroso-[2-[2-(2,2,2-trifluoroethoxy)phenoxy]ethyl]amino]propyl]-2,3-dihydroindole-7-carboxamide	Silodosin		1500	4	24 April 2024
<i>N</i> -Nitroso-sotalol (134720-07-3)	Sotalol		1500	4	24 August 2023
<i>N</i> -Nitroso-desmethyl sumatriptan	Sumatriptan		18	1	31 January 2024
<i>N</i> -Nitroso-desmethyl-tamoxifen / (<i>Z</i>)- <i>N</i> -(2-(4-(1, 2-diphenylbut-1-en-1-yl)phenoxy)ethyl)- <i>N</i> -methylnitrous amide	Tamoxifen		18	1	24 April 2024

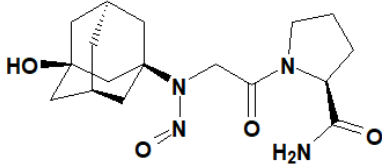
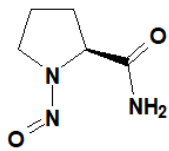
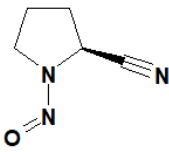
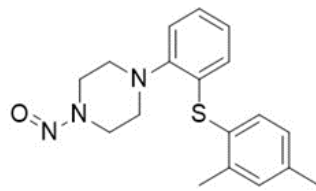
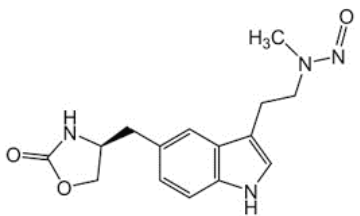
<i>N</i> -Nitroso-tamsulosin (2892260-31-8)	Tamsulosin		1500	4	20 July 2022 Updated 24 August 2023
<i>N</i> -Nitroso terazosin impurity C / <i>N</i> -nitroso 6,7-dimethoxy-2-(1-piperaziny)-4-quinazolinamine / <i>N</i> -nitroso 2-(1-piperaziny)-4-amino-6, 7-dimethoxyquinazoline	Terazosin		400	3	24 April 2024
<i>N</i> -Nitroso terazosin impurity N / (4-nitrosopiperazin-1-yl)(tetrahydrofuran-2-yl)methanone	Terazosin		400	3	24 April 2024
<i>N</i> -Nitroso-desmethyl-terbinafine / (<i>E</i>)- <i>N</i> -(6,6-dimethylhept-2-en-4-yn-1-yl)- <i>N</i> -(naphthalen-1-ylmethyl)nitrous amide (NDT / NHNA)	Terbinafine		18	1	31 January 2024
<i>N</i> -Nitroso-terbinafine impurity A / <i>N</i> -methyl- <i>N</i> -(naphthalen-1-ylmethyl)nitrous amide (296760-88-8, NTA / NMNA)	Terbinafine		18	1	31 January 2024
<i>N</i> -Nitroso-terbinafine degradant / <i>N</i> -[(2 <i>E</i>)-6,6-dimethyl-2-hepten-4-yn-1-yl]- <i>N</i> -nitrosomethanamine (NTD / NHMA)	Terbinafine		18	1	31 January 2024

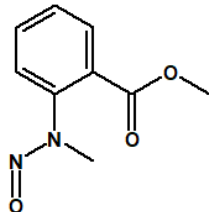
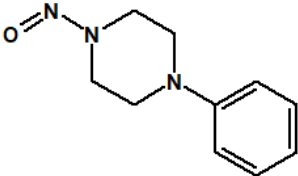
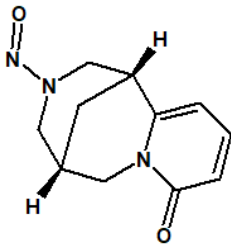
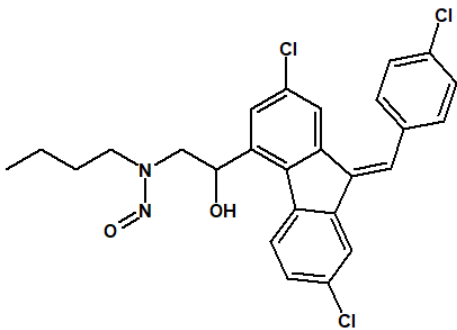
<i>N</i> -Nitroso-tetracaine	Tetracaine		400	3	31 January 2024
<i>N</i> -Nitroso-ticagrelor (2476859-55-7)	Ticagrelor		1500	5	31 January 2024
<i>N</i> -Nitroso-tigecycline / (4 <i>S</i> , 4 <i>aS</i> , 5 <i>aR</i> , 12 <i>aS</i>)-9-(2-(<i>tert</i> -butyl(nitroso)amino)acetamido)-4, 7-bis(dimethylamino)-3, 10, 12, 12 <i>a</i> -tetrahydroxy-1, 11-dioxo-1, 4, 4 <i>a</i> , 5, 5 <i>a</i> , 6, 11, 12 <i>a</i> -octahydrotetracene-2-carboxamide	Tigecycline		NMI		29 July 2024
<i>N</i> -Nitroso-desmethyl-tramadol / <i>N</i> -[[[(1 <i>R</i> ,2 <i>R</i>)-2-hydroxy-2-(3-methoxyphenyl)cyclohexyl]methyl]- <i>N</i> -methylnitrous amide	Tramadol		18	1	29 July 2024
<i>N</i> -Nitroso-trandolapril / (2 <i>S</i> ,3 <i>aR</i> ,7 <i>aS</i>)-1-(<i>N</i> -((<i>S</i>)-1-ethoxy-1-oxo-4-phenylbutan-2-yl)- <i>N</i> -nitroso-L-alanyl)octahydro-1 <i>H</i> -indole-2-carboxylic acid	Trandolapril		1500	5	29 July 2024

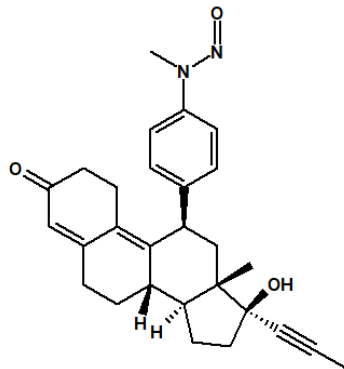
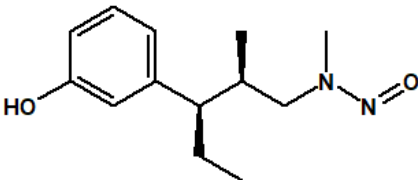
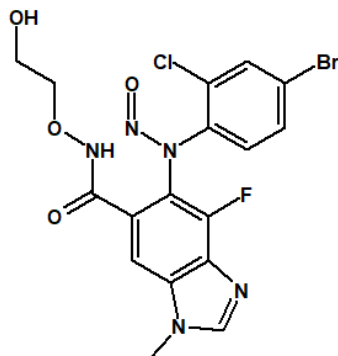
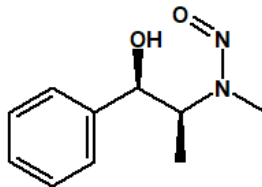
<i>N</i> -Nitroso-trimetazidine (92432-50-3, NTMZ)	Trimetazidine		400	3	24 August 2023
2-(<i>N</i> -Nitrosomethylamino)- <i>N</i> -[6-(trifluoromethoxy)-1,3-benzothiazol-2-yl]acetamide (NNT)	Troriluzole		100	2	30 April 2025
<i>N</i> -Nitroso-sarcosine / 2-[methyl(nitroso)amino]acetic acid (13256-22-9, NSAR)	Troriluzole		1500	4	30 April 2025
<i>N</i> -Nitroso-urapidil	Urapidil		1500	4	31 January 2024
<i>N</i> -Nitroso-varenicline (2755871-02-2, NNV)	Varenicline		400	3	20 July 2022 Updated 16 October 2023

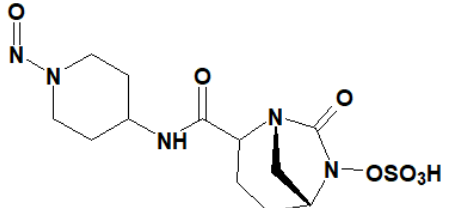
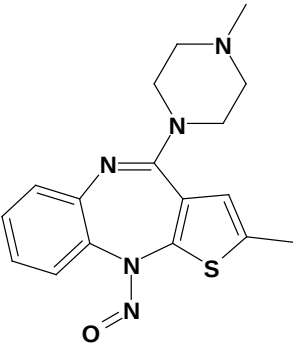
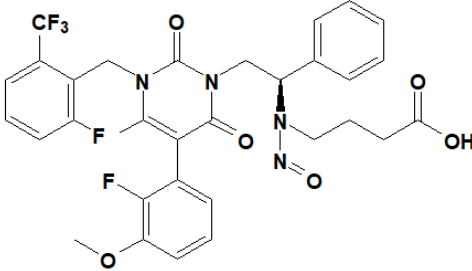
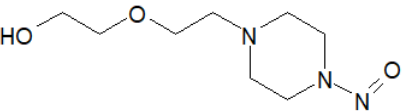
<i>N</i>-Nitroso-desvaleryl-valsartan / (<i>S</i>)-2-(((2'-(1<i>H</i>-tetrazol-5-yl)- [1,1'- biphenyl]-4-yl) methyl)(nitroso)amino)- 3- methylbutanoic acid (2254485-68-0)	Valsartan		NMI		29 July 2024
<i>N</i>-Nitroso-valsartan cyano- desvalerylmethylester / (<i>S</i>)-Methyl 2-(((2'-cyano-[1,1'-biphenyl]-4- yl)methyl)(nitroso) amino)-3- methylbutanoate	Valsartan		100	2	15 October 2024
<i>N</i>-Nitroso-vancomycin / (1<i>S</i>,2<i>R</i>,18<i>R</i>,19<i>R</i>,22<i>S</i>,25<i>R</i>,28<i>R</i>,40<i>S</i>)-48- [(2<i>S</i>,3<i>R</i>,4<i>S</i>,5<i>S</i>,6<i>R</i>)-3-[(2<i>S</i>,4<i>S</i>,5<i>S</i>,6<i>S</i>)-4-amino- 5-hydroxy-4,6-dimethyloxan-2-yl]oxy-4,5- dihydroxy-6-(hydroxymethyl)oxan-2- yl]oxy-22-(2-amino-2-oxoethyl)-5,15- dichloro-2,18,32,35,37-pentahydroxy-19- [[2<i>R</i>)-4-methyl-2- [methyl(nitroso)amino]pentanoyl]amino]- 20,23,26,42,44-penta-oxo-7,13-dioxo- 21,24,27,41,43- pentazaocyclo[26.14.2.23,6.214,17.18,1 2.129,33.010,25.034,39]pentaconta- 3,5,8(48),9,11,14,16,29(45),30,32,34(39),35, 37,46,49-pentadecaene-40-carboxylic acid (155386-25-7)	Vancomycin		1500	4	30 April 2025

<i>N</i> -Nitroso-vanzacaftor / (13 <i>S,Z</i>)-26-(3-(2-(dispiro[2.0.24.13]heptan-7-yl)ethoxy)-1 <i>H</i> -pyrazol-1-yl)-15,15-dimethyl-61,62-dihydro-5-thia-4,7-diaza-2(2,3),6(6,2)-dipyridina-1(1,3)-pyrrolidinacyclodecaphan-3-one 5,5-dioxide	Vanzacaftor		1500	4	15 October 2024
<i>N</i> -Nitroso venlafaxine EP Impurity D / <i>N</i> -(2-(1-hydroxycyclohexyl)-2-(4-methoxyphenyl)ethyl)- <i>N</i> -methylnitrous amide (2680662-11-5)	Venlafaxine		18	1	3 November 2025
<i>N</i> -Nitroso venlafaxine EP Impurity H / <i>N</i> -(2-(1-hydroxycyclohexyl)-2-(4-methoxyphenyl)ethyl)- <i>N</i> -(4-methoxyphenethyl)nitrous amide	Venlafaxine		100	2	3 November 2025
<i>N</i> -Nitroso-vildagliptin	Vildagliptin		1500	5	24 August 2023

<i>N</i> -Nitroso vildagliptin amide impurity / (<i>S</i>)-1-(2-(((1 <i>R</i> , 3 <i>R</i> , 5 <i>R</i> , 7 <i>S</i>)-3-hydroxyadamantan-1-yl)(nitroso)amino)acetyl)pyrrolidine-2-carboxamide	Vildagliptin		1500	5	15 October 2024
<i>N</i> -Nitroso- <i>L</i> -prolinamide / (<i>S</i>)-1-nitrosopyrrolidine-2-carboxamide (79108-51-3)	Vildagliptin		1500	4	4 February 2025
<i>N</i> -Nitroso- <i>L</i> -prolinenitrile / (<i>S</i>)-1-nitrosopyrrolidine-2-carbonitrile	Vildagliptin		1500	4	4 February 2025
<i>N</i> -Nitroso-vortioxetine	Vortioxetine		400	3	24 August 2023
<i>N</i> -Nitroso-desmethyl-zolmitriptan / <i>N</i> -methyl- <i>N</i> -[2-[5-[[[(4 <i>S</i>)-2-oxo-1,3-oxazolidin-4-yl]methyl]-1 <i>H</i> -indol-3-yl]ethyl]nitrous amide	Zolmitriptan		18	1	4 February 2025

<i>N</i> -Methyl- <i>N</i> -nitrosoanthranilate / methyl 2-(methyl(nitroso)amino)benzoate (68061-82-5, NO-MMA)	Methyl <i>N</i> -methylantranilate		100	2	29 January 2026
<i>N</i> -Nitroso-4-phenylpiperazine / 1-nitroso-4-phenylpiperazine (14340-33-1)	Levodropropazine		400	3	29 January 2026
<i>N</i> -Nitroso-cytisine / (1 <i>R</i> ,5 <i>R</i>)-3-nitroso-1,2,3,4,5,6-hexahydro-8 <i>H</i> -1,5-methanopyrido[1,2- <i>a</i>][1,5]diazocin-8-one (19634-60-7)	Cytisine		400	3	29 January 2026
<i>N</i> -Nitroso-desbutyl-lumefantrine / (<i>Z</i>)- <i>N</i> -butyl- <i>N</i> -(2-(2,7-dichloro-9-(4-chlorobenzylidene)-9 <i>H</i> -fluoren-4-yl)-2-hydroxyethyl)nitrous amide	Lumefantrine		1500		29 January 2026

<i>N</i> -Nitroso-desmethyl-mifepristone / <i>N</i> -[4-[(8 <i>S</i> ,11 <i>R</i> ,13 <i>S</i> ,14 <i>S</i> ,17 <i>S</i>)-17-hydroxy-13-methyl-3-oxo-17-prop-1-ynyl-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta[<i>a</i>]phenanthren-11-yl]phenyl]- <i>N</i> -methylnitrous amide	Mifepristone		100	2	29 January 2026
<i>N</i> -Nitroso-desmethyl-tapentadol / <i>N</i> -[(2 <i>R</i> ,3 <i>R</i>)-3-(3-hydroxyphenyl)-2-methylpentyl]- <i>N</i> -methylnitrous amide	Tapentadol		18	1	29 January 2026
<i>N</i> -Nitroso-selumetinib / 6-(4-bromo-2-chloro- <i>N</i> -nitrosoanilino)-7-fluoro- <i>N</i> -(2-hydroxyethoxy)-3-methylbenzimidazole-5-carboxamide	Selumetinib		78000		29 January 2026
<i>N</i> -Nitroso-ephedrine / <i>N</i> -[(1 <i>S</i> ,2 <i>R</i>)-1-hydroxy-1-phenylpropan-2-yl]- <i>N</i> -methylnitrous amide (7181-48-8)	Ephedrine		1500	4	29 January 2026

<i>N</i> -Nitroso-relebactam	Relebactam		400	3	29 January 2026
<i>N</i> -Nitroso-olanzapine	Olanzapine		1500	5	29 January 2026
<i>N</i> -Nitroso-elagolix	Elagolix		1500	4	29 January 2026
2-(2-(4-Nitrosopiperazin-1-yl)ethoxy)ethan-1-ol (73486-81-4)	Hydroxyzine		1500		29 January 2026

CPCA: Carcinogenic Potency Categorisation Approach

NMI: Non mutagenic impurity should be controlled to [ICH Q3A](#) and [ICH Q3B](#) guideline limits

- ¹ Acceptable Intake (AI) Limit to be applied to maximum daily dose (MDD) of the drug product. These limits are applicable only if a product contains a single *N*-nitrosamine.
- ² Potential presence of nitrosamine impurities with structures derived from drug substances or their related impurities. This does not mean that the impurity will be found in all products or pharmaceutical forms containing the drug substance. Please refer to [EMA's Q&A](#) on the risk factors for the presence of nitrosamines for details.