FUJIFILM
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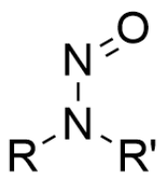
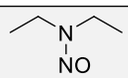
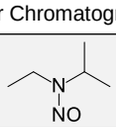
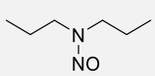
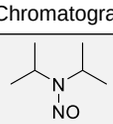
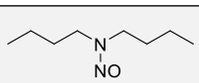
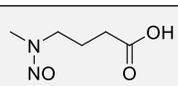
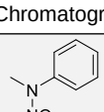
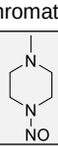
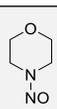
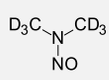
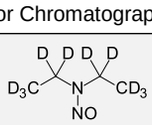
for Pharmaceutical, Food, and Water Environment Analysis

Analytical Standards of Nitrosamines

Nitrosamines are compounds of the chemical structure where hydrogen of the amine nitrogen is substituted with a nitroso group. And these are known to be carcinogenic. Nitrosamine are often detected as impurities during the manufacturing process of a drug product. Recently, nitrosamines were detected in some sartan and ranitidine drug products, and these products were recalled. In response to this event, in September 2019, the EMA (European Medicines Agency) requested the marketing authorization holders to evaluate the risk of the presence of nitrosamine impurities in their drugs and take appropriate risk mitigation measures.



Product List

N-Nitrosodimethylamine Standard		*N*-Nitrosomethylethylamine Standard		*N*-Nitrosodiethylamine Standard	
for Gas Chromatography		for Chromatography		for Chromatography	
					
Code No. 147-03781	Vol. 1 g	**Code No. 140-10001**	Vol. 50 mg	**Code No. 141-09921**	Vol.100 mg
Abbrev. NDMA	CAS RN® 62-75-9	Abbrev. NEMA, NMEA	CAS RN® 10595-95-6	Abbrev. NDEA	CAS RN® 55-18-5
N-Nitrosoethylisopropylamine Standard		*N*-Nitrosodi-*n*-propylamine Standard		*N*-Nitrosodiisopropylamine Standard	
for Chromatography		for Chromatography		for Chromatography	
					
Code No. 142-09951	Vol. 50 mg	**Code No. 140-09991**	Vol.100 mg	**Code No. 145-09941**	Vol. 50 mg
Abbrev. EIPNA, NEIPA	CAS RN® 16339-04-1	Abbrev. NDPA	CAS RN® 621-64-7	Abbrev. DIPNA, NDIPA	CAS RN® 601-77-4
N-Nitrosodi-*n*-butylamine Standard		*N*-Nitrosomethylaminobutyric Acid Standard		*N*-Nitrosomethylphenylamine Standard	
for Chromatography		for Chromatography		for Chromatography	
					
Code No. 149-09961	Vol. 100 mg	**Code No. 146-09971**	Vol. 50 mg	**Code No. 148-09931**	Vol. 50 mg
Abbrev. NDBA	CAS RN® 924-16-3	Abbrev. NMBA	CAS RN® 61445-55-4	Abbrev. NMPA	CAS RN® 614-00-6
N-Nitroso-*N*′-methylpiperazine Standard		*N*-Nitrosomorpholine Standard		*N*-Nitrosodimethylamine-d_6 Standard	
for Chromatography		for Chromatography		for Chromatography	
					
Code No. 143-09981	Vol. 50 mg	**Code No. 141-10031**	Vol. 100 mg	**Code No. 144-10021**	Vol. 100 mg
Abbrev. MeNP	CAS RN® 16339-07-4	Abbrev. NMOR	CAS RN® 59-89-2	Abbrev. NDMA-d_6	CAS RN® 17829-05-9
N-Nitrosodiethylamine-d_{10} Standard					
for Chromatography					
					
Code No. 147-10011	Vol. 50 mg				
Abbrev. NDEA-d_{10}	CAS RN® 1219794-54-3				

Regulatory Trends in Each Country

Nitrosoamine	Abbreviation	FDA	USP	EMA	Ph. Eur.
N-Nitrosodi-*n*-butylamine	NDBA	✓	✓	✓	✓
N-Nitrosodiethylamine	NDEA	✓	✓	✓	✓
N-Nitrosodiisopropylamine	DIPNA, NDIPA	✓	✓	✓	✓
N-Nitrosodimethylamine	NDMA	✓	✓	✓	✓
N-Nitrosodi-*n*-propylamine	NDPA				✓
N-Nitrosoethylisopropylamine	EIPNA, NEIPA	✓	✓	✓	✓
N-Nitrosomethylaminobutyric Acid	NMBA	✓	✓	✓	✓
N-Nitrosomethylphenylamine	NMPA		✓	✓	
N-Nitroso-*N'*-methylpiperazine	MeNP			✓	
N-Nitrosomorpholine	NMOR			✓	

Analytical Methods of USP and Ph. Eur

■ Ph. Eur. 10.6 2.4.42 *N*-Nitrosamine impurities in active substance (As of June 2021)

		Analyte	Internal Standard
Procedure A	LC/MS/MS	NDMA, NDEA, NMBA, DIPNA, EIPNA	NDEA-d_{10}
Procedure B	GC/MS	NDMA, NDEA	NEMA
Procedure C	GC/MS/MS	NDMA, NDEA, NDBA, DIPNA, EIPNA, NDPA	NEMA

■ USP <1469> *N*-Nitrosamine Impurities (As of June 2021)

		Analyte	Internal Standard
Procedure 1	LC/HRMS	NDMA, NDEA, NDIPA, NEIPA, NMBA, NDBA, NMPA	
Procedure 2	GC/MS	NDMA, NDEA, NDIPA, NEIPA	NDMA-d_6
Procedure 3	LC/MS/MS	NDMA, NDEA, NDIPA, NEIPA, NMBA, NDBA	NDMA-d_6, NMBA-d_3, NDEA-d_{10}, NDBA-d_{18}
Procedure 4	GC/MS/MS	NDMA, NDEA, NDIPA, NEIPA, NDBA, NMPA	NDMA-$^{13}C_2$-d_6

*The regulated components and analytical methods are based on the information available as of June 2021.
For details, see the website of each pharmacopoeia.
*Please check our website for details.
Pharma Manufacturing & QC > QC Test > Analytical Standards of Nitrosamines
https://labchem-wako.fujifilm.com/us/category/02128.html

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