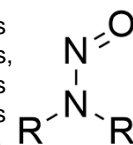


for Pharmaceutical, Food, and Water Environment Analysis Analytical Standards of Nitrosamines

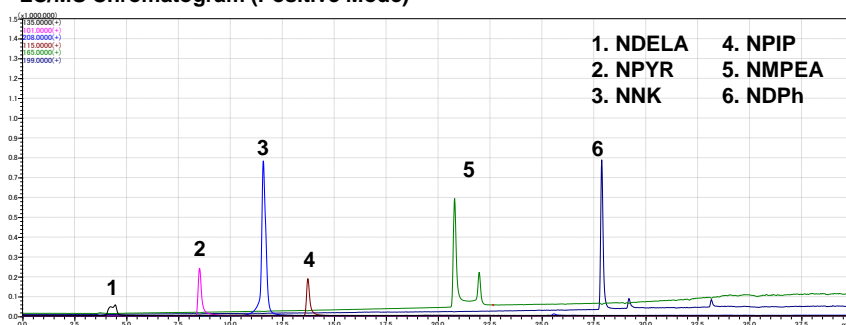
Nitrosamines are compounds of the chemical structure where hydrogen of the amine nitrogen is substituted with a nitroso group. These compounds are widely used industrially in plasticizers, additives, etc., but at least some of them are known to be carcinogenic. Nitrosamine are often detected as impurities during the manufacturing process of a drug product. Recently, nitrosamines were detected in some sartan and ranitidine products, and these products were recalled. In response to this event, in September 2019, the EMA requested the marketing authorization holders to evaluate the risk of the presence of nitrosamine impurities in their drugs and take appropriate risk mitigation measures. Fujifilm Wako offers a wide range of analytical standards of nitrosamines.



Mixture Standard Solution

✓ Mixture standard solutions of nitrosamines regulated by USP, Ph. Eur., And EMA!

6 Nitrosamines Mixture Standard Solution LC/MS Chromatogram (Positive Mode)



[HPLC]

Column: Wakopak® Ultra C18-3 4.6 × 150 mm
Column temperature: 40°C
Eluent: A) 0.1 vol% HCOOH in H₂O
B) 0.1 vol% HCOOH in CH₃OH

Time (min.)	B conc. (%)
0-30	10-95
30-40	95

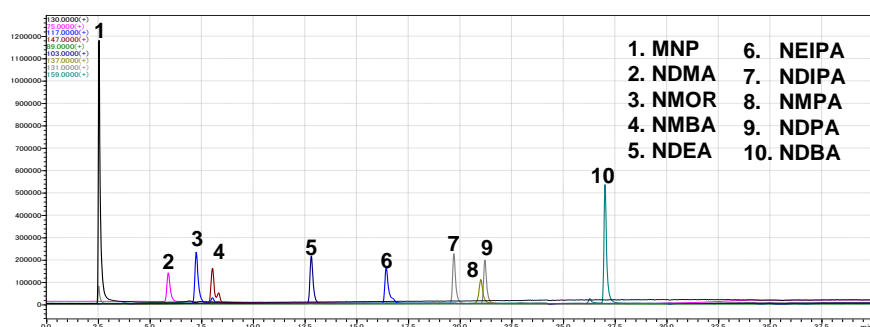
Flow rate: 0.5 mL/min.

[MS]

Ionization: ESI
Mode: SIM

Monitoring ion (m/z)	Mode	Monitoring ion (m/z)	Mode	Monitoring ion (m/z)	Mode
NDELA	135	+	NNK	208	+
NPYR	101	+	NPIP	115	+
			NMPEA	165	+
			NDPh	199	+

10 Nitrosamines Mixture Standard Solution LC/MS Chromatogram (Positive Mode)



[HPLC]

Column: Wakopak® Ultra C18-3 4.6 × 150 mm
Column temperature: 40°C
Eluent: A) 0.1 vol% HCOOH in H₂O
B) 0.1 vol% HCOOH in CH₃OH

Time (min.)	B conc. (%)
0-30	10-95
30-40	95

Flow rate: 0.5 mL/min.

[MS]

Ionization: ESI
Mode: SIM

Monitoring ion (m/z)	Mode	Monitoring ion (m/z)	Mode	Monitoring ion (m/z)	Mode
MNP	130	+	NMBA	147	+
NDMA	75	+	NDEA	103	+
NMOR	117	+	NEIPA	117	+
			NDIPA	131	+
			NMPA	137	+
			NDPA	131	+
			NDBA	159	+

Code No.	Product Name	Grade	Volume
142-10201	6 Nitrosamines Mixture Standard Solution (each 2 µg/mL Methanol Solution)	for Chromatography	1 mL×5A
145-10051	10 Nitrosamines Mixture Standard Solution (each 2 µg/mL Methanol Solution)	for Chromatography	1 mL×5A

Analytical Standard

Code No.	Product Name	Abbreviation	Grade	Volume
133-19451	4-(Methylnitrosoamino)-1-(3-pyridinyl)-1-butanone Standard (mixture of isomers)	NNK	for Chromatography	100 mg
138-19381	<i>N</i> -Methyl- <i>N</i> -nitrosophenethylamine Standard (mixture of isomers)	NMPEA	for Chromatography	50 mg
149-09961	<i>N</i> -Nitrosodi- <i>n</i> -butylamine Standard	NDBA	for Chromatography	100 mg
140-10121	<i>N</i> -Nitrosodiethanolamine Standard	NDELA	for Chromatography	100 mg
141-09921	<i>N</i> -Nitrosodiethylamine Standard	NDEA	for Chromatography	100 mg
147-10011	<i>N</i> -Nitrosodiethylamine- <i>d</i> ₁₀ Standard	NDEA- <i>d</i> ₁₀	for Chromatography	50 mg
145-09941	<i>N</i> -Nitrosodiisopropylamine Standard	NDIPA	for Chromatography	50 mg
147-03781	<i>N</i> -Nitrosodimethylamine Standard	NDMA	for GC	1 g
144-10021	<i>N</i> -Nitrosodimethylamine- <i>d</i> ₆ Standard	NDMA- <i>d</i> ₆	for Chromatography	100 mg
146-10101	<i>N</i> -Nitrosodiphenylamine Standard	NDPh	for Chromatography	100 mg
140-09991	<i>N</i> -Nitrosodi- <i>n</i> -propylamine Standard	NDPA	for Chromatography	100 mg
142-09951	<i>N</i> -Nitrosoethylisopropylamine Standard	NEIPA	for Chromatography	50 mg
146-09971	<i>N</i> -Nitrosomethylaminobutyric Acid Standard	NMBA	for Chromatography	50 mg
140-10001	<i>N</i> -Nitrosomethylethylamine Standard	NMEA	for Chromatography	50 mg
148-09931	<i>N</i> -Nitrosomethylphenylamine Standard	NMPA	for Chromatography	50 mg
143-09981	<i>N</i> -Nitroso- <i>N'</i> -methylpiperazine Standard	MNP	for Chromatography	50 mg
141-10031	<i>N</i> -Nitrosomorpholine Standard	NMOR	for Chromatography	100 mg
149-10071	<i>N</i> -Nitrosopiperidine Standard	NPIP	for Chromatography	50 mg
143-10111	<i>N</i> -Nitrosopyrrolidine Standard	NPYR	for Chromatography	100 mg

* This product is not USP/Ph. Eur. reference standard.

* Please check our website for details.

TOP > Analytical Chemistry Test for Medicinal Chemicals Nitrosamines Test

https://labchem-wako.fujifilm.com/us/category/analysis/medicinal/nitrosamines_test/index.html



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