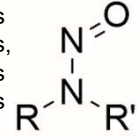


for Pharmaceutical, Food, and Water Environment Analysis Analytical Standards of Nitrosamines

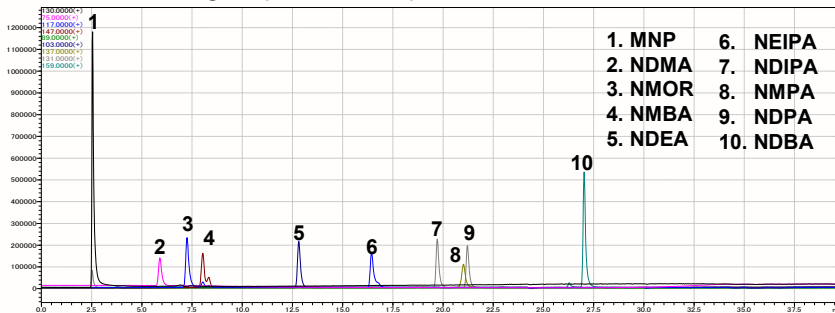
Nitrosamines are compounds of the chemical structure where hydrogen of the amine nitrogen is substituted with a nitroso group. These compounds are widely used industrially in plasticizers, additives, etc., but at least some of them are known to be carcinogenic. Nitrosamine are often detected as impurities 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 solution of 10 nitrosamines regulated by USP, Ph. Eur., And EMA!

LC/MS Chromatogram (Positive Mode)



[Internal Standard]

N-Nitrosomethylethylamine Standard

[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

Gradient:

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

Flow rate: 0.5 mL/min.

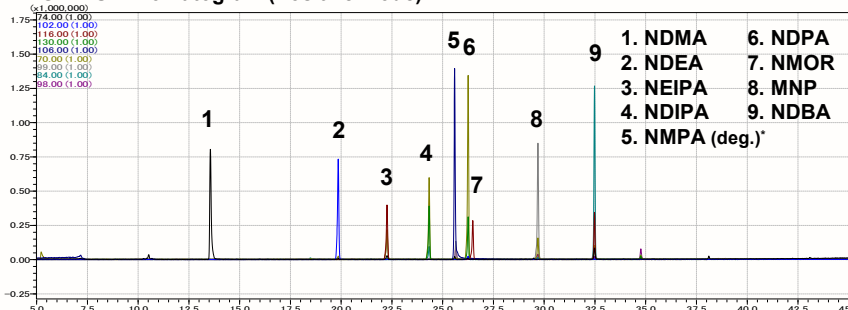
[MS]

Ionization: ESI

Mode: SIM

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

GC/MS Chromatogram (Positive Mode)



[Internal Standard]

N-Nitrosomethylethylamine Standard

[GC]

Column: DB-624UI 1.40 μm, 0.25 mm × 30 m

Column temperature: 40°C (5 min.) → 5°C/min.

→ 260°C (11 min.)

Injection temperature: 260°C

Carrier gas: He 1.3 mL/min.

Splitless: 1 min.

[MS]

Ionization: EI

Interface temperature: 250°C

* Since NMPA is easily decomposed under thermal conditions¹⁾, it is detected as a decomposition peak under this conditions.

1) Mutsuga, M. *et al.*: *Am. J. Anal. Chem.*, **4**, 277 (2013).

* NMBA is rarely detected in GC/MS.

Code No.	Product Name	Grade	Volume
145-10051	10 Nitrosamines Mixture Standard Solution (each 2μg/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	NIPEA 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 > Pharma Manufacturing & QC > QC Test > Nitrosamines Analysis
<https://labchem-wako.fujifilm.com/us/category/02128.html>



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