Nitrosamines Capabilities

Cambrex has extensive experience in method development, validation and testing for screening and quantitation of N-nitrosamines in API and Drug Product. Our team of veteran scientists are well-equipped with the latest in mass spectrometry (MS) technology to perform impurity identification or confirmatory testing under cGMP for products at any stage of clinical or commercial development.

Our capabilities include performance of the initial Risk Assessment for the potential to form nitrosamines in your chemical process, chemical process development and synthesis of custom nitrosamines, qualification of nitrosamine reference standards and cGMP testing. Expedited rush timelines also available by request.

Our team of experts provides custom analytical methodologies specific for your product. Provided below are some of the most common nitrosamine impurities we routinely screen for our clients.

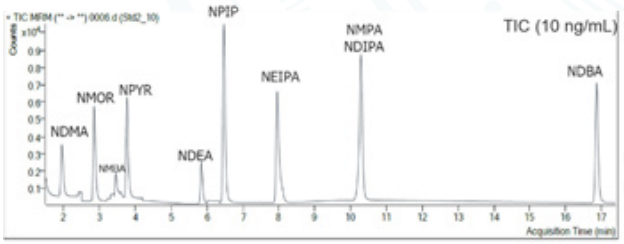
There are many examples of platform methods for common nitrosamines in the scientific literature and public domain, however the greatest value is having experience to analyze in the API or Drug Product matrix. We regularly hear from our customers that they need a partner who has this experience for analysis of trace level (ppm and ppb) nitrosamines impurities in complex matrices, which is why they put their trust in Cambrex.

Quite often, the sample preparation procedure must be carefully controlled to enhance method sensitivity, improve specificity and resolution, accuracy and method precision or sample and standard stability. Cambrex offers the complete solution for your needs to control for nitrosamines in your products.

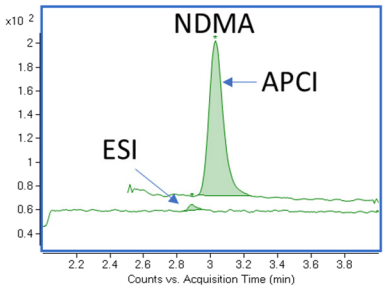
List of Most Common Nitrosamines Analyzed by Cambrex

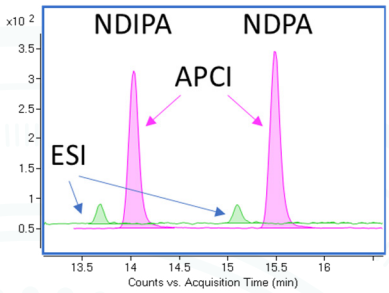
Available MS Detection Platforms	Nitrosamine Chemical Name	Acronym	Limit ng/day
UPLC triple quadrupole (QQQ) MS/MS with ESI or APCI sources	*N*-nitroso-dimethylamine	NDMA	96.0
	N-nitroso-diethylamine	NDEA	26.5
	N-nitroso-ethylisopropylamine	EIPNA	26.5
	N-nitrosodiisopropylamine	DIPNA	26.5
	N-nitroso-n-methyl-4-aminobutyric acid	NMBA	96.0
UPLC Q-ToF (ESI)	*N*-nitroso-di-n-butylamine	NDBA	26.5
	N-nitroso-methylphenylamine	NMPA	34.3
HS/DI-GC with EI source and single quadrupole or QQQ MS/MS	*N*-nitroso-morpholine	NMOR	127
	N-nitroso-di-n-propylamine	NDPA	26.5
	N-nitroso-piperidine	NPip	1300
	N-nitroso-1,2,3,6-tetrahydropyridine	NTHP	37
	N-methyl-*N*-nitrosophenethylamine	NMPEA	8
	N-nitroso-pyrrolidine	NPYR	1700

LC-MS/MS Total Ion Chromatogram from Multiple-Reaction Monitoring (MRM) for Selected Nitrosamines premixed at 10 ng/mL



Comparison of LC-MS/MS Chromatograms for Selected Nitrosamines using APCI vs. ESI Sources





Capability Highlights

- State-of-the-art analytical facilities with veteran team of scientists.
- Process development and chemical synthesis, impurity identification and reference standard qualification, method development and testing, all in the same facility.
- Expedited cGMP testing options available.

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance development and manufacturing across the entire drug lifecycle, as well as comprehensive analytical and IND enabling services.

With over 40 years of experience and a team of 2,000 experts servicing global clients from North America and Europe, Cambrex offers a range of specialized drug substance technologies and capabilities, including continuous flow, controlled substances, solid-state science, material characterization, and highly potent APIs.

How can we help you advance? **cambrex.com**