

Nitrosamine Impurity & Control Testing

Accurate and reliable analytical data are foundational to ensuring the quality, safety, and efficacy of pharmaceutical and advanced therapy products. From assay development to contract testing for clinical and commercial products, partnership with a contract testing organization (CTO) or contract development and manufacturing organization (CDMO) at any phase requires trust in their ability to deliver the right answers at the right time. With deep expertise and a broad range of cutting-edge technologies across our facilities, SK pharmteco has the capacity and capabilities to support partners in analytical development and testing for projects of every scope and scale.

The presence of nitrosamines and nitrosamine drug substance-related impurities (NDSRIs) in active pharmaceutical ingredients (APIs) and drug products poses significant risks to patient health. Regulatory agencies worldwide have implemented stringent guidelines to ensure the safety of pharmaceuticals. The FDA has recently issued new guidance setting strict acceptable intake limits (AIs) for NDSRIs. By August 1, 2025, manufacturers must ensure that all NDSRIs in their products adhere to these newly established AI limits.

SK pharmteco's experienced scientists and their expertise in nitrosamines and genotoxic impurity assessment deliver exceptional results. Our comprehensive analytical solutions help you navigate the challenges of nitrosamines and genotoxic impurities by providing robust testing services for identification and quantification, safeguarding product quality and patient trust.

SK pharmteco's Nitrosamine Testing Expertise

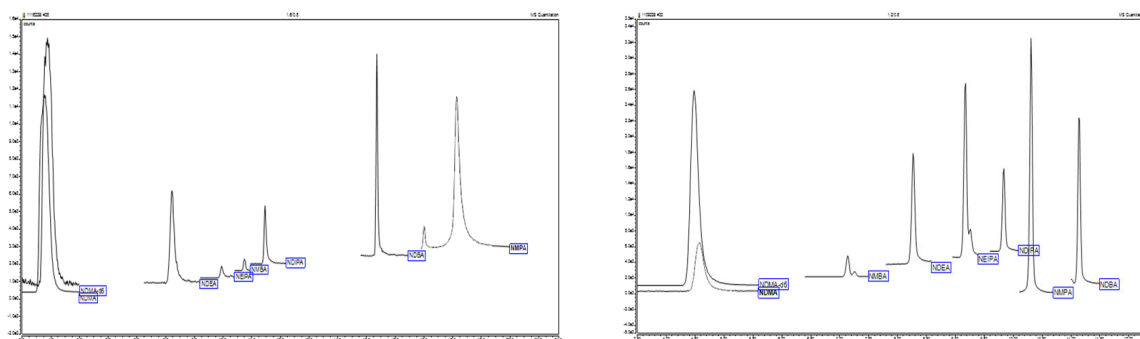
SK pharmteco is a recognized leader in providing comprehensive solutions to address nitrosamine challenges within the pharmaceutical industry. With a deep understanding of the complex regulatory landscape and the potential risks associated with nitrosamines, we offer tailored services to ensure product safety and compliance.

Our team of experienced scientists and regulatory experts brings a wealth of knowledge to every project. Leveraging state-of-the-art analytical techniques, such as LC-MS, GC-MS, HR-MS, LC-MS/MS (including LC-QTOF & LC-QQQ), we deliver accurate and reliable nitrosamine analysis.

SK pharmteco is committed to staying at the forefront of industry advancements, enabling us to offer innovative solutions to our clients. We have three validated platform methods, including two orthogonal LC-MS/MS methods for seven general nitrosamines, in place to quickly develop and qualify methods for new sample matrices. LC-MS/MS detection limits for general nitrosamines are in the tens of pg/mL, with limits of quantitation in the tens of pg – ng /mL range. This sensitivity enables analysis in the ppb regime for high soluble materials.

LC-MS/MS Sensitivity

Nitrosamine	Chemical Name	Detection Limit (ng/mL)	Quantitation Range (ng/mL)
NDMA	N-Methyl-N-nitrosomethanamine	0.04	0.08 - 2.0
NDEA	N-Ethyl-N-nitrosoethanamine	0.02	0.04 - 1.0
NMBA	4-[Methyl(nitroso)amino] butanoic acid	0.02	0.04 - 1.0
NDIPA	N-Isopropyl-N-nitrosoisopropylamine	0.02	0.04 - 1.0
NEIPA	N-Ethyl-N-nitroso-2-propanamine	0.02	0.04 - 1.0
NDBA	N-Butyl-N-nitroso-1-butanamine	0.02	0.04 - 1.0
NMPA	N-Methyl-N-nitrosophenylamine	0.02	0.04 - 1.0



General Nitrosamine Sensitivity of LC-MS/MS Platform Methods

SK pharmteco's Comprehensive Nitrosamine Services

Identifying Potential Risks

SK pharmteco employs a comprehensive approach to assess the potential formation of nitrosamines within your pharmaceutical products. Our experts meticulously evaluate your manufacturing processes, raw materials, and product formulations to identify potential nitrosamine precursors and reaction conditions. By understanding the inherent risks, we can develop targeted strategies to mitigate nitrosamine formation.

Monitoring Nitrosamine Formation

SK pharmteco conducts comprehensive stability testing to evaluate the impact of storage conditions, temperature, and humidity on nitrosamine levels. By understanding the kinetics of nitrosamine formation, we can help you establish appropriate shelf-life and storage recommendations.

Sensitive Analysis and Validation

To ensure accurate and reliable nitrosamine detection, SK pharmteco specializes in developing and validating sensitive analytical methods. Our state-of-the-art laboratories employ cutting-edge techniques to detect even trace levels of nitrosamines. Through rigorous validation processes, we guarantee the accuracy and robustness of our analytical methods, providing you with confidence in your product quality.

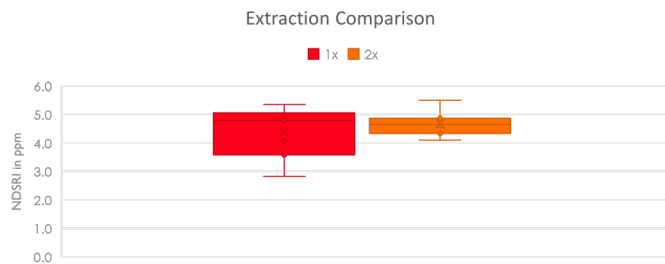
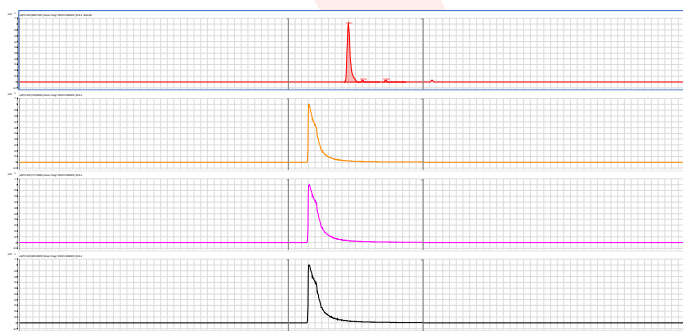
Navigating Regulatory Requirements

Staying up to date with the evolving regulatory landscape is essential for compliance. SK pharmteco offers expert guidance on navigating complex regulatory requirements and preparing necessary documentation. Our team assists with regulatory submissions, providing the necessary support to ensure a smooth approval process.

NDSRI Control – Case Study

Case Study: Method for Nitroso API in Tablet DP at ppb/low ppm levels

- Tablets don't dissolve in common diluents, extraction in Methanol/Formate Buffer mixture.
- NDSRI coelutes with API, all development efforts failed to baseline resolve API from the nitroso impurity.
- With QTOF, leveraged mass resolution to quantify nitroso API, with relatively narrow mass filter (± 0.0025 m/z). Clean instrument and good tune required for accurate analysis.
- Extraction efficiency was demonstrated through increasing volume studies demonstrating adequate recovery of NDSRI.



Commitment to Quality and Compliance

SK pharmteco is steadfast in our commitment to delivering the highest quality services that meet the rigorous demands of the pharmaceutical and research industries. Our operations adhere strictly to international regulatory standards, including ICH, FDA, and EMA guidelines, ensuring compliance and minimizing risks.

We have implemented robust quality management systems that are certified to industry-recognized standards, providing a solid foundation for your projects. Our commitment to quality extends beyond compliance; it encompasses every aspect of our operations, from project initiation to final report delivery.

By partnering with SK pharmteco, you can be confident that your nitrosamine and NDSRI projects are in capable hands, supported by a team dedicated to excellence.

About SK pharmteco:

At SK pharmteco our mission is to build strong relationships that create happiness for our customers through the shared goal of producing and delivering life-changing therapies that improve patient outcomes and save lives. With our network of six global, cutting-edge, facilities our capabilities cover the entire product lifecycle, from initial development to commercial manufacturing. We work with customers in a flexible 'One Team' approach, prioritizing collaboration, transparency, and trust to make every interaction easy and seamless.

SK pharmteco offers CDMO services for small molecule APIs and cell and gene therapies as well as analytical testing services; contact our experts to learn more!