Nitrosamine Analysis and Impurities in Pharmaceuticals and Medical Devices Factsheet

What are Nitrosamines?

Nitrosamines are a class of potentially harmful chemical compounds that contain a nitroso group (-NO) attached to an amine group (-NH2). They can be formed as impurities in certain pharmaceutical products and medical devices during manufacturing processes or storage. Nitrosamines have been classified as probable human carcinogens by various health authorities.

Our Services:

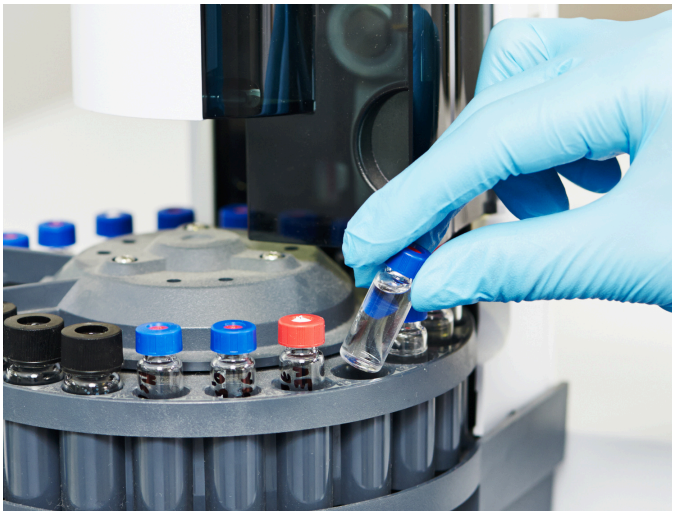
We provide comprehensive Nitrosamine Analysis services tailored to meet the needs of medical device and pharma- ceutical manufacturers. Our services include:

- **Determination of Nitrosamine Presence:** We offer testing to detect the presence of nitrosamines in raw materials, drug substances, and finished pharmaceutical products.
- **Identification of Nitrosamine Impurities:** Our analytical methods can accurately identify specific nitrosamines present in your products, ensuring compliance with regulatory requirements.
- **Quantification of Nitrosamines:** We perform quantitative analysis to measure the levels of nitrosamines in pharmaceutical formulations and medical devices, ensuring they are within permissible limits, as nitrosamines have been classified as probable human carcinogens by various health authorities.

Our Approach:

To ensure accurate and reliable results, we utilise state-of- the-art analytical instruments and validated methods for nitrosamine analysis. Our team of highly skilled scientists follows these steps:

- **Sample Preparation:** We carefully prepare samples to extract and isolate nitrosamines from the matrix, ensuring representative and precise measurements.
- **High-Performance Liquid Chromatography (HPLC):** We employ HPLC coupled with advanced detectors to separate and identify nitrosamines present in the samples.
- **Mass Spectrometry (MS):** Our MS instruments allow us to precisely quantify nitrosamines, providing information on their concentration levels.
- **Method Validation:** All our analysis methods are validated according to industry standards, ensuring the accuracy and reliability of the results.



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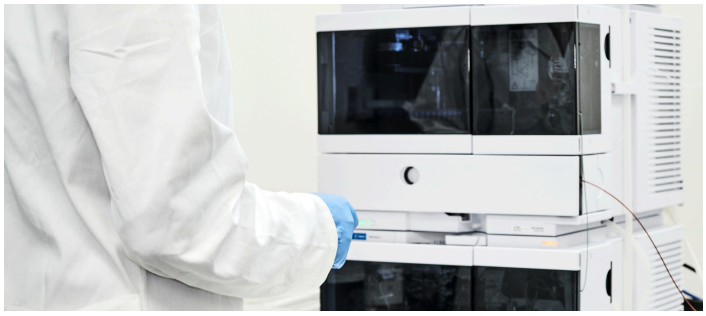
Regulatory Compliance:

We understand the importance of complying with international regulations regarding nitrosamine impurities. Our services are designed to help medical device and pharmaceutical manufacturers adhere to guidelines set forth by regulatory authorities such as:

- United States Food and Drug Administration (**FDA)**
- European Medicines Agency **(EMA)**
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use **(ICH)**
- Other regional health authorities and regulatory bodies



Why Choose Us:

With over 60 years of experience and expertise, Cormica delivers the highest quality testing to ensure patient safety and regulatory compliance for medical device and pharmaceutical manufacturers:

- **Expertise:** Our team of experienced scientists specialises in nitrosamine analysis, ensuring precise and reliable results.
- **Advanced Technology:** We employ cutting-edge instruments and validated methodologies for accurate analysis.
- **Compliance:** We understand the regulatory landscape and help clients meet the necessary guidelines.
- **Confidentiality:** Client data and information are treated with the utmost confidentiality and security.

Conclusion:

With the increasing focus on patient safety and regulatory scrutiny, it is crucial for medical device and pharmaceutical manufacturers to ensure their products are free from nitrosamine impurities. Our Nitrosamine Analysis services can help you identify, quantify, and control these impurities, ensuring the safety and efficacy of your products and compliance with regulatory requirements.

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Find out more about Cormica by scanning this QR code