



The Automated Total Nitrosamine Analyser



Nitrosamines

In recent years nitrosamines have been a particular issue for the pharmaceutical industry with several high-profile product recalls. Because of these cases, regulatory bodies have required pharmaceutical companies to monitor their products, ingredients and processes for the potential to form nitrosamines.

Screening the ingredients and excipients for nitrites, nitrates and nitrosamines using a speciated analysis is expensive and time consuming; so pharmaceutical companies tend to screen the formulated products for nitrosamines and perform risk assessments for the likelihood of nitrosamine formation during storage.

Historically this has been performed using mass spectrometry coupled to a GC or HPLC system. This has, however, proved very inefficient for pharmaceutical companies due to the sheer volume of samples and sample types, the often-complex sample preparation required, the extremely low detection limits and the potential for false positives.

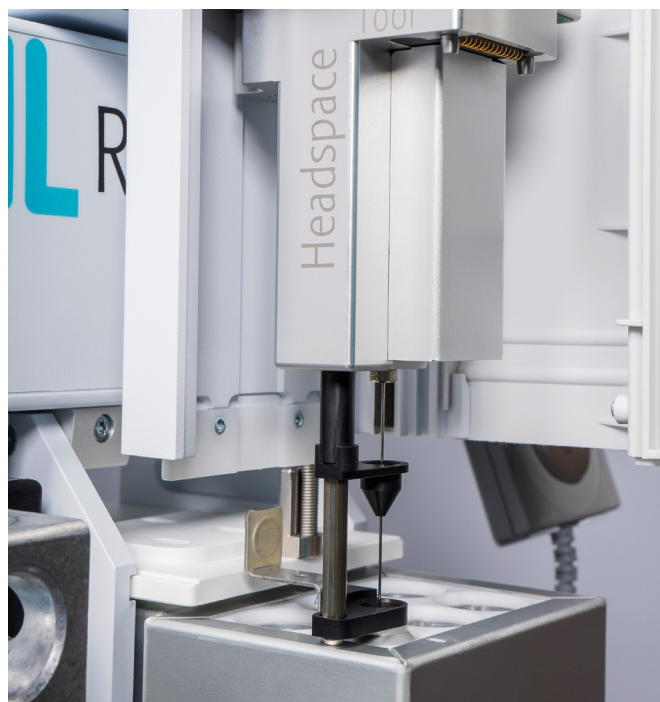
What are nitrosamines and why is impurity analysis important?

Nitrosamines are a general term used to designate a group of organic N-nitroso compounds with the chemical structure $R_2N-N=O$. N-nitrosamines are produced by the reaction of a secondary or tertiary amine with a nitrating source such as nitric oxide, nitrites, nitrates (to a lesser extent than nitrites), dinitrogen tetroxide, or nitrous acid. These reactions may be catalysed under acidic conditions or at elevated temperatures.

As many excipients contain nitrites/nitrates, these should also be screened so that excipients with high concentration of nitrites/nitrates are not combined with amine based API's thus eliminating the risk of nitrosamine formation.

Nitrosamines are known to be carcinogens when ingested. They have been shown to cause tumours in the liver, lung, nasal cavity, oesophagus, pancreas, stomach, urinary tract, bladder, colon, kidneys, and central nervous system. Nitrosamines exist in safe, low concentrations in a wide variety of goods, including cosmetics, rubber products, tobacco products, processed meats, brewing and malting, agrochemicals, packaging and pharmaceutical drugs.

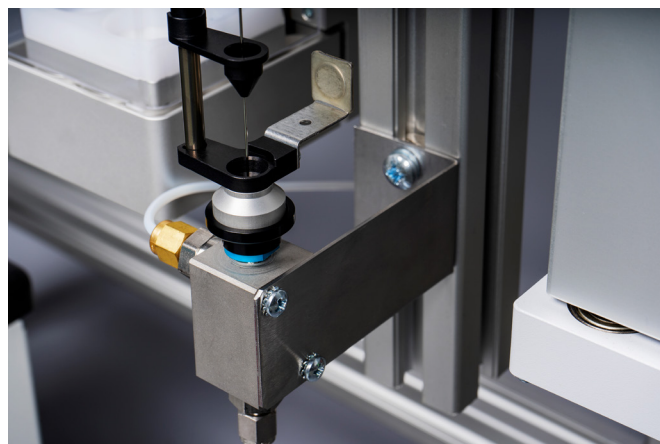
Current guidance from the US Food and Drug Administration (FDA) recommends the acceptable intake limits of 96ng/day for NDMA & NMBA and 26.5 ng/day for NDEA, NMPA, NIPEA, and NDIPA.



Automating Total Nitrosamine Testing

The Automated Total Nitrosamine Analyser (ATNA) is Ellutia's newest tool for detecting nitrosamine impurities. It offers a unique method for the rapid detection of nitrosamine containing compounds.

The ATNA offers a simple, accurate, and reliable test that delivers a clear pass/fail result for apparent total nitrosamine content (ATNC) within minutes. Samples can be immediately cleared for processing or positive samples sent for further testing by gas chromatography (GC) or liquid chromatography (LC). It allows manufacturers within various industries to meet the legal requirements of risk assessments without needing to outsource testing of raw materials or products at different stages of the manufacturing process.



ATNA Specifications

Size and Weight:

Width-92cm (37in.)

Height-35cm (14in.)

Depth-56cm (22in.)

Weight - 30kg (66lbs)

Detection Limit:

1ppb of NDMA

Sample Capacity:

120 10ml headspace vials

Sample Rate:

Up to 10 samples per hour

Compounds:

Nitrosamines, Nitrates, Nitrites

Can be integrated with a GC for full speciated analysis of volatile nitrosamines.

Achieve Regulatory Limits for Nitrosamine Impurity Analysis

The European Medicines Agency (EMA) and the FDA regulatory agencies now require pharmaceutical manufacturers to be able to classify nitrosamine content. Manufacturers need to have confidence in the accuracy of results and the instruments used.

Not only can nitrosamines be present in raw materials but also in active pharmaceutical ingredients (APIs), depending on the ingredients and solvents used in the manufacturing process. When present, even in small amounts, they present a health and safety risk and therefore a major concern for pharmaceutical manufacturers. Manufacturers need to trust the tools they use and the results they get at different points along a production line in a complex or multi-step reaction.

Where Can the ATNA be Used?

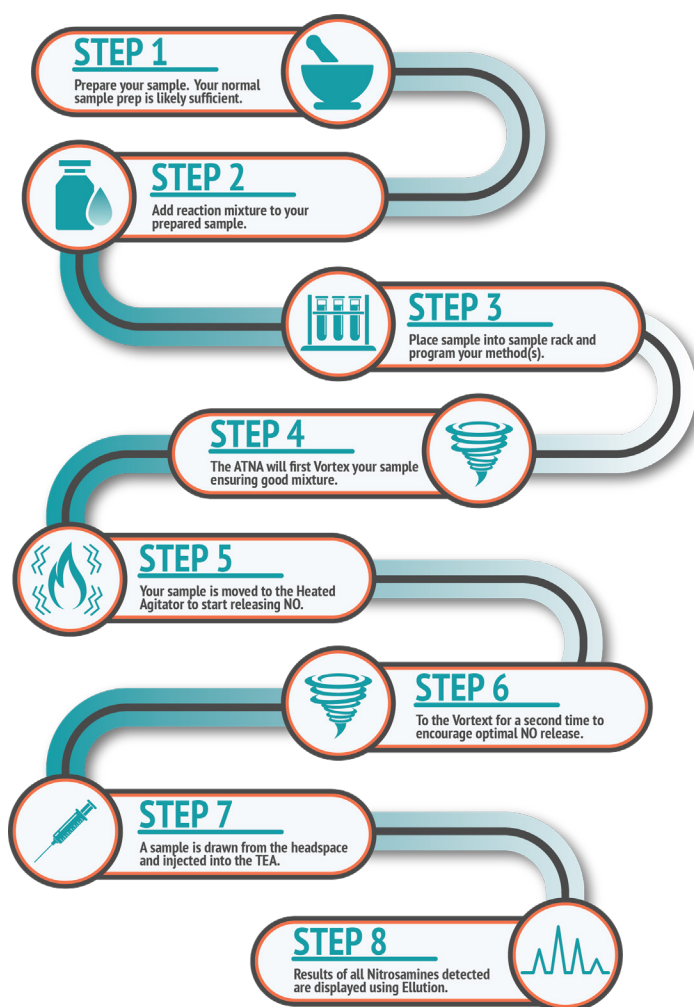
The ATNA is versatile and can be used for several different application areas:

- Pharmaceutical
- Food and beverage
- Packaging
- Rubber products
- Cosmetics
- Tobacco and vapes
- Brewing and malting
- Water and wastewater



“The ATNA is unlike anything else available on the market for detecting ATNC and is the scientist’s choice for nitrosamine testing.”

How Does the ATNA Work?



ATNA Features

The ATNA addresses critical challenges faced by laboratories in the analysis of nitrosamine impurities. As a cost-effective partner to GC and LC-MS instruments, the ATNA enables thorough analysis down to low ppb levels.

By providing a quick and reliable screening method, it eliminates the need for detailed speciated analysis, making it easier to identify “at-risk” samples efficiently. This not only increases the speed of sample analysis but also allows for the examination of various sample types, including excipients for nitrites/nitrates.

The versatility of the ATNA ensures seamless integration into any laboratory without compromising sensitivity or selectivity in identifying nitrogen-containing compounds. Moreover, it significantly contributes to reducing waste and costs while enhancing the safety of products.

The ATNA system empowers laboratories to identify potential risks, thereby expanding the scope of testing and ensuring the safety of their products.

Screening Excellence

The ATNA is a system that allows users to rapidly screen samples down to ppb levels to confirm samples are free from nitrosamine contamination. This means that a single result is given for nitrosamine content regardless of the nitrosamine molecule present or number of different nitrosamines present. This means even unexpected nitrosamines, or ones that there is not a standard available for, can be detected.

By using this technique only samples positive for nitrosamine content will need to be passed on for further investigation and targeted analysis. It also potentially offers a quick way of screening the quality of incoming ingredients to ensure they are not unexpectedly introducing nitrites, nitrates, and nitrosamines.

Total Nitrosamine testing is not designed to replace speciated analysis but to support it by enabling you to identify samples with nitrosamine content much quicker. This allows you to then be able to focus efforts where they are needed.



To learn more about the ATNA, please scan the QR code below
or visit www.ellutia.com/ATNA



Colston House, 200 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NX, UK

Tel: +44 (0)1353 669916 Web: www.ellutia.com

Ellutia Limited Registered in England Number 2967460

Registered Address Colston House, 200 Lancaster Way Business Park, Ely, Cambridgeshire, England, CB6 3NX



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