



# Delivering scientific excellence

## NITROSAMINES

Unacceptable levels of nitrosamine impurities were first reported in June 2018. Further nitrosamine impurities were subsequently detected in other medications.

Guideline classifies them as **Class 1 impurities** or mutagenic carcinogens and they are categorized as probable carcinogens by the International **Agency for Cancer Research (IARC)**.

LabAnalysis has developed a method for the determination of nitrosamines, especially in Active Pharmaceutical Ingredient, finished products and raw materials based on US FDA published methods that uses High Resolution LC/MS/MS (Orbitrap) that gives a performance of 30 ppb or less. Therefore our team is able to detect the following nitrosamines:



- N-NITROSODIMETHYLAMINE
- N-NITROSODIETHYLAMINE
- N-NITROSOETHYLISOPROPYLAMINE
- N-NITROSODIISOPROPYLAMINE
- N-NITROSODI-n-BUTYLAMINE
- N-NITROSO-N-METHYL-4-AMINO BUTYRIC ACID
- N-NITROSO-N-METHYLPHENYLAMINE
- N-NITROSODIPHENYLAMINE
- N-NITROSODI-n-PROPYLAMINE
- N-NITROSOMETHYLETHYLAMINE
- N-NITROSOMORPHOLINE
- N-NITROSOPIPERIDINE
- N-NITROSO-N-ETHYLPHENYLAMINE

- N-NITROSODIBENZYLAMINE
- N-NITROSOETHYL-n-BUTYLAMINE
- N-NITROSODI(3,5,5-TRIMETHYLHEXYL)AMINE
- N-NITROSOPIRROLIDINE
- N-NITROSO-N-METHYLBUTYLAMINE
- N-NITROSOPIPERAZINE
- N-NITROSODIETHANOLAMINE
- 1-METHYL-4-NITROSOPIPERAZINE
- 1-CYCLOPENTYL-4-NITROSOPIPERAZINE

In order to maximize performance, deuterated internal standards were used to increase the robustness and accuracy of the method and a step of purification can be included to minimize matrix effect.

Please don't hesitate to contact us for further information about the services you need. Our technical division will help you find the right solution for your analytical enquiries.

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