



# Enlarged list of nitrosamines detected by LabAnalysis

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-NITROSOPYRROLIDINE**
- **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.

Contact us today to learn more about nitrosamine testing.