CURRENTA

Your Nitrosamine Determination under GMP Conditions

CURRENTA Analytik

Caring for Your Products Safety!

We offer

- product-specific validations on our accredited methods for nitrosamines determination under GMP conditions,
- product testing for nitrosamines under GMP, GLP or DIN EN ISO/IEC 17025 conditions,
- many years of experience in nitrosamines analysis also from complex matrices.

This means for you

- Safety in terms of analytics for risk assessment of your chemically synthesized pharmaceuticals for nitrosamines impurities.

Benefit from our expertise!

- In order to meet the high requirements on selectivity and sensitivity, CURRENTA Analytik uses mass spectrometry.
- We have achieved very low detection limits for our customers.

Samples such as blisters or other packaging, tablets, powders, active ingredients and other matrices can be analyzed.

www.currenta.com

Your Solution with Our Support

Choose from 3 validated measurement methods

- Methods of the draft Ph.Eur. 2.4.36: N-Nitrosamines in active substances
  - Limit test according to method A (LC-MS/MS)
  - Limit test according to method C (GC-MS/MS)
- CUR Analytik in-house method (GC-MS/MS)

In-house method	Method C of Ph. Eur.	Method A of Ph. Eur.
N-Nitrosodibutylamin (NDBA)	N-Nitrosodibutylamin (NDBA)	N-Nitrosodiethylamin (NDEA)
N-Nitrosodiethylamin (NDEA)	N-Nitrosodiethylamin (NDEA)	N-Nitrosodi-i-propylamin (NDiPA)
N-Nitrosodimethylamin (NDMA)	N-Nitrosodi-i-propylamin (NDiPA)	N-Nitrosodimethylamin (NDMA)
N-Nitrosodi-n-propylamin (NDPA)	N-Nitrosodimethylamin (NDMA)	N-nitroso-N-methyl-4-amino-butyric acid (NMBA)
N-Nitrosomethylbenzylamin (NMBenzA)	N-Nitrosodi-n-propylamin (NDPA)	N-nitroso-ethyl-isopropylamine (NEiPA)
N-Nitrosomethylethylamin (NMEA)	N-nitroso-ethyl-isopropylamine (NEiPA)	
N-Nitrosomethylphenylamin (NMPhA)		
N-Nitrosomorpholin (NMOR)		
N-Nitrosopiperidin (NPIP)		
N-Nitrosopyrrolidin (NPYR)		

We will gladly determine further nitrosamines on request by method adaptations.

Process of Your Product Specific Validation

1. Customized order coordination
2. Preliminary tests on your sample matrix
3. You receive your individual validation offer
4. Creation of the validation plan with your approval
5. Execution of the validation in the four-eyes principle
6. Quality assurance through final testing
7. Final report with your approval

From now on, we are at your side as a safe partner for your product analysis.

Pre-tests

to estimate

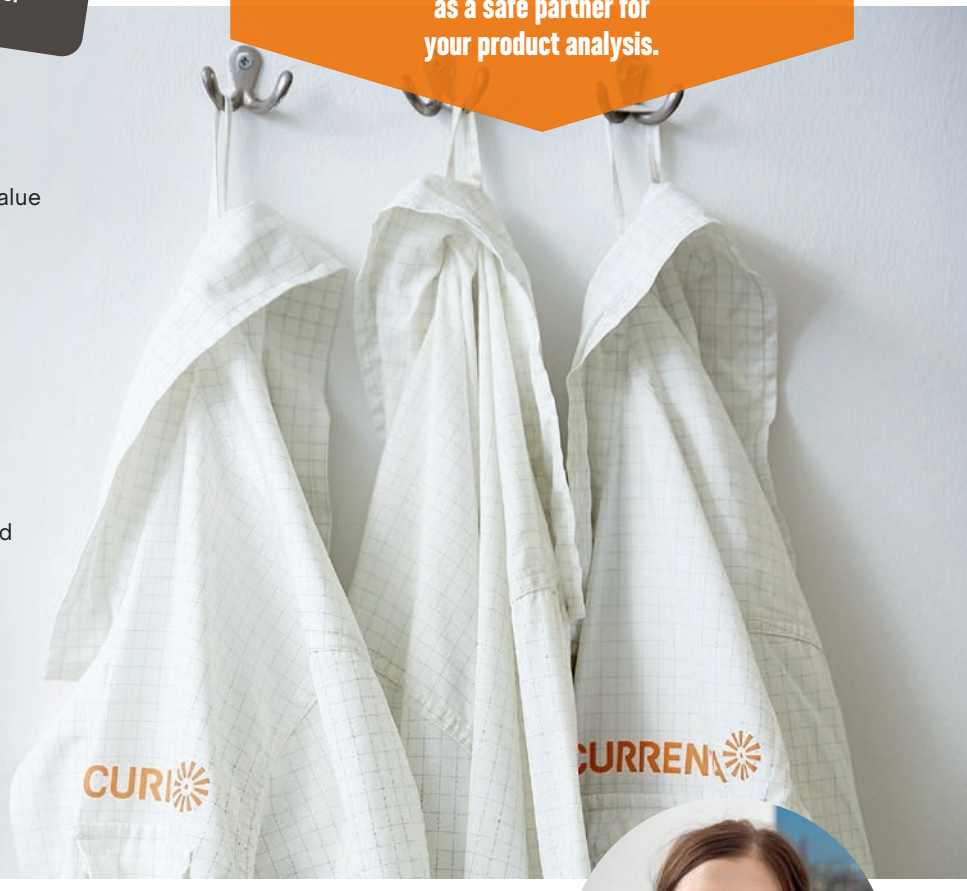
- **the limit of determination:** Our experienced value is approx. 20 – 30 ppb at 1 g sample weight.
- **the sample preparation:** e.g. cold extraction, steam distillation, Soxhlet extraction.
- **the background level:** Is the sample already contaminated with nitrosamines? We measure without and with sample spiking.

The validation scope

for your product-specific validation is determined with you individually for

- Limit test or
- Quantification.

We will need at least 20 g of your product.



Feel free to call me!

Contact for mass spectrometry GMP

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