



NITROSAMINE ANALYSIS

BACKGROUND

Nitrosamines or N-Nitrosamines are chemical compounds believed to be **carcinogenic** to humans based on animal studies. They are formed between nitrates or nitrites and certain amines under **acid conditions** such as in the **human stomach**.

Contamination with Nitrosamines have been detected in **various drugs** emphasizing the necessity of an **inspection of production processes**.

Since 2020 authorities such as the **FDA and the EMA** have been cooperating to share information and develop methods for the detection and identification of Nitrosamines in order to **ensure drug safety and quality**.

SOURCES OF CONTAMINATION

- Raw materials and intermediate products
- Solvents (such as DMF)
- Reagents and catalysts
- Development during chemical synthesis
- Packing material ...

Critical values acc. ICH M7 (R1)

Nitrosamine	Tolerated dose (ng/day)
NDMA, NMBA	96,0
NDEA, DIPNA, EIPNA	26,5



GMP COMPLIANT DETERMINATION

acc. Ph. Eur.

- Identification
- Quantification
- Limit test

from blisters, pills, powders, active ingredients, ...



GMP COMPLIANT METHOD VALIDATION

incl.

- Standard validation
- Validation after method transfer
- Revalidation



REFERENCE ANALYTICS TECHNOLOGY

- accurate and reliable analysis with GC-MS within very low detection limits
- LC-MS/MS - highly selective device for customized solutions