Nitrosamines analysis

Nitrosamines are likely to be carcinogenic after prolonged exposure. The secondary/tertiary amine functional group in the skeleton can react with NOX present in reagents to form N-nitrosamines under certain environmental conditions. These N-nitrosamines have the mutagenic potential to cause significant DNA damage. With this in mind, robust and sensitive methods are required to detect these compounds in a formulation to remove them and safeguard patients. Recipharm has the expertise to help pharmaceutical companies achieve this goal.

Our solution

- Method development and validation for sensitive nitrosamine detection
- Regulatory compliance support
- Risk assessment and mitigation strategies
- Continuous monitoring programmes

Designed to test the presence of known and unknown N-nitrosamine compounds, such as:

- Drug substance – API
- Drug product
- Excipients
- Container closure systems
- Process components

Regulations

Our lab is equipped with state-of-the-art analytical instrumentation that supports international regulations from EMA, US-FDA, ANVISA, PMDA and more. As we work with leading scientists dedicated to providing customised solutions, your next project is in safe hands.

- ICH-M7 guideline
- EMEA/H/A-5(3)/1490
- FDA-2020-D-1530

Evaluation	Technique	Regulations
SVOC	GC-MS	EMEA/ H/A-5(3)/1490 FDA-2020-D-1530 ICH-M7
NVOC	LC-MS	
Unknown	LC-HRMS	

Our approach

- General screening/specific mutagenic impurity analysis
- Selection of analytical technique
  - Nature/type of impurity
  - Identification of critical impurity
  - Performance evaluation of the method
  - Method validation (LOQ limit 0.03ppm)/ verification / QC release testing
- Confirmatory screening of regulatory listed nitrosamines
- NDMA, NDEA, NDIPA, NIPEA, NMBA & NDBA

Specialty lab equipment list

Technique	Make	Specification	Software*
LC-HRMS	Thermo	Orbitrap	Chromeleon/compound discoverer
LC-MSMS	AB Sciex	Q Trap/triple quad	Analyst/Sciex OS
HS-GC/MSMS	Agilent	Triple quad	Mass hunter
GC-FID/MSMS	Agilent	Triple quad	Mass hunter

About us

Established in 1995, Recipharm's manufacturing, fill & finish, and delivery-device services encompass a wide variety of drug dosage forms and modalities. Recipharm is an industry leading CDMO with over 30 facilities and 9,000 employees globally – supporting companies that are developing small molecules, biologics, and drug-device combinations. The company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US.

Introducing ReciBioPharm, Recipharm's biologics business combining the capabilities of recently acquired CDMOs Arranta Bio, GenIbet and Vibalogics. Our expanded biologics drug development and manufacturing services encompass technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, recombinant proteins, nucleic acid-based mRNA and plasmid DNA production.