



Nitrosamine Testing

Extensive experience with in-house methods for ICH M7(R2) impurities

N-nitrosamines are potentially carcinogenic impurities that can form during the manufacturing process, storage, and formulation of active pharmaceutical ingredients (APIs) and drug products (DPs). With increasing regulatory oversight due to major recalls, N-nitrosamine contamination risks costly delays, financial losses, and reputational damage for pharmaceutical companies.

From fast screening to fully validated quantification in drug substances and drug products

Solvias provides rapid nitrosamine screening, development and cGMP validation of control methods for small nitrosamines, nitrosamine drug substance related impurities (NDSRIs), and any other genotoxic impurities with unparalleled sensitivity and selectivity.

- ✓ Generic methods available for **screening** samples at single digit ppb levels (R&D)
- ✓ Method **development** and **validation** of product specific methods, using LC/MS/MS or GC/MS/MS (**cGMP**)
- ✓ **Quantification** of N-nitrosylated APIs or intermediates in drug products including the synthesis of stable isotope-labeled reference standards

Unparalleled Expertise

With a long-standing history in the analysis of impurities, Solvias boasts a team of experts in mass spectrometry who can navigate the entire analytical process, regardless of the matrix.

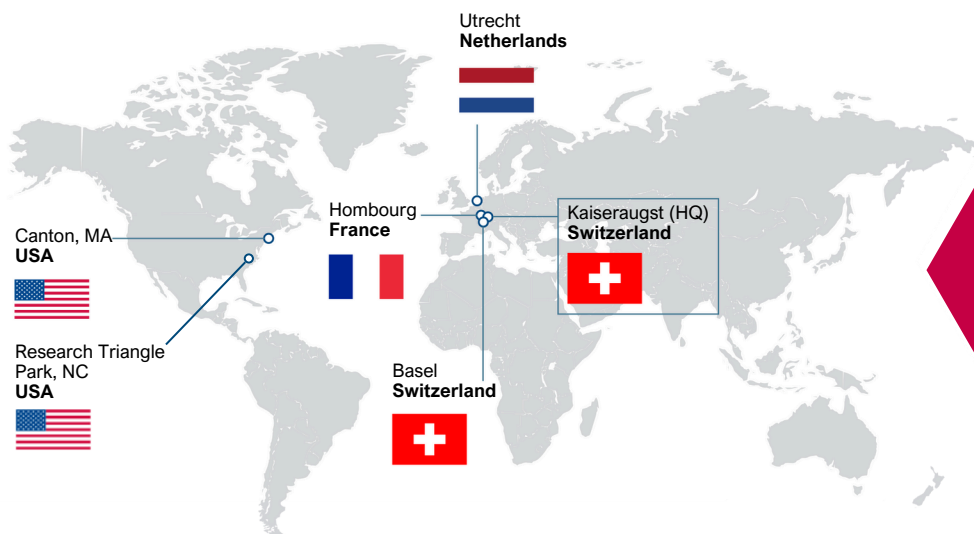
Cutting-Edge Technology

We utilize well-established **GC/MS/MS** and **LC/MS/MS** methods which showcase exceptional accuracy, consistently delivering outstanding performance within the low parts-per-billion thresholds mandated by regulatory authorities.



Why partner with us?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 6 centers of excellence



Contact us to speak with
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  [solvias.com](https://www.solvias.com)

