

Welcome to Mikromol 25 years of excellence

At Mikromol, we go beyond the standard, with unparalleled depth of knowledge, decades of manufacturing experience and unrivalled scientific excellence in the world of pharmaceutical reference standards for impurities analysis.

We offer truly global technical expertise, making a positive, measurable difference to your work, wherever you are. Today, our quality enables your accuracy, but we won't stop at the benchmark. Constantly pushing to help you create ever better, safer medicines. Each and every time. So when we say we go beyond the standard, we mean it.



High quality pharmaceutical standards produced in our laboratories in Germany

- Over 5,000 impurity, API and excipient reference standards for qualitative and quantitative analysis
- Comprehensive Certificate of Analysis
- GMP principles and dedicated analytical and synthesis departments

Specialist service and support

- Dedicated customer service in local language and time zone
- Expert technical support
- Advice on technical applications for pharmacopoeial methods and internally developed protocols

Logistics and delivery expertise through LGC distribution hubs in Germany, the United States and China

- State-of the-art logistics
- Fast delivery from local stock
- Expertise in customs, local clearance and imports. Strong experience with controlled substances
- Support for e-procurement and integrated purchasing

Making a positive, measurable difference.



Over

5,000

pharmaceutical reference standards

It's easy to order at:



Igcstandards.com/ mikromol

mikromol@lgcgroup.com

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Impurities are always present in a drug substance and can significantly alter a drug's effects on the patient. Limit and threshold values are required by official bodies as well as legislation to detect, identify, quantify and qualify impurities in accordance with ICH Guidelines.

The Mikromol portfolio of over 4,000 impurity reference standards is of the highest quality, and comes with an extensive Certificate of Analysis to give you greater analytical certainty – supporting accurate results.

Mikromol Certificates of Analysis provide a full description of the material to which they relate and summarise the analyses undertaken during the characterisation process.

Current Certificates of Analysis for individual lots of products in the range are available on our website, **Igcstandards.com/mikromol** on the relevant product pages.

Example details about the impurity reference standard:

- I. Identity
 Ia. 1H-NMR Spectrum
 Ib. Mass Spectrum
- Ic. IR Spectrum

 II. Purity
 IIa. High Performance Liquid
 Chromatography (HPLC)
 IIb. Water Content
 IIc. Residual Solvents
- III. Final results



4,000

impurity reference standards for

1,000+

API families

Excipient reference standards

Excipients are used during the production of finished dosage forms (FDFs) to add certain galenic or general characteristics, or to facilitate the production process. Mikromol excipient reference standards can be used for the quality control of excipients during the pharmaceutical production process.

Our catalogue of over 80 excipient reference standards comes with a detailed Certificate of Analysis including identity, purity and assay data, suitable for use with non-compendial analytical methods.

Active Pharmaceutical Ingredient (API) reference standards

Mikromol has different ranges of API reference standards and you can identify which group is the most suitable for your need.

In our catalogue, a group of them described under the product code LGCQUANT, fulfil ICH, FDA and other regulatory bodies' requirements for pharmaceutical quality control. This products are manufactured under ISO 17034 and come with a detailed Certificate of Analysis, including identity checks by several qualitative techniques. Assay information is provided by an ISO/IEC 17025 accredited technique like qNMR, and the assay is confirmed by a second independent method (e.g. mass balance).

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Explore the outsourcing services offered by an expert team

If you're developing your own reference standards, we can provide a broad range of modular services enabling you to outsource single process steps - enhancing flexibility,

Ask about our outsourcing services: mikromol@lgcgroup.com

efficiency and cost saving.

The value chain:

- Sourcing candidate material
- Quality control
- Packaging
- Characterisation to ISO/IEC 17025
- Certification
- Temperature controlled storage
- Distribution

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