



Mikromol™



**Together,
beyond the
standard.**

Reference standards
for the pharmaceutical
industry.

QUALITY | ISO 9001 ISO | IEC 17025
ISO 17034 | GMP

lgcstandards.com/mikromol



Welcome to Mikromol, a global leader in pharmaceutical reference standards.

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.

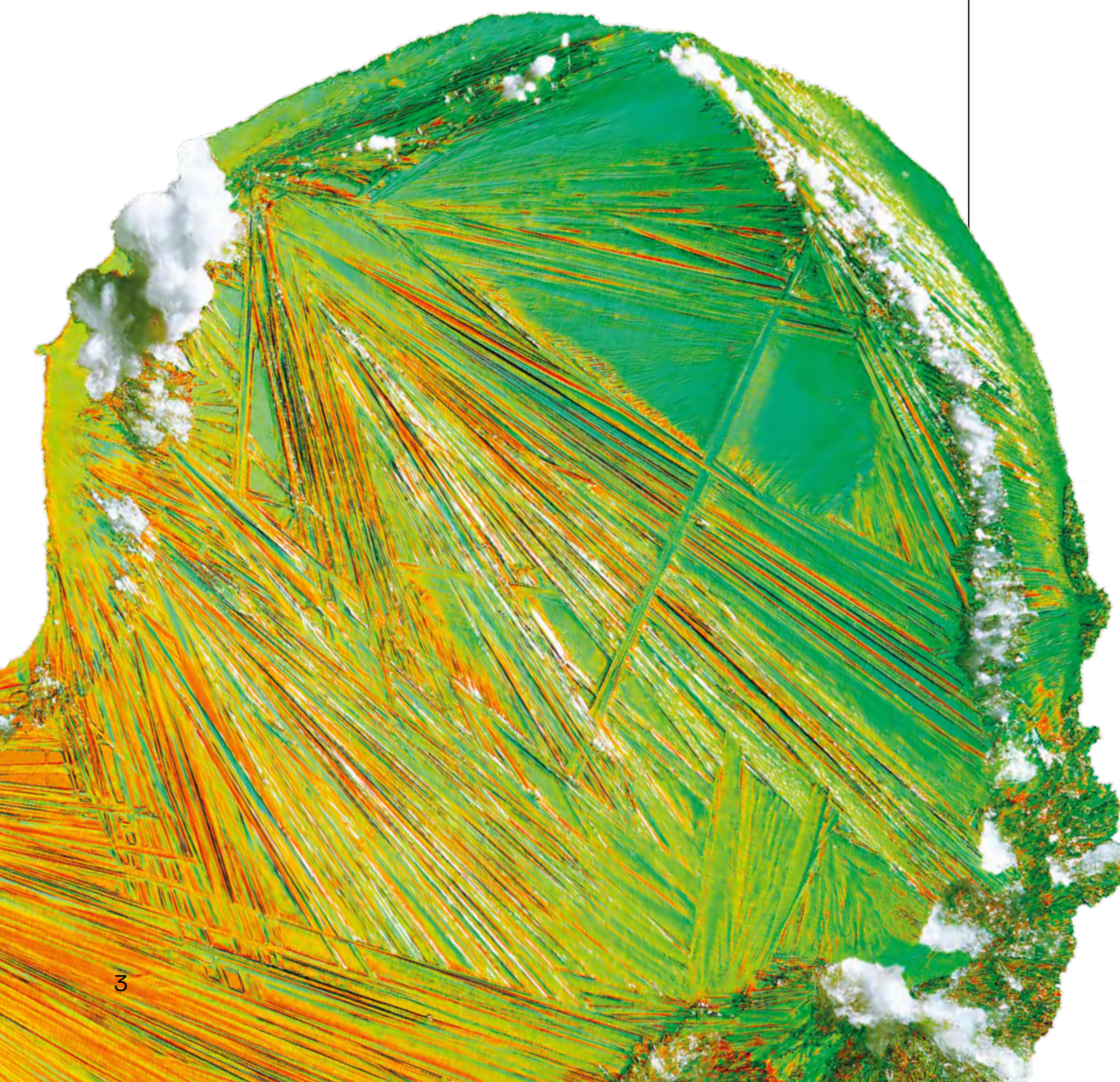
We offer truly global technical expertise, making a positive, measurable difference to your work, wherever you are. Today, our quality enables your accuracy, but we won't stop at the benchmark, constantly pushing to help you create ever better, safer medicines. Each and every time. So when we say we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



25 years of excellence providing you with high quality pharmaceutical reference standards and best-in-class expert support:

- Over 5000 impurity, API and excipient reference standards, including products which are unique in the market
- Suitable for qualitative and/or quantitative uses
- Accompanied by a comprehensive Certificate of Analysis, for greater analytical certainty
- Produced in our laboratories in Germany, following a highly detailed process, proven over time
- Expert technical support

Over
5,000
impurity, API
and excipient
reference
standards



The value chain: what it means for you.

In choosing Mikromol, you choose a standard certified to the quality you need and manufactured in an accredited facility; you choose transparent documentation; you choose a history of expertise and superlative depth of experience, all to support your testing methods.



Sourcing

Our expert team ensures the materials are of the highest quality, testing every batch before use



Quality control

Highly experienced chemists (including PhDs) perform extensive analysis, using a range of techniques, during identification and purity assessment in a certified lab environment, complying with the certified processes



Packaging

To guarantee the quality of our products is maintained over time, we pack all products following GMP processes under controlled atmosphere conditions, using pharma-graded vials and ampoules



Characterisation

We make use of several validated and independent analytical methods for ID and purity with the most cutting-edge equipment, and perform regular quality tests to make sure we provide you with the accuracy you need



Certification

Our Certificate of Analysis provides you with valuable and comprehensive information about methods and testing procedures to save you time and money



Storage and distribution

Our products are stored and distributed through a state-of-the-art distribution hub, which allows us to fulfil strict storage specifications and temperature control (from -80°C to 21°C in different zones) and to comprehensively manage our inventory (including controlled substances). That way the Mikromol products can be supplied to you everywhere you are, every time you need them



Expert technical support

If you need further assistance, our professional team will be happy to guide you at Mikromol@lgcgroup.com



Our quality enables your accuracy.

Each Mikromol product comes with an comprehensive Certificate of Analysis to help 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. This rigorous process makes Mikromol products valuable tools for the development and validation of non-compendial methods for release and stability testing, for which compendial standards are not necessarily suitable, having been qualified for use with their accompanying monographic methods only.

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

Example details provided for an 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 result

Acetylation of 2,6-Dimethylaniline during the synthesis of Lidocaine. (Impurity N-(2,6-Dimethylphenyl) acetamide, MM0102.08)

How to read your Certificate of Analysis (CoA).

Chemical name of the material.

Structural formula of the material.

Molecular formula of the material.

Molecular weight of the material.

CAS No.
A unique identifier – if available – assigned by the Chemical Abstracts Service.

Date of shipment (DOS)
Specifies when the product left our premises. The expiry date of the certificate is based on the DOS, see sentence below DOS.

Catalogue number
The unique identification code for the product is given in the certificate.

Lot number
Identification number for a specific batch of material.

Long-term storage
These are the storage requirements based on stability studies.

Appearance
How the substance appears at first glance.

Melting point information.

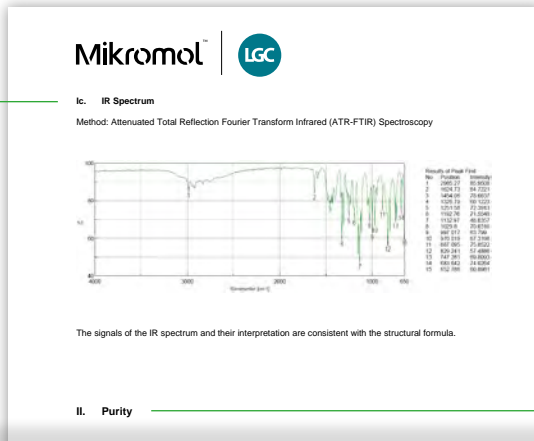
Assay
Given 'as is', corrected for volatile contents and organic impurities (see also footnote on last page of CoA).

Start of identity section
Contains major ID techniques performed on the substance in order to establish correct identity.

Identity by 1H-NMR
Shows spectrum and a formal sentence confirming the identity by either interpretation of data, or comparison with literature data.

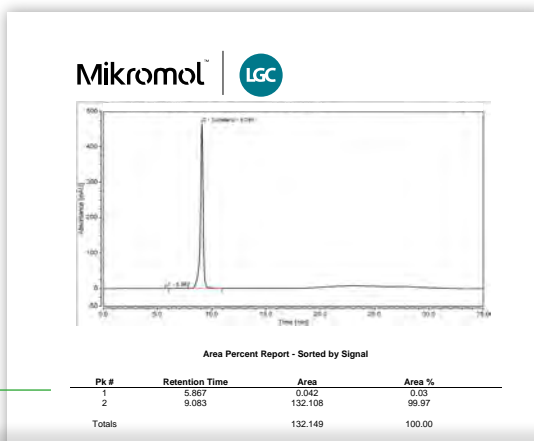
Identity by mass spectrometry
Shows spectrum and a formal sentence confirming the identity by either interpretation of data, or comparison with literature data.

Identity by infrared spectroscopy
Shows spectrum and a formal sentence confirming the identity by either interpretation of data, or comparison with literature data.

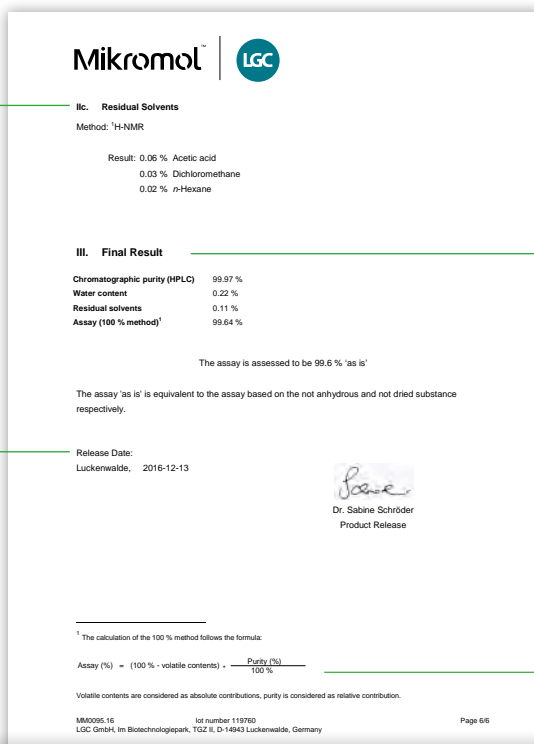


Purity section
Usually contains HPLC data to assess the organic purity of the material, as well as data on water and residual solvent content (continues on next pages).

Purity section continued.



Purity section continued.



Final result section
Lists relevant data used for calculation of assay figure. Calculation performed using equation in footnote.

Release date
Date of first release of specific lot. Material is re-tested at intervals to justify expiry approach explained on first page.

Footnote on assay calculation.

Best in class. Best for you.

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- Save or send your quote before converting it into an order
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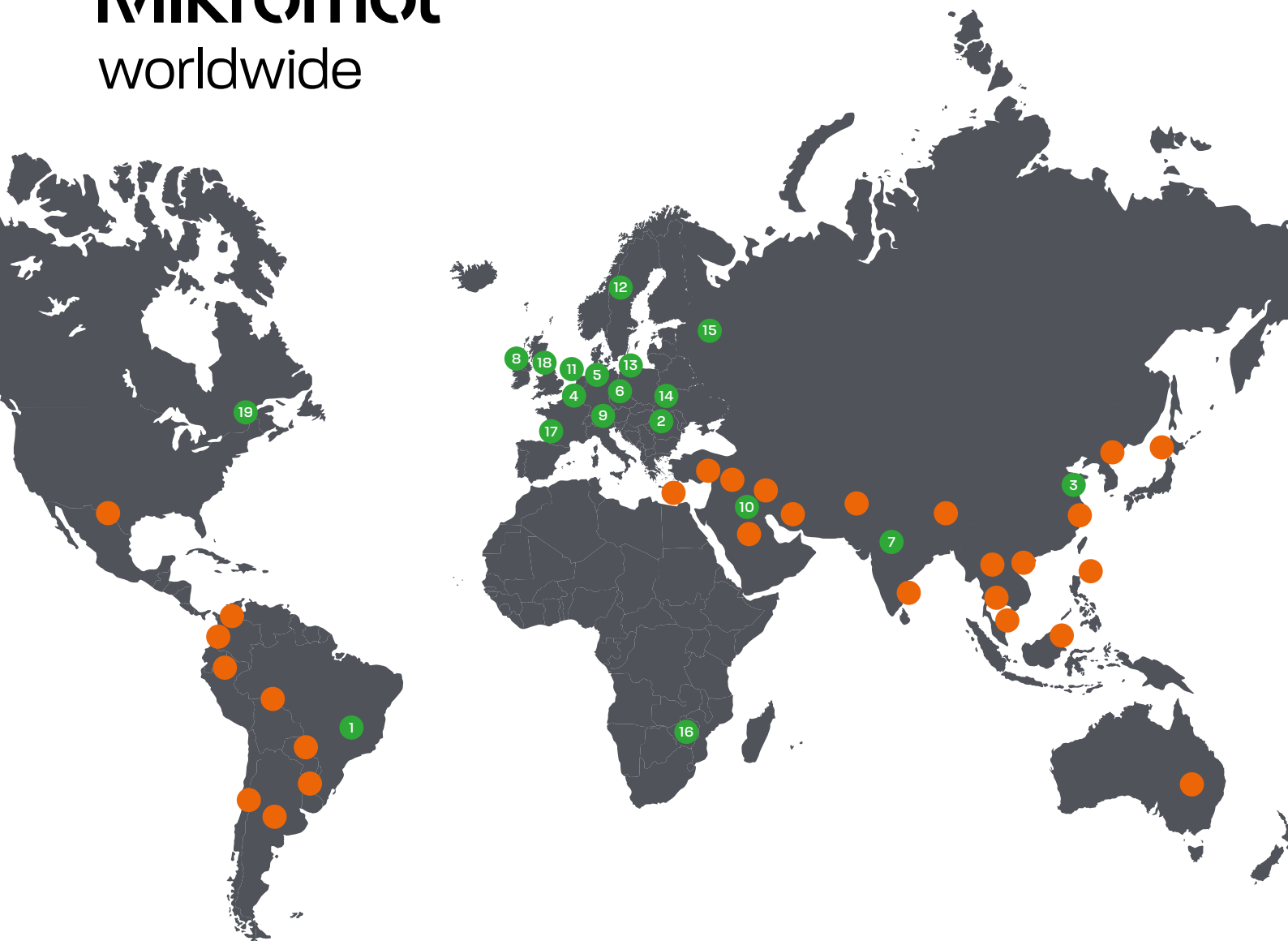
Phase separation during the liquid-liquid extraction of Enalapril Maleate. (Impurity Imidazole, MM0015.02)





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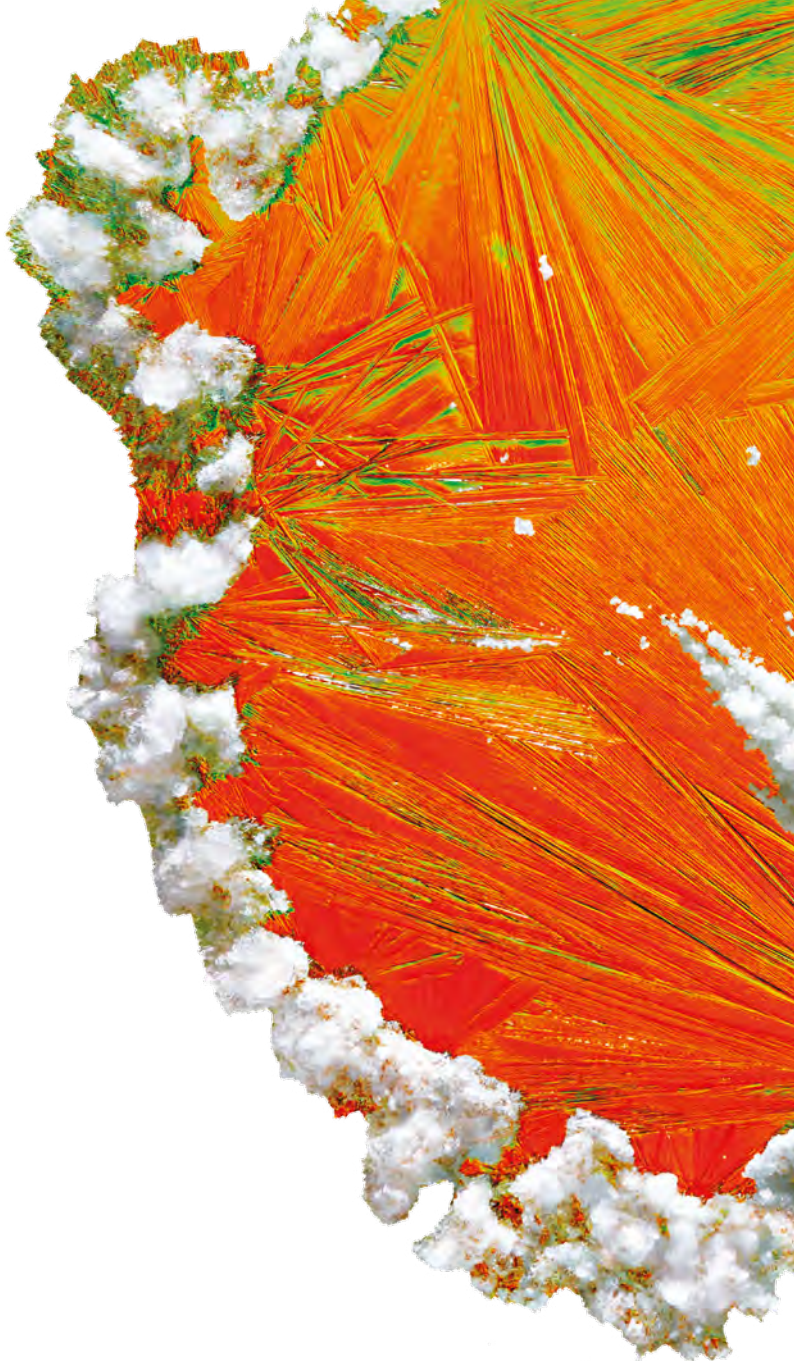
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Crystallization of Metformin Hydrochloride after
removal of Methanol from the reaction mixture.
(Impurity Cyanoguanidine, MM0056.01)

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