



Pharmaceutical API standards

detailed certificates of analysis • acknowledged by regulatory authorities worldwide • pharmaceutical impurities • custom synthesised impurities • pharmaceutical API standards





About LGC

LGC is a global leader in the production and distribution of reference materials for the pharmaceutical industry. Our extensive ranges of impurities and active pharmaceutical ingredients (API) reference materials and custom products are now complemented by a new range of in-house manufactured primary standards. LGC's international production facilities have an unparalleled depth of capabilities: from sourcing and characterisation and certification. This

experience developed over many years combined with our comprehensive accreditation portfolio gives confidence in the quality and robustness of all our reference materials, including the new primary standards. LGC also offers a comprehensive catalogue of materials from the world's Pharmacopoeias, and other materials relevant to the pharmaceutical industry.



LGC API standards fulfill ICH, FDA and other regulatory body requirements.



Our API standards in brief

- Fully characterised and designed to satisfy GMP requirements
- Certified under ISO Guide 34
- Comprehensive certificates of analysis detailing identity and purity
- Packed under argon for maximum stability
- Custom preparation and certification services to meet your specific needs
- Appropriate pack sizes for ease of use
- Far more cost effective than you may think

Are you looking for a special API standard for your analytical purpose but cannot find a supply source?

LGC also manufactures these materials on a custom basis.
Simply contact your local office!

The background of the page is a close-up photograph of several glass vials. Each vial contains a different type of pill. One vial in the foreground contains two white, oblong tablets. To its right, a vial contains several dark brown, oval-shaped tablets. In the lower-left corner, a vial contains several bright yellow, round tablets. Other vials with various colored pills are visible in the background, creating a sense of a diverse pharmaceutical inventory.

Our API standards

If no official standard from a pharmacopoeia exists for a given purpose, API standards from other sources can be used. For such API reference standards the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and Food and Drug Administration (FDA) demand a reference standard of the highest possible purity and full characterisation.

LGC has produced and certified a new range of pharmaceutical API standards that fulfill ICH, FDA and other regulatory body requirements for pharmaceutical quality control.

Using LGC's API reference standards ensures that you are well equipped and prepared for all audits or inspections.

From Allopurinol to Zileuton: API standards with detailed certificates of analysis

Our API standards are produced under our accreditation to ISO Guide 34. This accreditation enables us to manufacture the materials and issue detailed certificates of analysis under processes that satisfy the GMP requirements of our customers who examined and acknowledged our procedures during audits.

The APi standards are also packed under argon atmosphere to provide maximum stability of unopened containers.


The detailed certificate of analysis includes:

Comprehensive identity information

- Nuclear magnetic resonance (NMR) spectrum
- Infrared spectrum (IR)
- Mass spectrometry data (MS)

Detailed purity/assay data

- Assay information by accredited technique, qNMR whenever possible
- Confirmation by orthogonal method, e.g. mass balance

To browse our most recent list of API standards please refer to our catalogue **Pharmaceutical impurities and APi reference standards**, available for download at lgcstandards.com. All products in this interactive catalogue link directly to our webshop .

For further information, or if you require substances or materials not currently listed please contact one of our local sales offices:

Brazil

Tel: +55 12 3302 5880
Email: bz@lgcstandards.com

Bulgaria

Tel: +359 (0)2 971 4955
Email: bg@lgcstandards.com

China

Tel: 800 810 4630 (toll-free)
Email: infochina@lgcgroup.com

France

Tel: +33 (0)3 88 04 82 82
Email: fr@lgcstandards.com

Germany

Tel: +49 (0)281 9887 0
Email: de@lgcstandards.com

Hungary

Tel: +49 (0)281 9887 0
Email: de@lgcstandards.com

India

Tel: +91 9082974025
Email: india@lgcgroup.com

Ireland

Tel: +44 7879556983
Email: ire@lgcstandards.com

Italy

Tel: +39 02 2412 6830
Email: it@lgcstandards.com

Middle East

Tel: +49 (0)281 9887 0
Email: de@lgcstandards.com

Netherlands

Tel: +31 (0)643 775 422
Email: nl@lgcstandards.com

Nordic countries

Tel: +49 (0)281 9887 0
Email: de@lgcstandards.com

Poland

Tel: +48 22 751 31 40
Email: pl@lgcstandards.com

Romania

Tel: +40 364 116890
Email: ro@lgcstandards.com

Russia

Tel: +7 812 777 04 88
Email: ru@lgcgroup.com

South Africa

Tel: +27 (0)11 466 4321
Email: info@industrialanalytical.co.za

Spain

Tel: +34 (0)93 308 4181
Email: es@lgcstandards.com

Turkey

Tel: +90 216 360 0870
Email: tur@lgcstandards.com

United Kingdom

Tel: +44 (0)20 8943 8480
Email: uksales@lgcstandards.com

USA + Canada

Tel: 1-855-LGC-USA1 (toll-free)
Email: lgcusa@lgcstandards.com

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