DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the testing laboratory

LGC GmbH
Louis-Pasteur-Straße 30, 14943 Luckenwalde

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notices of 05.07.2024 with accreditation number D-PL-14176-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

Registration number of the accreditation certificate: **D-PL-14176-01-00**

Berlin, 05.07.2024 Dr. Olga Lettau
Head of Technical Unit

Translation issued:
11.07.2024 Dr. Olga Lettau
Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

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Europa-Allee 52
60327 Frankfurt am Main

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Bundesallee 100
38116 Braunschweig

The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

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Annex to the Accreditation Certificate D-PL-14176-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: **05.07.2024**

Date of issue: 11.07.2024

Holder of accreditation certificate:

LGC GmbH
Louis-Pasteur-Straße 30, 14943 Luckenwalde

with the location

LGC GmbH
Im Biotechnologiepark 3, TGZII, 14943 Luckenwalde

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Tests in the fields:

physical, physico-chemical and chemical determinations on identity, purity and assay of pure organic compounds and salts thereof (e. g. pharmaceutically and forensically relevant substances) as pure substances or in solution

The testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the modification, development and refinement of testing methods.
The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de.

Abbreviations used: see last page

1 Identity tests of organic compounds with melting point analysis (capillary method)

SOP 06-010 2015-03	Melting Point – Identity test of solid, organic pure substances by melting point measurement (capillary method)
Ph. Eur. 9.1 Kap. 2.2.14 2020	Melting point analysis - capillary method

2 Identity tests and assay determinations of organic compounds with elementary analysis

SOP 06-039 2015-07	Elemental Analysis – Determination of C-, H- and N-content of liquid and solid organic pure substances using elemental analysis for the test on identity – Content determination of liquid and solid organic pure substances using carbon titration of the elemental analysis

3 Identity tests and purity determinations of organic compounds with Infrared spectroscopy

SOP 06-036 2018-04	IR – Identity test of solid and liquid organic pure substances by infrared spectroscopy (FTIR-ATR)
Ph. Eur. 9.7 Kap. 2.2.24 2020	IR - Spectroscopy

4 Purity and assay determinations of organic compounds with quantitative nuclear magnetic resonance (NMR)

SOP 06-053 2019-01	NMR – Identity test of liquid and solid organic pure substances by 1H NMR spectroscopy and by 13C NMR spectroscopy
SOP 06-044 2019-01	Quantitative NMR – Assay determination of solid and liquid organic pure substances – Determination of residual solvent contents in pure organic compounds using quantitative NMR - spectroscopy
Ph. Eur. 9.0 Kap. 2.2.33 2020	NMR - Nuclear magnetic resonance spectroscopy

5 Assay determinations of organic compounds with UV-Vis spectroscopy

SOP 06-029 2018-11	UV-Vis Spectrophotometry - Assay determination of organic substances with UV-Vis spectroscopy
Ph. Eur. 9.0 Kap. 2.2.25 2020	Absorption spectrophotometry UV and Vis

6 Identity tests and purity determinations of organic compounds with mass spectrometry

SOP 06-022 2019-01	MS – Identity test of solid and liquid organic pure substances by mass spectrometry (ESI)
SOP 06-022, Annex 3 2019-01	Determination of the degree of deuteration of organic compounds with HRMS
Ph. Eur. 9.0 Kap. 2.2.43 2020	Mass spectrometry

7 Purity determinations of organic compounds with gravimetry

SOP 06-028 2015-06	Sulfated Ash – Determination of inorganic components in organic pure substances as limit test by Sulphated Ash in a microwave oven
SOP 06-035 2017-05	LOD – Determination of residual solvent content of solid organic pure substances by Loss On Drying (LOD)
SOP 06-037 2019-07	TGA – Determination of residual solvent content of solid organic pure substances by thermal gravimetric analysis
Ph. Eur. 9.8 Kap. 2.2.32 2020	Loss On Drying
Ph. Eur. 9.1 Kap. 2.2.34 2020	Thermal analysis
Ph. Eur. 9.0 Kap. 2.4.14 2020	Sulfated Ash

8 Purity and assay determinations of organic compounds and assay determinations of organic substances in solutions with titration

SOP 06-006 2010-03	Titration – Assay determination of solid and liquid organic pure substances (in solution) by potentiometric titration
SOP 06-024 2017-10	KFT – Determination of water content up to a content of 20% in solid and liquid organic pure substances by Karl-Fischer-Titration - Testing Procedure
Ph. Eur. 9.8 Kap. 2.5.32 2018	Micro determination of water - Coulometric titration
Ph. Eur. 9.4 Kap. 2.5.12 2020	Semi micro determination of water
Ph. Eur. 9.0 Kap. 2.2.20 2020	Potentiometric titration

9 Purity and assay determinations of organic compounds also in solution with gas chromatographie (GC-FID)

SOP 06-064 2011-02	Purity and assay determinations of organic compounds with GC
SOP 06-073 2010-05	GC-Headspace FID– Residual solvent content in wt% in organic pure substances
Ph. Eur. 9.6 Kap. 2.2.28 2020	Gas chromatography
Ph. Eur. 9.0 Kap. 2.4.24 2020	Residual solvent per GC Headspace

10 Purity and assay determinations of organic compounds also in solution with gas chromatographie (GC-MS)

SOP 06-064 2011-02	Purity and assay determinations of organic compounds with GC
Ph. Eur. 9.6 Kap. 2.2.28 2020	Gaschromatographie

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11 Purity and assay determinations of organic compounds also in solution by liquid chromatography (HPLC, UPLC) with conventional detectors DAD, CAD

SOP 06-032 2019-01	LC – Purity determination of solid and liquid organic pure substances by LC - Testing Procedure
Ph. Eur. 9.6 Kap. 2.2.29 2020	Liquid chromatography

12 Identity tests and purity determinations of organic compounds with differential scanning calorimetry (DSC)

SOP 06-038 2019-01	DSC – Purity determination of solid, temperature-stable, organic pure substances by DSC or melting point determination derived from it
Ph. Eur. 9.1 Kap. 2.2.34 2020	Thermal analysis

13 Identity tests and purity determinations of organic compounds with polarimetry

SOP 06-033 2019-12	Determination of optical rotation and optical purity of chiral substances by polarimetry
Ph. Eur. 9.5 Kap. 2.2.7 2020	Optical rotation

Abbreviations used:

DSC	Differential Scanning Calorimetry
ESI	Electrospray-Ionisation
FTIR-ATR	Fourier Transform Infrared Spectroscopy – Attenuated Total Reflectance
GCMS	Gas Chromatography-Mass Spectrometry
HPLC	High-Performance Liquid Chromatography (or High-Pressure Liquid Chromatography)
NMR	Nuclear magnetic resonance
SOP	Standard operation procedure at LGC GmbH
Produkt LGC xxx	House method at LGC GmbH with regard to a defined LGC product