DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

LGC GmbH
Im Biotechnologiepark 3, 14943 Luckenwalde

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out tests in the following 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 accreditation certificate shall only apply in connection with the notice of accreditation of 04.12.2020 with the accreditation number D-PL-14176-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

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

Berlin, 04.12.2020	Dipl.-Ing. Andrea Valbuena Head of Division	Translation issued: 04.12.2020	Valbuena Head of Division

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
https://www.dakks.de/en/content/accredited-bodies-dakks

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

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

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Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). 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 Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

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: **04.12.2020**

Date of issue: 04.12.2020

Holder of certificate:

LGC GmbH
Im Biotechnologiepark 3, 14943 Luckenwalde

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

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

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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
SOP 06-029, Annex 4 2014-02	Assay determination of ethanol in aqueous solution with UV/VIS Spectrophotometry via derivatisation with ADH and comparison to a standard
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 2020	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

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