

Deutsche Akkreditierungsstelle GmbH

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

Valid from: 07.06.2019

Date of issue: 07.06.2019

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.

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

Abbreviations used: see last page

*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>*

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

SOP 06-010 Melting Point – Identity test of solid, organic pure substances by
2015-03 melting point measurement (capillary method)

EXAMPLES

Product LGCQUANT0123.00 Identity test of Ethinylestradiol
2014-08-05

Product LGCQUANT1443.00 Identity test of Brotizolam
2014-08-05

Ph. Eur. 6.5 Kap. 2.2.14 Melting point analysis - capillary method
2009

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

SOP 06-039 Elemental Analysis
2015-07 – 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 spectroscopy

SOP 06-036 IR – Identity test of solid and liquid organic pure substances by
2018-04 infrared spectroscopy (FTIR-ATR)

SOP 06-053 NMR – Identity test of liquid and solid organic pure substances by ¹H
2019-01 NMR spectroscopy and by ¹³C NMR spectroscopy

Ph. Eur. 6.5 Kap. 2.2.24 IR - Spectroscopy
2009

Ph. Eur. Kap. 2.2.33 NMR - Nuclear magnetic resonance spectroscopy
2010

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

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. 7.0 Kap. 2.2.33 NMR - Nuclear magnetic resonance spectroscopy
2010

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. 7.2 Kap. 2.2.25 Absorption spectrophotometry UV and Vis
2011

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. 6.5 Kap. 2.2.43 Mass spectrometry
2009

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

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SOP 06-035 2009-04	LOD – Determination of residual solvent content of solid organic pure substances by Loss On Drying (LOD)
SOP 06-037 2010-05	TGA – Determination of residual solvent content of solid organic pure substances by thermal gravimetric analysis
Ph. Eur. 6.5 Kap. 2.2.32 2009	Loss On Drying
Ph. Eur. 6.5 Kap. 2.2.34 2009	Thermal analysis
Ph. Eur. 7.0 Kap. 2.4.14 2010	Sulfated Ash

8 Purity and assay determinations of organic compounds in solution 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. 6.5 Kap. 2.5.32 2009	Micro determination of water - Coulometric titration
Ph. Eur. 6.5 Kap. 2.2.20 2009	Potentiometric titration

9 Purity and assay determinations of organic compounds with gas chromatographie (GC)

SOP 06-064 2011-02	Purity and assay determinations of organic compounds with GC-MS
SOP 06-073 2010-05	GCMS-Headspace – Residual solvent content in wt% in organic pure substances

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EXAMPLES

Product LGCAMP0078.07-11 Purity determination of 7-Aminonitrazepam 1.0 mg/ml in Acetonitrile
2011-07-04

Product LGCAMP0420.00-01 Purity determination of Chlorpromazine Hydrochloride 1.0 mg/ml in
2011-06-30 Methanol (as free base)

Ph. Eur. 6.5 Kap. 2.2.28 Gas chromatography
2009

Ph. Eur. 7.2 Kap. 2.4.24 Residual solvent per GC Headspace
2011

10 Purity and assay determinations of organic compounds with LC

SOP 06-032 LC – Purity determination of solid and liquid organic pure substances
2019-01 by LC (LC with UV-Detector) - Testing Procedure

EXAMPLES

Produkt LGCQUANT0431.00 Purity determination of Methyl Parahydroxybenzoate
2013-06-04

Produkt LGCQUANT0432.00 Purity determination of Propyl Parahydroxybenzoate
2013-09-10

Ph. Eur. 6.5 Kap. 2.2.29 liquid chromatography
2009

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

SOP 06-038 DSC – Purity determination of solid, temperature-stable, organic pure
2019-01 substances by DSC or melting point determination derived from it

Ph. Eur. 6.5 Kap. 2.2.34 Thermal analysis
2009

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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

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