

Deutsche Akkreditierungsstelle GmbH

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

Period of validity: 20.11.2018 to 04.08.2019 Date of issue: 20.11.2018

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

Abbreviations used: see last page

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.

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

SOP 06-010
2009-05 Melting Point – Identity test of solid, organic pure substances by melting point measurement (capillary method)

SOP 06-011
2009-05 Melting Point – Identity test of solid organic pure substances by melting point measurement – Method Development

EXAMPLES

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

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

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

SOP 06-039
2009-11 Elemental Analysis – Determination of C-, H- and N-content of liquid and solid organic pure substances using elemental analysis for the test on identity

SOP 06-039
2009-11 Elemental Analysis – 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
2010-03 IR – Identity test of solid and liquid organic pure substances by infrared spectroscopy (FTIR-ATR)

SOP 06-053
2011-12 NMR – Identity test of liquid and solid organic pure substances by ¹H NMR spectroscopy and by ¹³C NMR spectroscopy

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

SOP 06-044
2014-02 Quantitative NMR - Assay determination of solid and liquid organic pure substances

SOP 06-044
2014-02 Quantitative NMR – Determination of residual solvent contents in pure organic compounds

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5 Assay determinations of organic compounds with UV-Vis spectroscopy

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| SOP 06-029 2013-05 | UV-Vis Spectrophotometry - Assay determination of organic substances |
| 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 |

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

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| SOP 06-022 2014-02 | MS – Identity test of solid and liquid organic pure substances by mass spectrometry (ESI) |
| SOP 06-022, Annex 3 2014-02 | Determination of the degree of deuteration of organic compounds with HRMS |

7 Purity determinations of organic compounds with gravimetry

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| SOP 06-028 2009-11 | Sulfated Ash – Determination of inorganic components in organic pure substances as limit test by Sulphated Ash in a microwave oven |
| 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 |

8 Purity and assay determinations of organic compounds in solution with titration

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| SOP 06-006 2010-03 | Titration – Assay determination of solid and liquid organic pure substances (in solution) by potentiometric titration |
| SOP 06-024 2010-03 | KFT – Determination of water content up to a content of 20% in solid and liquid organic pure substances by Karl-Fischer-Titration - Testing Procedure |

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

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

EXAMPLES

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

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

10 Purity and assay determinations of organic compounds with LC

SOP 06-031
2010-04 LC – Purity determination of solid and liquid organic pure substances by LC (LC with UV-Detector) – Method Development

SOP 06-032
2011-09 LC – Purity determination of solid and liquid organic pure substances by LC (LC with UV-Detector) - Testing Procedure

SOP 06-052
2010-05 LC – Purity determination of solid and liquid organic pure substances by LC (LC with UV-Detector) - Method Validation

EXAMPLES

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

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

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

SOP 06-038
2009-05 DSC – Purity determination of solid, temperature-stable, organic pure substances with a content >98.5% by DSC

SOP 06-038
2009-05 Melting Point – Identity test of solid organic pure substances by melting point measurement (DSC)

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Abbreviations used:

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|-----------------|---|
| 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 |