

# Deutsche Akkreditierungsstelle GmbH

## Annex to the Accreditation Certificate D-RM-14176-01-00 according to DIN EN ISO 17034:2017

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

Holder of certificate:

**LGC GmbH**

on the sites

**Louis-Pasteur-Straße 30, 14943 Luckenwalde**  
**Im Biotechnologiepark 3, 14943 Luckenwalde**

Reference material production in the fields:

**reference materials and certified reference materials for organic neat compounds and salts thereof  
(e. g. pharmaceutically or forensically relevant substances);**  
**reference materials in form of solutions (e. g. pharmaceutically or forensically relevant substances)**

Abbreviations used: see last page

**Annex to the accreditation certificate D-RM-14176-01-00**

**1 Certified reference materials for organic neat compounds and salts thereof (e. g. pharmaceutically or forensically relevant substances)**

Product	Characteristic	Range	Relative uncertainty in %	Method
Pure Organic Substances	Identity	-----	-----	At least 4 of the following methods: FTIR-ATR, 1H NMR, 13C NMR, MS, melting point (capillary method, DSC), elemental analysis
	Assay	≥ 95 % m/m	0,3 %	Conformity of the test results within the limits of the measurement uncertainty of at least two methods: Titration, qNMR, 100%-Method LC or GC, 100%-Method DSC, carbon titration of the elemental analysis

**2 Reference materials for organic neat compounds and salts thereof (e. g. pharmaceutically or forensically relevant substances)**

Product	Characteristic	Range	Relative uncertainty in %	Method
Pure Organic Substances	Identity	-----	-----	Thorough identity checking by several of the following methods or comparison to an international accepted standard: FTIR-ATR, 1H NMR, 13C NMR, MS, melting point (capillary method, DSC), elementary analysis
	Assay	≥ 90 % m/m	≤ 2 %	Assay detection by accredited absolute method or 100%-method (mass balance) with accredited (validated) testing methods Additional assay verification by an independent testing method

**3 Reference materials in form of solutions of organic neat compounds and salts thereof (e.g. pharmaceutically or forensically relevant substances)**

Product	Characteristic	Range	Method
Solutions of pure organic substances	Assay	0,005 – 10 g/l	Gravimetric production with high precision weighing, on the basis of highly pure starting materials (characterised by quantitative analysis with accredited testing method like e.g. carbon titration of the elemental analysis, examined by 100% - impurities), verified by quantitative analysis (LC/GC) against external standard, contamination-free homogenisation and filling

**Abbreviations used:**

DSC	Differential Scanning Calorimetry
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