

Deutsche Akkreditierungsstelle GmbH

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

Valid from: 07.06.2019

Date of issue: 07.06.2019

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)

**The reference material producer maintains an up-to-date list of certified reference materials in the
accredited area**

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>*

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

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

Product	Characteristic	Range	1. Characterization strategy/ 2. procedure
Pure Organic Substances	Identity	-----	1. Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy, at least one of which is a fully validated method. 2. Thorough identity checking by several of the following methods or comparison to an international accepted standard: FTIR-ATR, ¹ H NMR, ¹³ C NMR, MS, melting point (capillary method, DSC), elementary analysis
	Content	≥ 90 % m/m	Assay detection by accredited absolute method or 100%-method (mass balance) with accredited (validated) testing methods Additional assay verification by an independent testing method

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

Product	Characteristic	Range	1. Characterization strategy/ 2. procedure
Solutions of pure organic substances	Content	0,005 – 10 g/l	1. Characterization based on mass or volume of ingredients used in the preparation of the RM according to ISO 17034 paragraph 7.12.3 Note 1e) 2. 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

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

Product	Characteristic	Range	Relative uncertainty in relation to content	1. Characterization strategy/ 2. procedure
Pure Organic Substances	Identity	-----	-----	<p>1. Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories according to ISO 17034 paragraph 7.12.3 Note 1b)</p> <p>Or value transfer from an RM to a closely matched candidate RM performed using a single measurement procedure performed by one laboratory according to ISO 17034 paragraph 7.12.3 Note 1d)</p> <p>2. At least 4 of the following methods: FTIR-ATR, ¹H NMR, ¹³C NMR, MS, melting point (capillary method, DSC), elemental analysis</p>
	Content	≥ 95 % m/m	≤1,0 %	<p>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</p>

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