

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 reference material producer

LGC GmbH

on the sites

Louis-Pasteur-Straße 30, 14943 Luckenwalde
Im Biotechnologiapark 3, 14943 Luckenwalde
Im Biotechnologiapark 7 (TGZ III), 14943 Luckenwalde

is competent under the terms of DIN EN ISO 17034:2017 to produce reference materials in the area:

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 accreditation certificate shall only apply in connection with the notice of accreditation of 15.12.2020 with the accreditation number D-RM-14176-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

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

Berlin,
15.12.2020

Dipl.-Ing. Andrea Valbuena
Head of Division

Translation issued:
15.12.2020


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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10117 Berlin

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60327 Frankfurt am Main

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38116 Braunschweig

The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkKS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkKS.

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

Deutsche Akkreditierungsstelle GmbH

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

Valid from: 15.12.2020

Date of issue: 15.12.2020

Holder of certificate:

LGC GmbH

on the sites

Louis-Pasteur-Straße 30, 14943 Luckenwalde
Im Biotechnologiepark 3, 14943 Luckenwalde
Im Biotechnologiepark 7 (TGZ III), 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**

The management system requirements in DIN EN ISO 17034 are written in language relevant to operations of reference material producer and operate generally in accordance with the principles of DIN EN ISO 9001.

*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