



# CERTIFICATE



This is to certify that

## LGC GmbH

Louis-Pasteur-Str. 30  
14943 Luckenwalde  
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:  
development, production, analysis and distribution of reference substances

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 9001 : 2015

Certificate registration no.	102448 QM15
Certificate unique ID	170706311
Effective date	2018-07-30
Expiry date	2021-07-29
Frankfurt am Main	2018-07-30



## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director







## Annex to certificate

**Certificate registration No.: 102448 QM15**

**Certificate unique ID: 170706311**

**Effective date: 2018-07-30**

## LGC GmbH

Louis-Pasteur-Str. 30  
14943 Luckenwalde  
Germany

### Location

### Scope

#### LGC GmbH

Louis-Pasteur-Str. 30  
14943 Luckenwalde  
Germany

development, production, analysis and  
distribution of reference substances

#### LGC GmbH

Im Biotechnologiepark 3  
14943 Luckenwalde  
Germany

development, production, analysis and  
distribution of reference substances





## Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

# Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the reference material producer

**LGC GmbH**

on the sites

**Louis-Pasteur-Straße 30, 14943 Luckenwalde  
Im Biotechnologiepark 3, 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 07.06.2019 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,  
07.06.2019

Dipl.-Ing. Andrea Valbuena  
Head of Division

Translation issued:  
07.06.2019

  
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

### 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>



**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, <sup>1</sup> H NMR, <sup>13</sup> 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

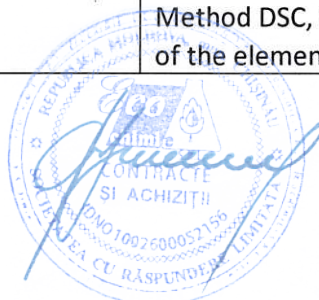
**2 Reference materials in form of solutions of organic neat compounds and salts thereof (e. g. pharmaceutically or forensically relevant substances)**

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:</p> <p>FTIR-ATR, <sup>1</sup>H NMR, <sup>13</sup>C 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:</p> <p>Titration, qNMR, 100%-Method LC or GC, 100%-Method DSC, carbon titration of the elemental analysis</p>





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

**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







# Standard Compliance Certificate



This is to certify that

## LGC GmbH

Louis-Pasteur-Str. 30  
14943 Luckenwalde  
Germany

has implemented and maintains a  
**EXCiPACT™ : 2017 Certification Standard for  
Pharmaceutical Excipient Suppliers:**

## Good Manufacturing Practice Good Distribution Practice

The certificate is only valid in conjunction with a valid ISO 9001 certificate

**This assessment also meets the requirements of  
NSF/IPEC/ANSI 363-2016  
Good Manufacturing Practice for Pharmaceutical Excipients**

Scope:

Development, production and distribution of chemical reference substances as typically used for pharmaceutical products.

Certificate registration no. 102448 EXCI

Valid from 2018-11-26

Valid until 2021-08-01

Date of certification 2018-11-26

international excipients  
certification



## DQS GmbH

Stefan Heinloth  
Managing Director

