

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-RM-21273-01-00 according to DIN EN ISO 17034:2017

Valid from: **20.10.2020**

Date of issue: 14.01.2021

Holder of certificate:

WITEGA Laboratorien Berlin-Adlershof GmbH
James-Franck-Straße 4
12489 Berlin

Reference material production in the fields:

Reference materials and certified reference materials for pure organic substances and stable isotope labelled pure organic substances (veterinary pharmaceuticals)

The reference material producer maintains a current list of reference materials/certified reference materials in the accredited field.

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>*

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1 Reference materials for pure organic substances and stable isotope labelled pure organic substances (veterinary pharmaceuticals)

Product	Characteristic	Range	maximum measurement uncertainty	Characterization approach	Applied methods
Pure organic substances	Purity	≥ 99.0 %	$U \leq 2.0 \% *$	**	100 %-method (summation of all impurities)
	Identity	-	-		HPLC, NMR, elemental analysis, melting point
Stable isotope labelled pure organic substances	Purity	≥ 99.0 %	$U \leq 2.0 \% *$	**	100 %-method
	Identity	-	-		HPLC, NMR, LC/MS, elemental analysis, melting point

* expanded uncertainty U (with coverage factor $k = 2$ at a level of confidence of 95.45 %)

** Determination of purity according to ISO Guide 35:2017, chapter 9.6.3 „Indirect determination of purity“ via HPLC in combination with the exclusion of further impurities (organic solvents, water and inorganic impurities) according to ISO Guide 35:2017, chapter 9.8 „Presence/absence“

2 Certified reference materials for pure organic substances and stable isotope labelled pure organic substances (veterinary pharmaceuticals)

Product	Characteristic	Range	maximum measurement uncertainty	Characterization approach	Applied methods
Pure organic substances	Purity	≥ 99.0 %	$U \leq 2.0 \% *$	**	Determination of purity by a validated absolute method or the 100%-method
	Identity	-	-		HPLC, NMR, elemental analysis, melting point

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Product	Characteristic	Range	maximum measurement uncertainty	Characterization approach	Applied methods
Stable isotope labelled pure organic substances	Purity	≥ 99.0 %	$U \leq 2.0 \% *$	**	Determination of purity by a validated absolute method or the 100%-method
	Identity	-	-		HPLC, NMR, LC/MS, elemental analysis, melting point

* expanded uncertainty U (with coverage factor $k = 2$ at a level of confidence of 95.45 %)

** Determination of purity according to ISO Guide 35:2017, chapter 9.6.3 „Indirect determination of purity“ via HPLC in combination with the exclusion of further impurities (organic solvents, water and inorganic impurities) according to ISO Guide 35:2017, chapter 9.8 „Presence/absence“

Abbreviations used:

DIN	Deutsches Institut für Normung e. V.
EN	European Standard
HPLC	High-Performance Liquid Chromatography
ISO	International Organization for Standardization
LC/MS	Liquid Chromatography/Mass Spectrometry
NMR	Nuclear Magnetic Resonance