

REFERENCE MATERIAL CERTIFICATE

Reference Material

This certificate is designed in accordance with ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with a registered quality management system ISO 9001. All measurements were performed according to ISO/IEC 17025 by a DAkkS accredited laboratory (D-PL-19883-01-00).

Product Name
Gliclazide

Product Code
DRE-C14025500

CAS No.
21187-98-4

Mol. Weight
323.41

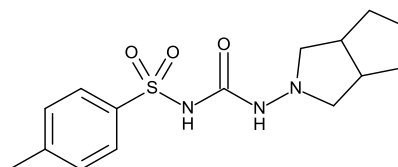
Mol. Formula
C₁₅H₂₁N₃O₃S

Lot Number
1048712

Format
Neat

Expiry Date
10 Dec 2023

Storage Temp
4°C ± 4°C



CERTIFIED

Purity
99.4% (g/g)

CERTIFIED

Expanded Uncertainty (U)
1.0% (g/g)

Uncertainty

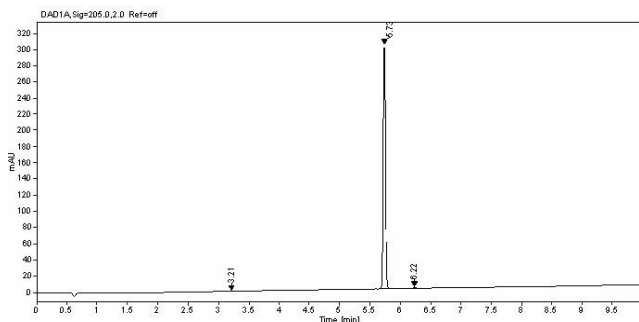
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY		CERTIFIED ON			RM Release
D. Schmid		10 Dec 2019			

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CHROMATOGRAM



Signal: DAD1A, Sig=205.0,2.0 Ref=off				
Nr.	RT [min]	Area	Height	Area%
1	3.21	0.71179	0.25	0.09
2	5.73	792.03454	301.37	99.48
3	6.22	3.44265	1.3	0.43

Instrument
UHPLC/DAD

Detection
DAD

Column
LUNA Omega C18
1.6 µm 100 x 2.1 mm

Method Details
see Batch Information

Inj.-Vol.
2.0 µL

Flow
0.5 mL/min

Method of Characterisation

Purity = 100% – Assay impurities – Water content (KF)

Method of Identification

EA, NMR, RT, UV, IR, MS

Batch Information

Water Content: <0.1% (g/g) by Karl-Fischer-Titration (U(exp) = 0.1% (g/g)).

Method Details:

Eluent A: 100% Acetonitrile

Eluent B: Water + 0.5% H3PO4

Time [min]	Eluent A [%]	Eluent B [%]
0	10	90
0.3	10	90
8	100	0
9.5	100	0

Intended Use

This RM is intended for use in a laboratory as a calibration and quality control standard or in method development for analytical techniques.

Safety

Proper precautions should be observed while handling. See Safety Data Sheet.

Traceability

The balances used for gravimetric measurements are calibrated with weights traceable to the national

standards (DKD). The calibration of the balances is verified daily internally and annually by an external accredited calibration service. Chromatographic methods are traceable to the International System of Units (SI).

Storage

The RM should be stored in the original sealed container at the indicated temperature.

Instructions for use

It is recommended to use 1 mg as the minimum sample size and if less material is used, to increase the certified uncertainty by a factor of two for half sample and four for a quarter of sample. If storage after opening is necessary, the RM should be tightly closed and kept from light and moisture. If the RM was in a sealed ampoule, it should be transferred to a vial with minimum head space. Visit the support section of our website lgcstandards.com for a series of Dr. Ehrenstorfer Tech Tip videos and frequently asked questions.