

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

Pirenzepine dihydrochloride

Product Code

DRE-C16247500

CAS No.

29868-97-1

Mol. Weight

424.32

Mol. Formula

C₁₉H₂₁N₅O₂ · 2ClH

Lot Number

1200857

Format

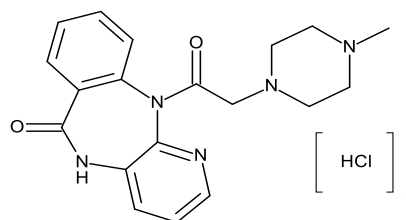
Neat

Expiry Date

16 Nov 2024

Storage Temp

20°C ± 4°C

**CERTIFIED**

Purity
95.1% (g/g)

CERTIFIED

Expanded Uncertainty (U)
3.0% (g/g)

Uncertainty

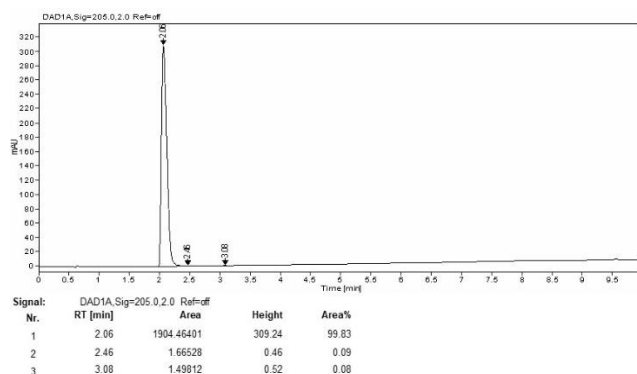
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation 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
N. Müller	16 Nov 2021		

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CHROMATOGRAM



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) – Residual Solvents (NMR)

Method of Identification

EA, NMR, RT, IR, MS, UV

Batch Information

Water Content: 4.6% (g/g) by Karl-Fischer-Titration ($U(\text{exp}) = 1.0\%$ (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.

LGC Labor GmbH
Bgm.-Schlosser-Straße 6A
86199 Augsburg, Germany
T | +49 821 906080
F | +49 821 9060888
E | dr.ehrenstorfer@lgcgroup.com