

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  
Nifedipine

Product Code  
DRE-C15522000

CAS No.  
21829-25-4

Mol. Weight  
346.33

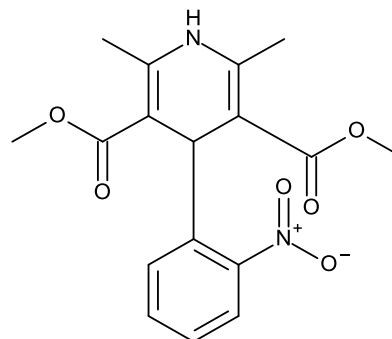
Mol. Formula  
C<sub>17</sub>H<sub>18</sub>N<sub>2</sub>O<sub>6</sub>

Lot Number  
1059635

Format  
Neat

Expiry Date  
06 Feb 2023

Storage Temp  
4°C ± 4°C



**CERTIFIED**

Purity  
99.0% (g/g)

**CERTIFIED**

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

Uncertainty

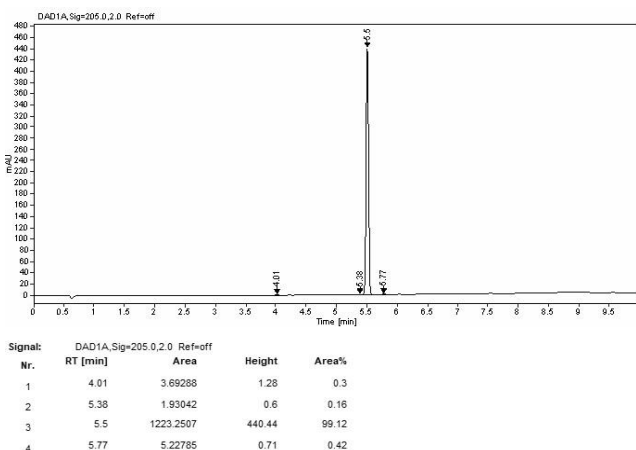
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation 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	
N. Müller	06 Feb 2020		RM Release

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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)

**Method of Identification**

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](http://lgcstandards.com) for a series of Dr. Ehrenstorfer Tech Tip videos and frequently asked questions.