

Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

Product Name
Simvastatin

Product Code
DRE-C16970100

CAS No.
79902-63-9

Mol. Weight
418.57

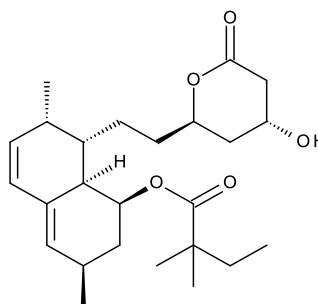
Mol. Formula
C₂₅H₃₈O₅

Lot Number
G1400445

Format
Neat

Expiry Date
20 Nov 2026

Storage Temp
4°C ± 4°C



| | |
|--|---|
| CERTIFIED Purity 98.90% (g/g) | CERTIFIED Expanded Uncertainty (U) 0.50% (g/g) |
|--|---|

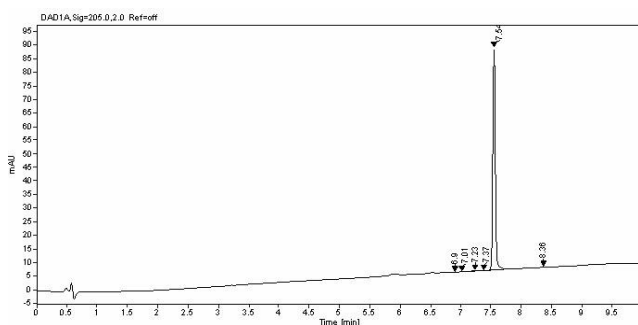
Uncertainty

The certified value(s) and uncertainty(ies) are determined in accordance with ISO 17034 with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation, homogeneity 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 | |
|-----------------|-------------|------------------------|------------|
| L. Messerschmid | 20 Nov 2023 | <i>L. Messerschmid</i> | RM Release |

CHROMATOGRAM



| Nr. | RT [min] | Area | Height | Area% |
|-----|----------|----------|--------|-------|
| 1 | 6.9 | 0.13434 | 0.05 | 0.06 |
| 2 | 7.01 | 0.11398 | 0.04 | 0.05 |
| 3 | 7.23 | 1.11138 | 0.27 | 0.46 |
| 4 | 7.37 | 0.2115 | 0.08 | 0.09 |
| 5 | 7.54 | 237.2972 | 81.71 | 98.98 |
| 6 | 8.36 | 0.87638 | 0.28 | 0.37 |

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, IR, MS, UV

Batch Information

Water Content: <0.10% (g/g) by Karl-Fischer-Titration (U(exp) = 0.03% (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).

Homogeneity

Random replicate samples of the final packaged RM have been analysed to prove homogeneity compliant with ISO 17034.

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

LGC Labor GmbH is accredited by
DAkKS accreditation numbers
D-RM-19883-01-00 & D-PL-19883-01-00
on ISO 17034:2017 & ISO/IEC 17025:2018

