



### 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

Ambroxol hydrochloride

#### Product Code

DRE-C10148800

#### CAS No.

23828-92-4

#### Mol. Weight

414.56

#### Mol. Formula

C<sub>13</sub>H<sub>18</sub>Br<sub>2</sub>N<sub>2</sub>O · ClH

#### Lot Number

G1147788

#### Format

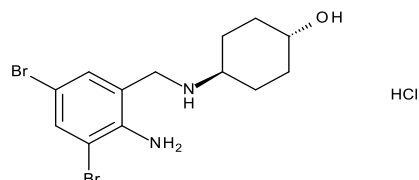
Neat

#### Expiry Date

28 May 2027

#### Storage Temp

4°C ± 4°C



**CERTIFIED**

Purity  
99.90% (g/g)

**CERTIFIED**

Expanded Uncertainty (U)  
0.30% (g/g)

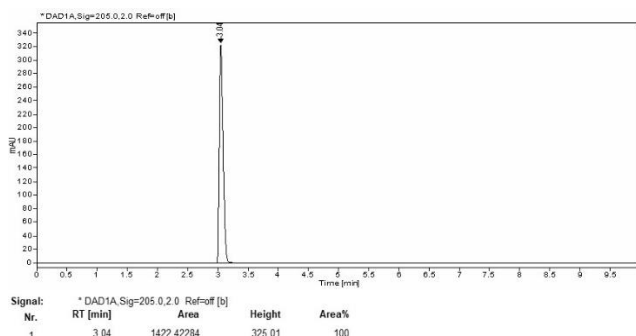
#### Uncertainty

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		
N. Müller	28 May 2021		RM Release

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

EA, NMR, RT, IR, UV

### Batch Information

Water Content: <0.10% (g/g) by Karl-Fischer-Titration (U(exp) = 0.04% (g/g)).

Method Details:

Eluent A: 100% Acetonitrile

Eluent B: Water + 0.5% H<sub>3</sub>PO<sub>4</sub>

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

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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

