

REFERENCE MATERIAL CERTIFICATE

ISO 17034

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

Mapenterol hydrochloride

Product Code Lot Number DRE-C14754000 G1545609

CAS No. Format 54238-51-6 Neat

Mol. Weight Expiry Date
361.23 07 May 2029
Mol. Formula Storage Temp

Mot. Formula Storage Fer $C_{14}H_{20}ClF_3N_2O \cdot ClH$ 4°C \pm 4°C

FF	OH H
H ₂ N	HCI

CERTIFIED

Purity 97.38% (g/g)

CERTIFIED

Expanded Uncertainty (U) 2.13% (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.

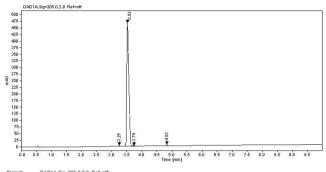
CERTIFIED BY	CERTIFIED ON	J. M. Jusic	RM Release
I. Milusic	07 May 2025		



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Signal:	DAD1A,Sig	=205.0,2.0 Ref=off		
Nr.	RT [min]	Area	Height	Area%
1	3.25	7.43848	2.77	0.33
2	3.52	2202.23096	465.32	98.93
3	3.74	4.80847	1.13	0.22
4	4.83	11.62820	4.64	0.52

Instrument

UHPLC/DAD

Detection

DAD

Column

LUNA Omega C18 $\,$ 1.6 $\,$ μ m $\,$ 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: 0.10% (g/g) by Karl-Fischer-Titration (U(exp) = 0.05% (g/g)).

Method Details:

Eluent A: 100% Acetonitrile Eluent B: Water + H3PO4

Time [min]	Eluent A [%]	Eluent B [%]
0	10	90
0.3	10	90
8	98	2
9.5	98	2

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

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LGC Labor GmbH is accredited by DAkkS as reference material producer on ISO 17034 (D-RM-19883-01-00).

All characterisation measurements at LGC Labor GmbH are accredited methods to ISO/IEC 17025.

