

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
Doxycycline hyclate

Product Code
DRE-C13084280

Lot Number
1116543

CAS No.
24390-14-5

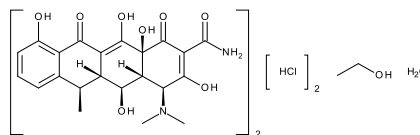
Format
Neat

Mol. Weight
1025.87

Expiry Date
13 Jan 2025

Mol. Formula
 $2C_{22}H_{24}N_2O_8 \cdot C_2H_6O \cdot 2ClH \cdot H_2O$

Storage Temp
 $20^{\circ}C \pm 4^{\circ}C$



CERTIFIED

Purity
98.0% (g/g)

CERTIFIED

Expanded Uncertainty (U)
2.0% (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		
D. Schmid	13 Jan 2021	p.p. <i>M. Beer</i>	RM Release



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CHROMATOGRAM

No chromatogram available.

Instrument

HPLC/DAD

Column

YMC-Pack ODS-AQ, 3 µm, 150 x 3 mm

Method Details

Eluent A: Acetonitrile

Eluent B: Water + 0.15% Formic Acid

Time [min]	Eluent A [%]	Eluent B [%]
0	15	85
3	15	85
9	35	65
10	100	0
14	100	0

Flow

0.5 mL/min

Method of Characterisation

Purity = 100% – Assay impurities – Water excess (KF)

Method of Identification

EA, NMR, RT, IR, MS, UV

Batch Information

Water Content: 2.0% (g/g) by Karl-Fischer-Titration (U(exp) = 0.2% (g/g)).

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.

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