LGC | DR EHRENSTORFER™

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
Efinaconazole

Product Code
DRE-C13111200

Lot Number
1101269

CAS No.
164650-44-6

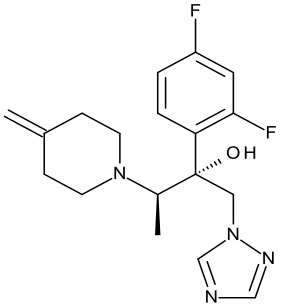
Format
Neat

Mol. Weight
348.39

Expiry Date
24 Feb 2024

Mol. Formula
$C_{18}H_{22}F_2N_4O$

Storage Temp
20°C ± 4°C



CERTIFIED	CERTIFIED
Purity 99.3% (g/g)	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		
N. Müller	24 Feb 2021		RM Release

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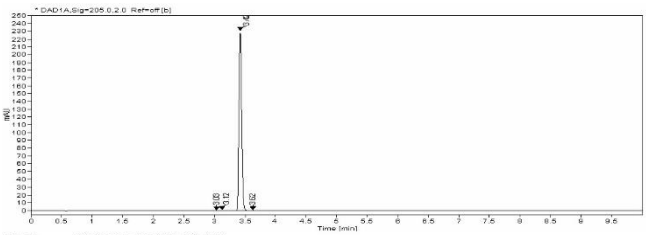
CHROMATOGRAM



Signal: * DAD1A,Sig=205,0,2,0 Ref=off (b)

Nr.	RT [min]	Area	Height	Area%
1	3.03	0.55288	0.16	0.08
2	3.12	1.97125	0.58	0.28
3	3.42	711.49828	230.39	99.52
4	3.62	0.9376	0.28	0.13

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: 0.2% (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 for a series of Dr. Ehrenstorfer Tech Tip videos and frequently asked questions.

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