



Certificate of Analysis

ISO Guide 34 Reference Material

Product Identification

Article Code: DRE-C16908002
Article Name: Sarafloxacin D8 hydrochloride
Formula: C₂₀D₈H₁₀F₂CIN₃O₃
Mol. Weight: 429.88
CAS No.:

Lot Number: G159143
Expiry Date: 05.12.2021
Storage Temperature: 20°C ± 4°C

Storage and handling: The RM should be stored in the original sealed bottle at the temperature given above. After use the bottle should be tightly closed and protected from moisture and light. The expiry date is valid for original sealed bottles under recommended storage conditions only.

Combined Purity:	90.15% (g/g)	Isotopic Purity:	98.62% (g/g)	Chemical Purity:	91.41% (g/g)
Expanded Uncertainty U=	0.65% (g/g)	Expanded Uncertainty U=	0.30% (g/g)	Expanded Uncertainty U=	0.58% (g/g)

The uncertainty of this standard is calculated in accordance with the ISO Guide 34 and EURACHEM/CITAC Guide - Quantifying Uncertainty in Analytical Measurement, Second Edition. The expanded uncertainty is $U(\text{exp}) = u(\text{RM}) \times k$, where k is the coverage factor at the 95% confidence level ($k=2$). Uncertainty $u(\text{RM})$ is based on the combination of the uncertainties associated with each individual operation involved in the analysis of the product: $u(\text{RM}) = \sqrt{u(\text{char})^2 + u(\text{bb})^2 + u(\text{ts})^2 + u(\text{sts})^2}$; $u(\text{char})$ is the uncertainty of purity determination; $u(\text{bb})$ uncertainty of homogeneity test; $u(\text{ts})$ uncertainty of stability test long-term; $u(\text{sts})$ uncertainty of stability test short-term. $u(\text{ts})$ and $u(\text{sts})$ are not included in the calculation as the stability statement is based on real evidence opposed to simulation.

Minimum sample: 1 mg is recommended as the minimal sample amount. If less material is used, it is recommended to increase the certified uncertainty by a factor of two for half sample and a factor of four for a quarter of sample.

Intended use: Use this RM as calibrant for chromatography or any other analytical technique.

Analytical Data

Traceability of chromatography: To the International System of Units (SI).

Instrument: HPLC/DAD

Detection: DAD

Column: YMC-Pack ODS-AQ 3 mm 150 x 3 mm

Inj.-Vol.: 3.0 µl

Flow: 1.0 ml/min

Ret. Time: 4.34 min

Method Details

Eluent A: WA + 0.15% Formic acid

Eluent B: Acetonitrile

Time [min]	Eluent A [%]	Eluent B [%]
0	80	20
1	80	20
10	0	100
11	0	100
12	80	20

Comment

Traceability: The balances used are calibrated with weights traceable to the national standards (DKD).

Calibrated class A glassware is used for volumetric measurements.

Certificate Revision 1

Water Content: 1.79% (g/g) by Karl-Fischer-Titration ($U(\text{exp}) = 0.03\%$ (g/g)).

Identity: EA, NMR, RT, IR, UV, MS

Certified on: 05.12.2017

Certified by: N. Müller

The LGC Labor GmbH, accredited by DAkkS as indicated by the accreditation number D-RM-19883-01 & D-PL-19883-01, has shown competence based on ISO Guide 34:2009 with relevant parts of DIN EN ISO/IEC 17025:2005 for production of certified reference materials in form of organic pure substances and in form of single and multi-component solutions of organic pure substances.

Data file: 16908002-02.dx

Instrument: DAD3

Sequence Name: 09102017-YMC1a

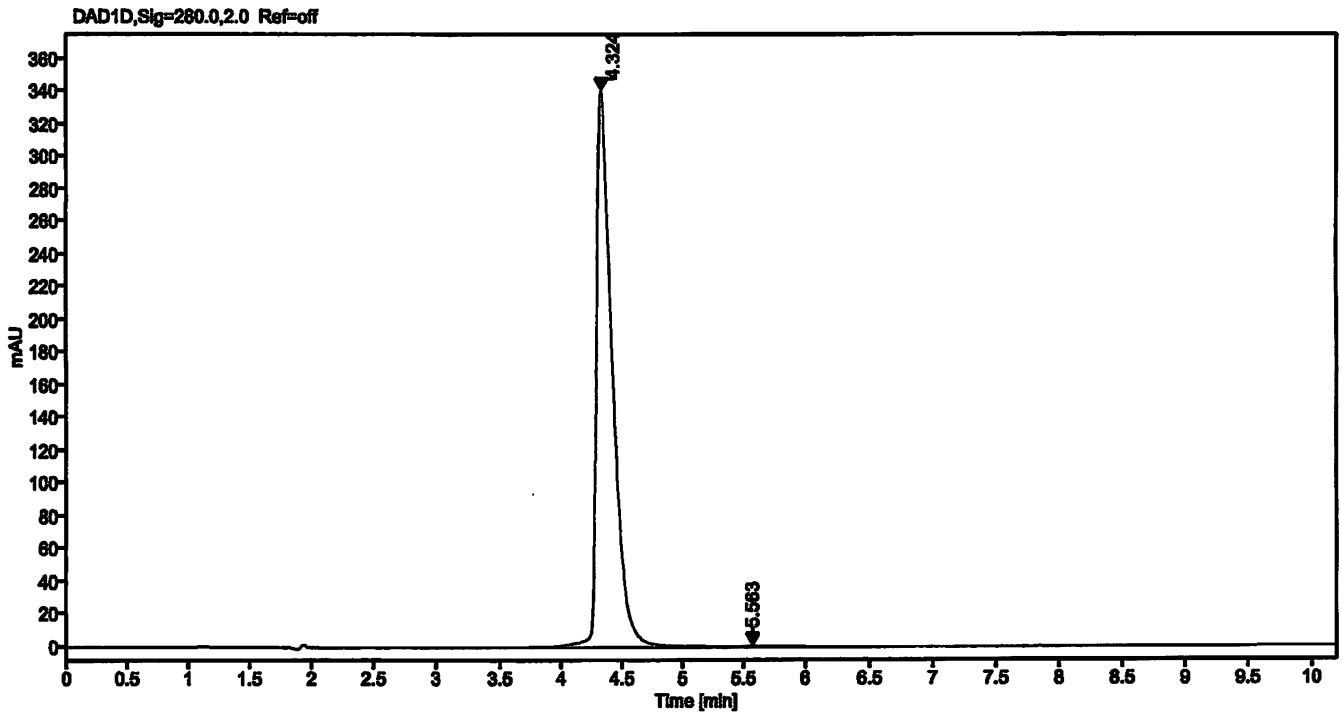
Inj. volume [μ l]: 3.0

Injection date: 10/9/2017 2:19:43 PM

Acq. method: Quinolone_Gradient_S2.amx

Location: 67

Sample Description Sarafloxacin D8 hydrochloride
Column: YMC-Pack ODS-AQ 3 mm 150 x 3 mm



Signal: DAD1D, Sig=280.0, 2.0 Ref=off

Nr.	RT [min]	Area	Height	Area%
1	4.324	3099.87043	341.14	99.56
2	5.563	8.80492	1.08	0.28
3	11.102	4.84158	1.03	0.16
	Sum	3113.52		