

# Certificate of Analysis

## ISO 17034 Reference Material

**EHRENSTORFER™**

### Product Identification

**Article Code:** DRE-C15400500  
**Article Name:** Nadifloxacin  
**Formula:** C<sub>19</sub>H<sub>21</sub>FN<sub>2</sub>O<sub>4</sub>  
**Mol. Weight:** 360.38  
**CAS No.:** 124858-35-1

**Lot Number:** G980111  
**Expiry Date:** 16.10.2022  
**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.

Purity: 97.59% (g/g)  
Expanded Uncertainty U= 0.30% (g/g)

The uncertainty of this standard is calculated in accordance with the ISO 17034 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:  $u(\text{RM}) = \sqrt{u(\text{char})^2 + u(\text{bb})^2 + u(\text{Its})^2 + u(\text{sts})^2}$ ;  $u(\text{char})$  is the uncertainty of characterisation;  $u(\text{bb})$  uncertainty of homogeneity test;  $u(\text{Its})$  uncertainty of stability test long-term;  $u(\text{sts})$  uncertainty of stability test short-term.  $u(\text{Its})$  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:	UHPLC/DAD	Method Details		
Detection:	DAD	Eluent A: WA + 0.5% H <sub>3</sub> PO <sub>4</sub>		
Column:	LUNA Omega C18 1.6 µm 100 x 2.1 mm	Eluent B: Acetonitrile		
Inj.-Vol.:	2 µl			
Flow:	0.5 ml/min	Time[min]	Eluent A [%]	Eluent B [%]
Ret.Time:	4.47 min	0	90	10
		0.3	90	10
		8	0	100
		9.5	0	100
		10	90	10

### Comment

Traceability: The balances used are calibrated with weights traceable to the national standards (DKD).  
Calibrated class A glassware is used for volumetric measurements.  
Water Content: 2.41% (g/g) by Karl-Fischer-Titration ( $U(\text{exp}) = 0.19\%$  (g/g)).  
Purity was determined by chromatographic assay, corrected by water content and/or residue solvents.  
Identity: EA, NMR, RT, IR, UV, MS  
Attachment: Exemplary chromatogram of given method  
Certificate Revision 1 - 16.10.2018 - M. Beck

Certified on: 16.10.2018  
Certified by: M. Beck  
RM Release

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 17034:2017 with relevant parts of DIN EN ISO/IEC 17025:2018 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.

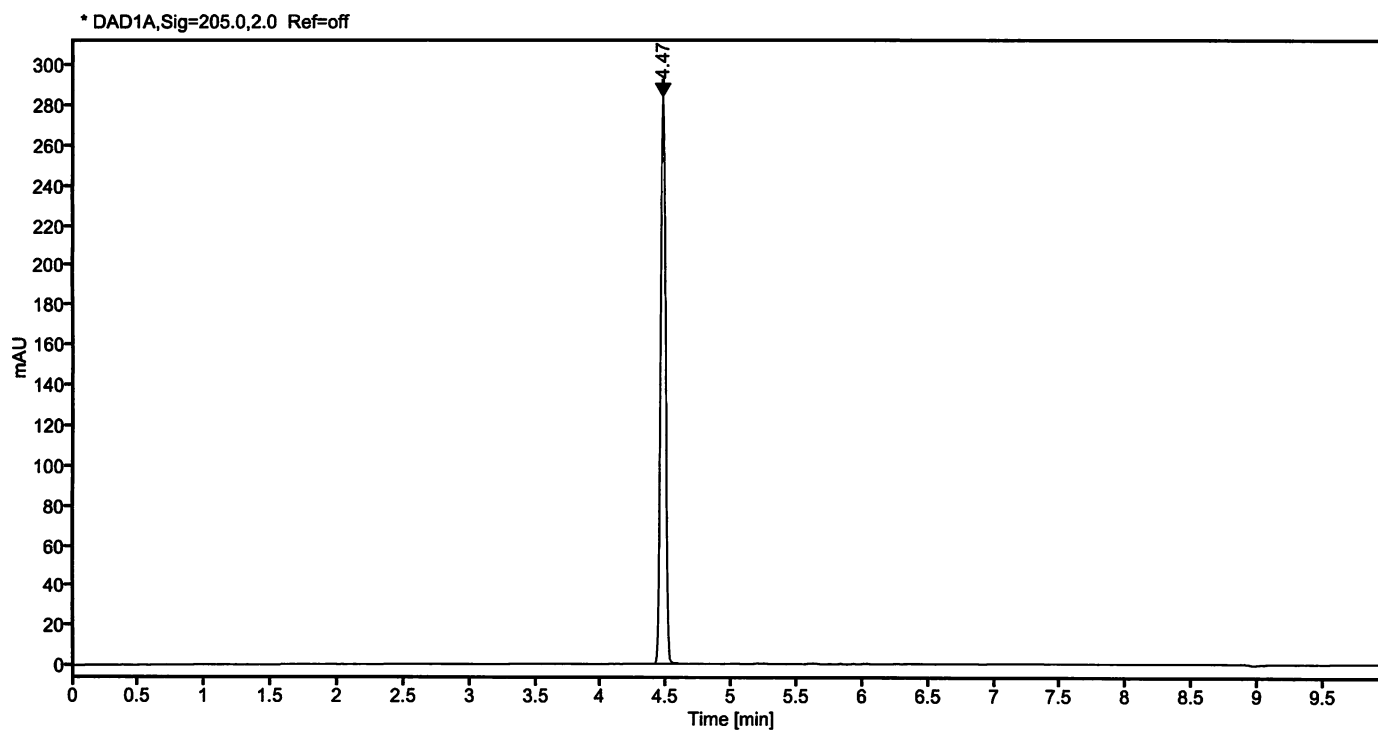
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Phone +49 821 906080 - Fax +49 821 9060888 - [augsburg.inquiry@lgcgroup.com](mailto:augsburg.inquiry@lgcgroup.com)  
The warranty for this product is limited to the purchasing price of this product.

11/09/2018

Data file: 15400500-03-r001.dx  
Sample name: 80907AL G980111  
Inj. volume [µl]: 2.0  
Acq. method: Gradient\_10-100\_P.amx

Instrument: UHPLC 2  
Sequence Name: 10092018-1  
Injection date: 9/10/2018 2:41:02 PM  
Location: P1-B3

Sample Description Nadifloxacin



Signal: \* DAD1A,Sig=205.0,2.0 Ref=off

Nr.	RT [min]	Area	Height	Area%
1	4.47	755.57205	282.86	100.00
	Sum	755.57		

*A. Beh*