

Certificate of Analysis

ISO 9001

Reference Material

Product name

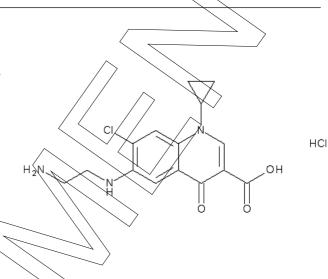
6-(2-Aminoethylamino)-7-chloro-1-cyclopropyl-4-oxo-1,4-dihy droquinoline-3-carboxylic Acid Hydrochloride

Product code Lot number MM0018.10 1021916

CAS number Appearance 528851-30-1 yellow solid

Molecular weight Melting point (DSC)

358.22 305 °C



Assay "as is" **91.6** %

Date of shipment: 02 Sep 2019

Producer confirms that this reference material (RM) meets the specification detailed on this Certificate of Analysis for **two years** from the date of shipment, provided the substance is stored under the recommended conditions unopened in the original container.

Release by: Date of Release:	0	
Dr. Sabine Schröder Luckenwalde, 05 Aug 2019	Toia	Product Release



Product information

For laboratory use only. Not suitable for human or animal consumption.

Before usage of the RM, it should be allowed to warm to room temperature. No drying required, as the certified value is already corrected for the content of water and other volatile materials.

The product quality is controlled by regularly performed quality control tests (retests).

Further content

Identity

Assay

Final result

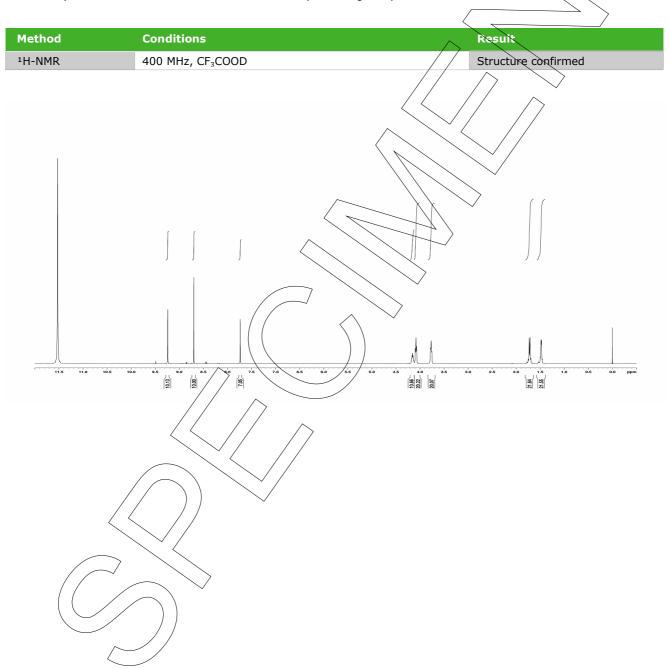
Revision table

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Identity

The identity of the reference material was established by following analyses.



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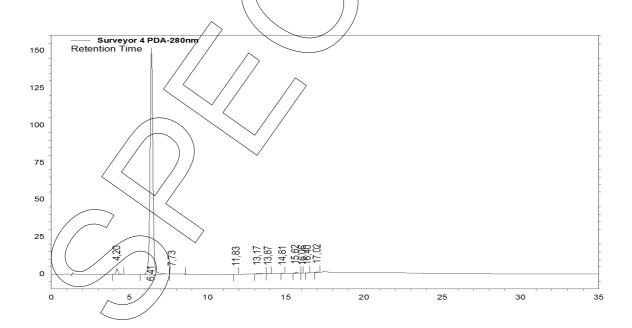
Assay

The assay of the reference material was assessed by following analyses.

Purity by High Performance Liquid Chromatography (HPLC)

HPLC Conditions:	
Column	LiChrospher 60/RP-select B; 5 µm, 125 x 4.0 mm
Column temperature	40 °C
Detector	DAD, 280 nm
Injector	Auto 3 µl; 0.042 mg/ml in Acetonitrile/Water 50/50 (v/v)
Flow rate	1.0 ml/min
Phase A	Water, 0.1 % H ₃ RO ₄
Phase B	Acetonitrile, 0.1 % H ₃ PO ₄
Gradient program	0-7 min A/B 85/15
	7-15 min A/B to 50/50
	15-20 min A/B 50/50
	20-25 min A/B to 85/15
	25-35 min A/B 85/15 (v/v)

HPLC chromatogram and peak table



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Area percent report - sorted by signal				
Pk #	Retention time	Area	Area %	
1	4.20	32336	1.64	
2	6.41	1910180	97,06	
3	7.73	3872	0,20	
4	11.83	698	0.04	
5	13.17	6097	0.31	
6	13.87	1170	0.06	
7	14.81	497	0.03	
8	15.62	7608	0.39	
9	16.06	316	0.02	
10	16.40	106	0.06	
11	17.02	4097	0.21	
Totals		1967977	100.00	

The content of the analyte was determined as ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %. System peaks were ignored in calculation.

Result (n = 6)

97.05 %; SD = 0.10 %

Volatile content

Water content	
Method	Karl Fischer titration
Result (n = 3)	5.64 %; SD = 0.03 %

LGC GmbH, Louis-Pasteur-Str. 30, D-14943 Luckenwalde, Germany



Residual solvents			
Method	¹ H-NMR		
Result (n = 1)	No significant amounts of residual solvents were dete	ected (< 0.0	5 %).

Final result

Assay "as is": 91.58 %

The assay "as is" is assessed by 100% method (mass balance) and is equivalent to the assay based on the not anhydrous and not dried substance respectively.

The calculation of the 100% method follows the formula:

Assay (%) = (100 % - volatile contents (%))

Purity (%) 100 %

Volatile contents are considered as absolute contributions and purity is considered as relative contribution. Inorganic residues are excluded by additional tests.

Revision table

Revision	Date	Reason for revision
00	05 Aug 2019	Release of the Certificate of Analysis - initial version

Product warranties for the RM are set out in the terms and conditions of purchase.

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