

Certificate of Analysis

ISO 9001

Reference Material

Product name

1-(Pentanoylamino)-N-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]met hyl]cyclopentanecarboxamide

Product code
MM0862.01-0025

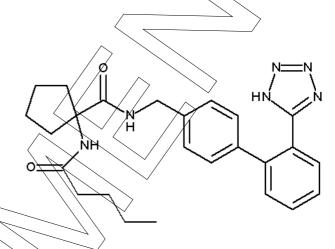
CAS number
748812-53-5

Molecular weight

Lot number
1030139

Appearance
off-white solid
Melting point

446.54 178 °C



Assay "as is" **97.8** %

Date of shipment:

13 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, 20 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

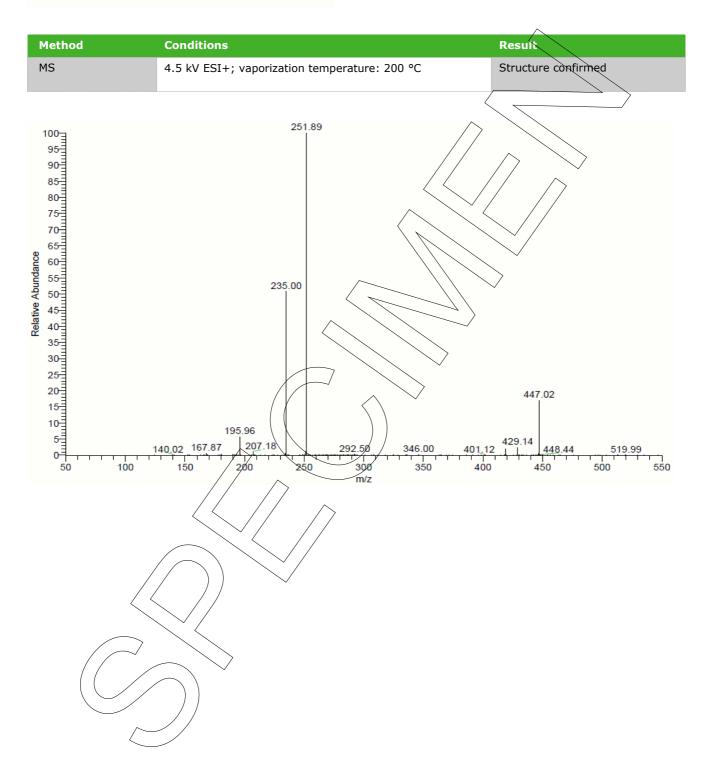


Identity

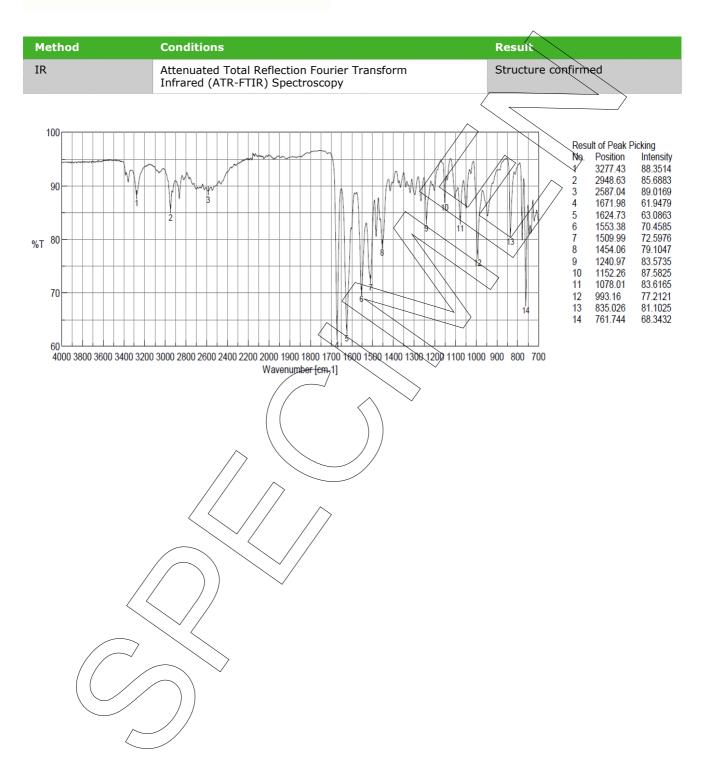
The identity of the reference material was established by following analyses.













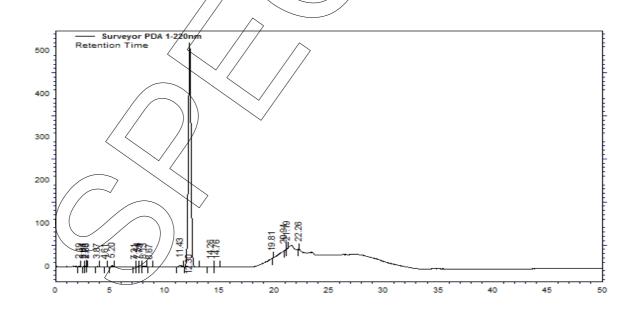
Assay

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

Purity by High Performance Liquid Chromatography (HPLC)

HPLC Conditions:	
Column	Hypersil Gold C/18, 5 μm, 150 x 4.6 mm
Column temperature	40 °C
Detector	DAD, 220 nm
Injector	Auto 4.00 µl; 0.170 mg/ml in Acetonitrile/Water 50/50 (v/v)
Flow rate	1.0 ml/min
Phase A	Water, 0.1 % H ₃ PO ₄
Phase B	Acetonitrile, 0.1 % H ₃ PO ₄
Gradient program	0-15 min A/B 67/33
	15-20 min A/B to 20/80
	20-25 min A/B 20/80
	25-30 min A/B to 67/33
	30-50 min A/B 67/33 (v/v)

HPLC chromatogram and peak table



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Area percent repor	t - sorted by signal		
Pk #	Retention time	Area	Area %
1	2.19	873	0.01
2	2.61	571	0.01
3	2.76	1236	0.01
4	2.86	1124	0.01
5	3.87	2540	0.03
6	4.61	1265	0.01
7	5.20	17722	0.20
8	7.31	2026	0.02
9	7.54	5577	0.06
10	7.73	7727	0.03
11	8.13	24868	0.28
12	8.67	2162	0.02
13	11.43	598 08	0.68
14	12.30	8613682	98.22
15	14.26	/12971	0.15
16	14.76	7017	0.08
17	19.81	2549	0.03
18	20.91	1728	0.02
19	21.19	6274	0.07
20	22:26	3115	0.04
Totals		8769835	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)

98.22 %; SD = 0.02 %

Volatile content

Water content		/		\rangle		>
Method	Karl Fischer titration		/	/	\wedge	
Result (n = 3)	0.41 %; SD = 0.02 %		\searrow			

Residual solvents		
Method	¹H-NMR	
Result (n = 1)	Sum: 0.06 %	
	0.06 % Methanol	

Final result

Assay "as is": 97.76 %

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:

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

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

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Revision table

Revision	Date	Reason for revision
00	20 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.