

Certificate of Analysis



Organisation certified to ISO 9001 | DQS 102448 and GMP (EXCIPACTTM)

Producer: LGC GmbH Louis-Pasteur-Str. 30 D-14943 Luckenwalde Germany www.lgcstandards.com Page 1/7



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

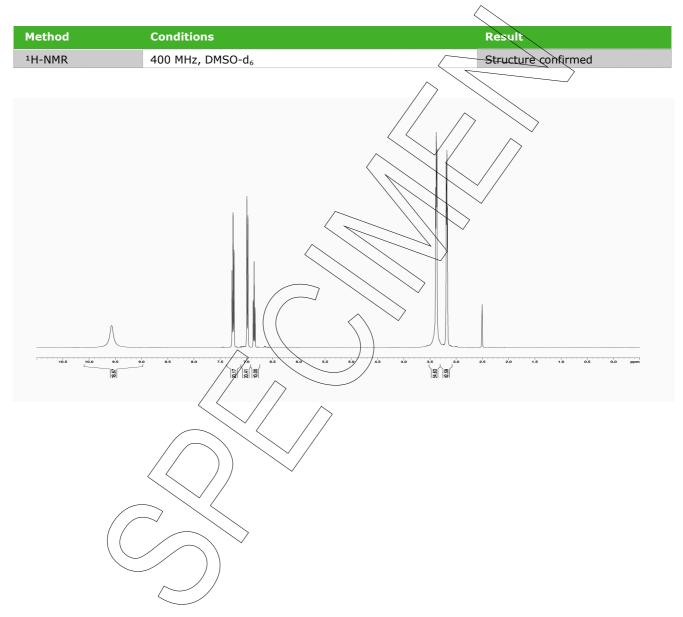
Identity Assay Final result

Revision table

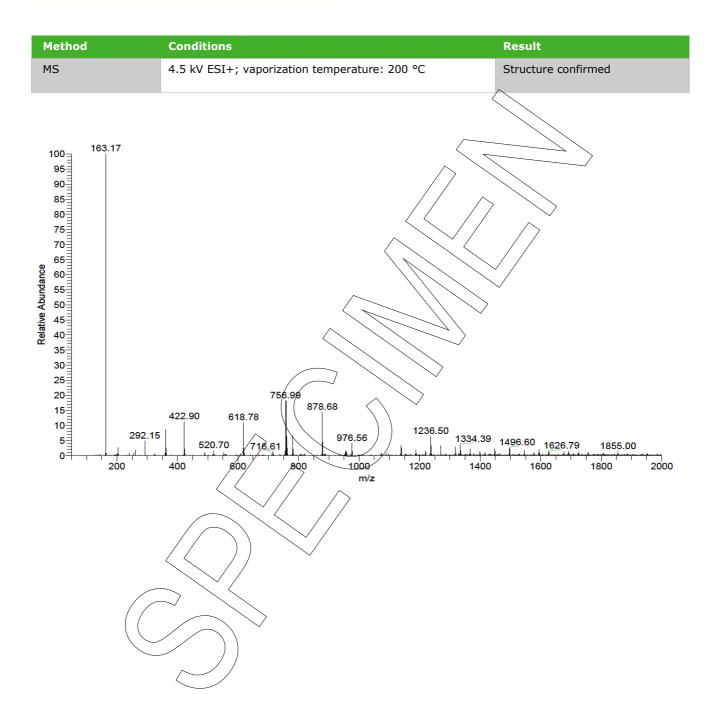


Identity

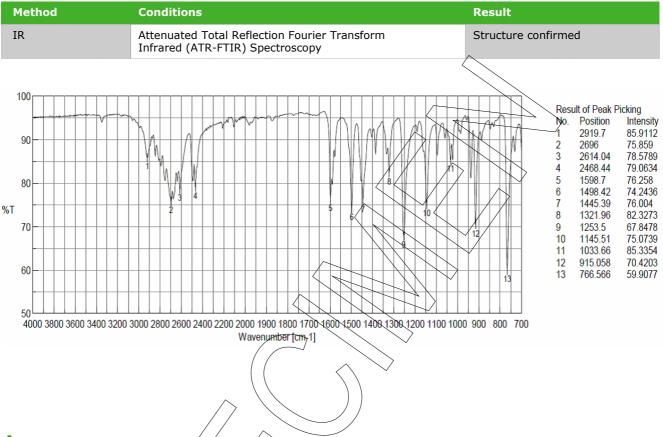
The identity of the reference material was established by following analyses.











Assay

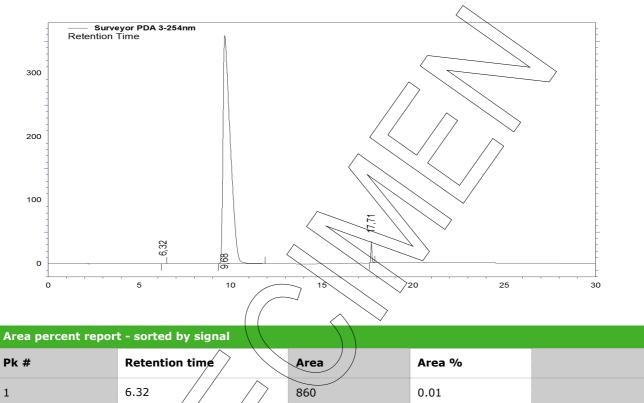
The assay of the reference material was assessed by following analyses.

Purity by High Performance Liquid Chromatography (HPLC)

HPLC Conditions:				
Column	Hypersil Gold C18; 5 µm, 150 x 4.6 mm			
Column temperature	40 °C			
Detector	DAD, 254 nm			
Injector	Auto 5 µl; 0.422 mg/ml in Water			
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	0-10 min A/B 95/5			
	10-15 min A/B to 60/40			
	15-20 min A/B 60/40			
	20-25 min A/B to 95/5			
	25-30 min A/B 95/5 (v/v)			



HPLC chromatogram and peak table



2	9.68	9875134	98.57
3	17.71	142050	1.42
Totals		10018044	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)

1

98.57 %; SD < 0.01 %



Volatile content

Water content		~
Method	Karl Fischer titration	
Result (n = 3)	0.05 %; SD = 0.01 %	

Residual solvents	\land	
Method	¹ H-NMR	
Result (n = 1)	No significant amounts of residual solvents were d	letected (0.05 %).</th

Final result

Assay "as is": 98.52 %

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:

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

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



RevisionDateReason for revision0016 Nov 2021Release of the Certificate of Analysis - initial version

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