

Certificate of Analysis

ISO 9001

Reference Material

Product name

N-Formylfluoxetine

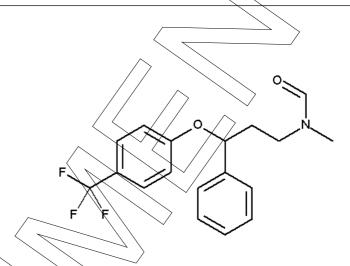
Product code Lot number MM0256.16 1030518 CAS number Appearance

Molecular weight

199188-97-1

337.34

colourless liquid



Assay "as is" **99.6** %

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:	Soia	
Dr. Sabine Schröder Luckenwalde, 26 Aug 2019		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

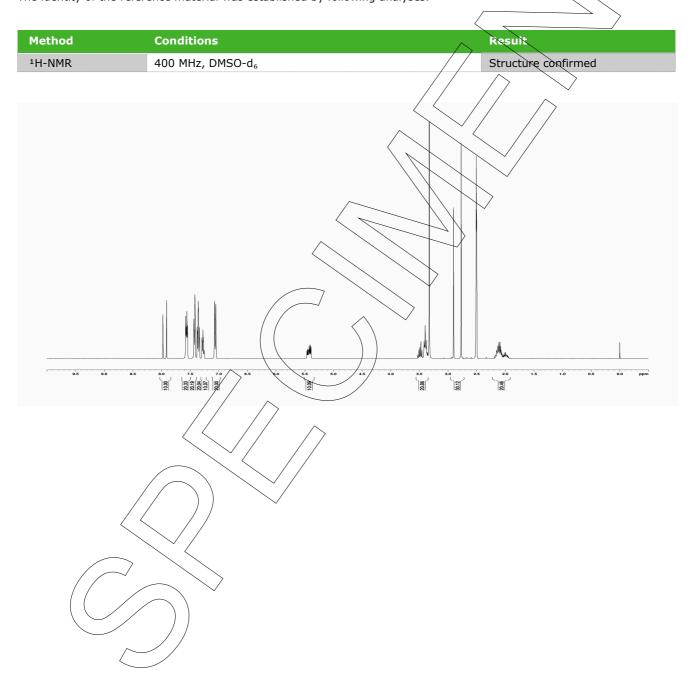
Final result

Revision table



Identity

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





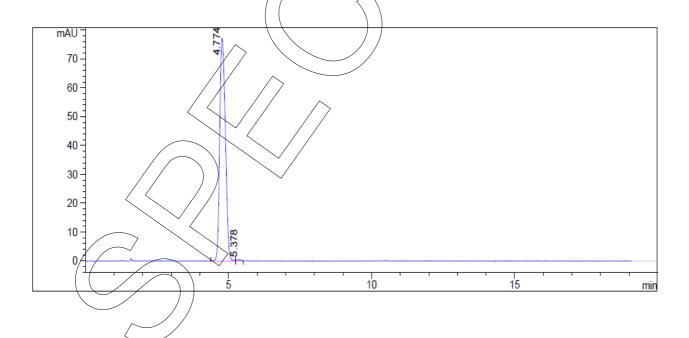
Assay

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

Purity by High Performance Liquid Chromatography (HPLC)

HPLC Conditions:	
Column	LiChrospher 60/RP-select Β; 5 μm, 125 x 4.0 mm
Column temperature	40 °C
Detector	DAD, 235 nm
Injector	Auto 5.00 μl; 0.220 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	A/B-50/50 (v/v)





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Area percent report - sorted by signal			
Pk #	Retention time	Area	Area %
1	4.77	1060.26	99.64
2	5.38	3.87	0.36
Totals		1064.13	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)	99.67 %; SD = 0.07 %	

Volatile content

Water content	
Method	Karl Fischer titration
Result (n = 3)	0.06 %; \$D = 0.01 %

Residual solvents	
Method	/¹H-NMR
Result (n = 1)	No significant amounts of residual solvents were detected (< 0.05 %).



Final result

Assay "as is":

99.61 %

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:

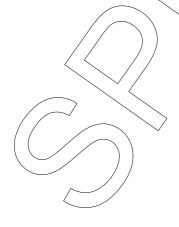
Assay (%) = (100 % - volatile contents (%)) *
$$\frac{\text{Purity (\%)}}{100 \%}$$

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	26 Aug 2019	Release	of the Certifical	te c	of Analysis - initial version

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



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