



Mikromol™



Certificate of Analysis

ISO 9001

Reference Material

Product name

7 α -[9-[(4,4,5,5,5-Pentafluoropentyl)sulfonyl]nonyl]estra-1,3,5
(10)-triene-3,17 β -diol (Fulvestrant Sulfone)

Product code

MM3296.01-0025

CAS number

98008-06-1

Molecular weight

622.77

Molecular formula

C₃₂H₄₇F₅O₄S

Lot number

1030367

Appearance

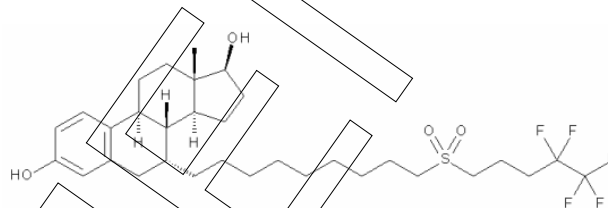
white solid

Melting point

117 °C

Long-term storage

2 to 8 °C, dark



Assay "as is"
95.2 %

Date of shipment:

13 Sep 2019

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

Release by:	Date of Release:		Product Release
Dr. Sabine Schröder	Luckenwalde, 03 Sep 2019		



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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

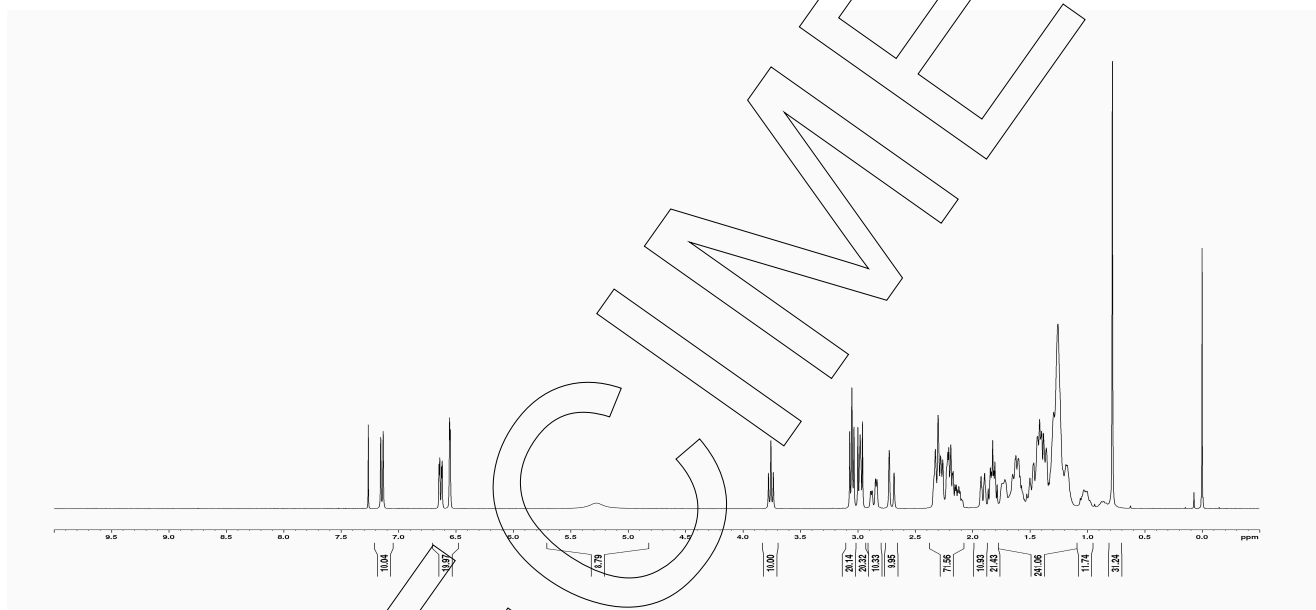
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Identity

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

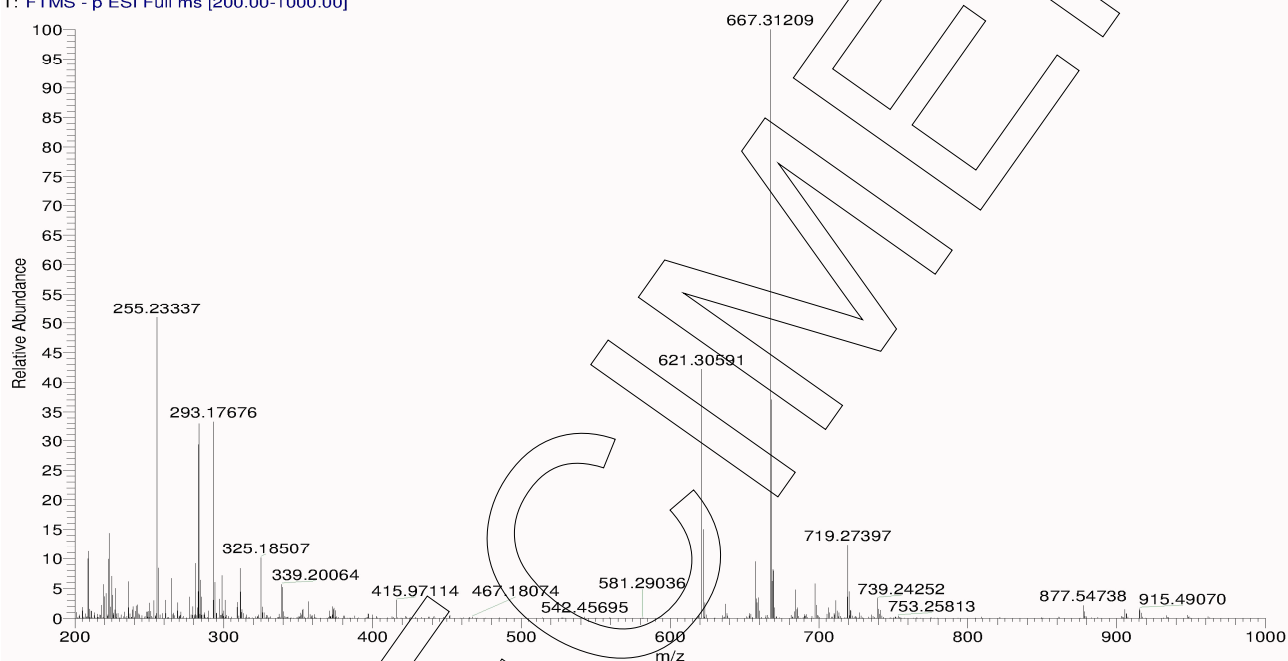
Method	Conditions	Result
¹ H-NMR	400 MHz, CDCl ₃	Structure confirmed





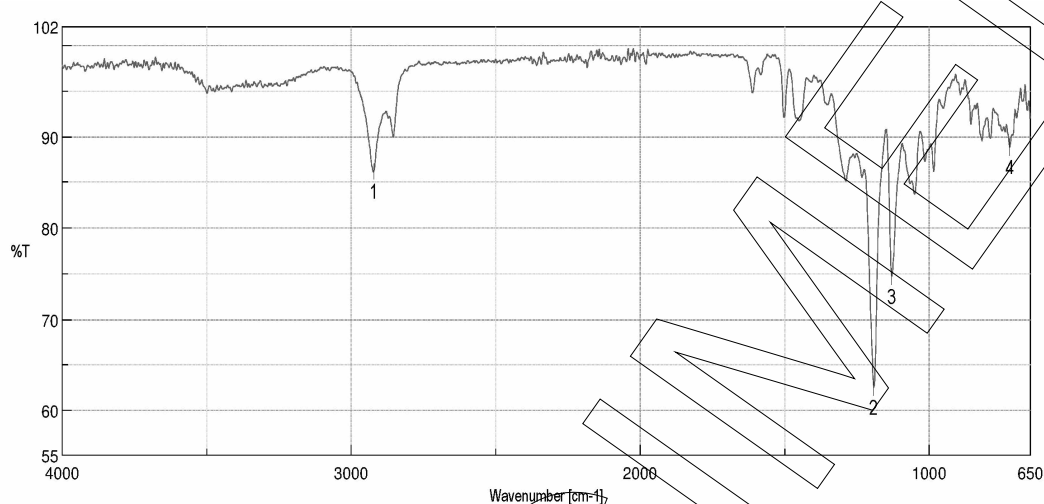
Method	Conditions	Result
MS	3.2 kV ESI-; capillary temperature: 269 °C Theoretical value: 621.30424	Structure confirmed

43190 #1-222 RT: 0.00-1.00 AV: 222 NL: 1.78E6
T: FTMS - p ESI Full ms [200.00-1000.00]





Method	Conditions	Result
IR	Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy	Structure confirmed



Results of Peak Find

No.	Position	Intensity
1	2922.59	86.1408
2	1191.79	62.5004
3	1129.12	74.6658
4	721.247	88.8648



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, 210 nm
Injector	Auto 2.00 µl; 0.202 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 min A/B 98/2 0-20 min A/B to 3/97 20-22 min A/B 3/97 22-25 min A/B to 98/2 25-30 min A/B 98/2 (v/v)

HPLC chromatogram and peak table





Area percent report - sorted by signal			
Pk #	Retention time	Area	Area %
1	17.973	28.4124	97.60
2	19.803	0.0806	0.28
3	19.997	0.1512	0.52
4	22.263	0.4674	1.61
Totals		29.1116	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 = 3)	97.59 %; SD = 0.02 %
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Volatile content

Water content	
Method	Karl Fischer titration
Result (n = 3)	0.82 %; SD = 0.03 %

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



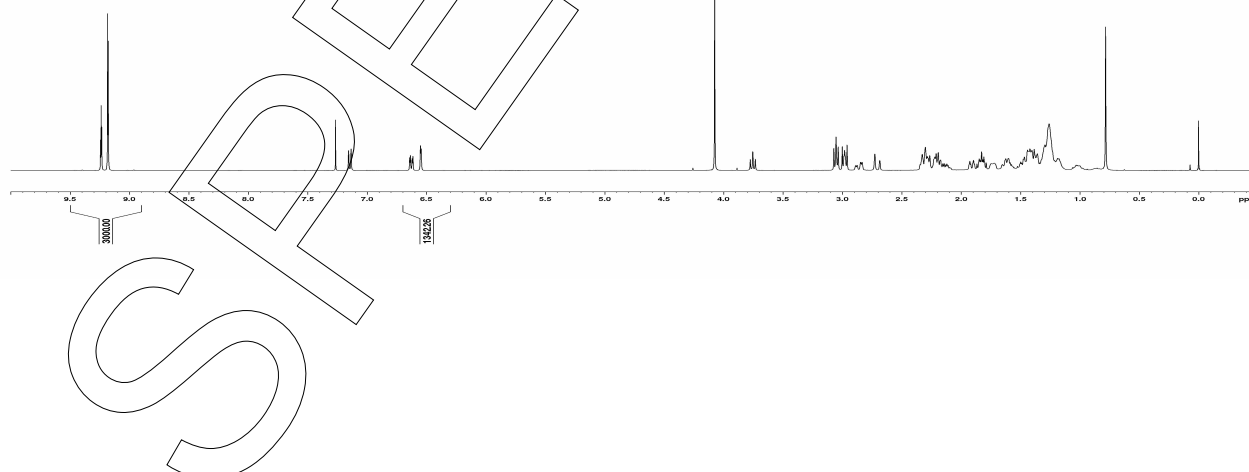
Final result

Assay "as is": **95.22 %**

The assay "as is" is assessed by quantitative NMR spectroscopy and is equivalent to the assay based on the not anhydrous and not dried substance respectively.

Method: Value assigning technique - quantitative NMR spectroscopy	
Conditions	400 MHz, CDCl ₃
Internal standard	Methyl 3,5-dinitrobenzoate (certified reference material), signal 8.9 - 9.5 ppm, 3 H
Result (mass fraction, n = 3)	95.22 %; SD = 0.02 %

Quantitative NMR spectrum





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Revision table

Revision	Date	Reason for revision
00	03 Sep 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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