



Certificate of Analysis

ISO 9001

Reference Material

Product name

Losartan Methyl Ether

Product code

MM0168.12-0025

CAS number

114798-94-6

Molecular weight

436.94

Molecular formula

C₂₃H₂₅ClN₆O

Lot number

1127806

Appearance

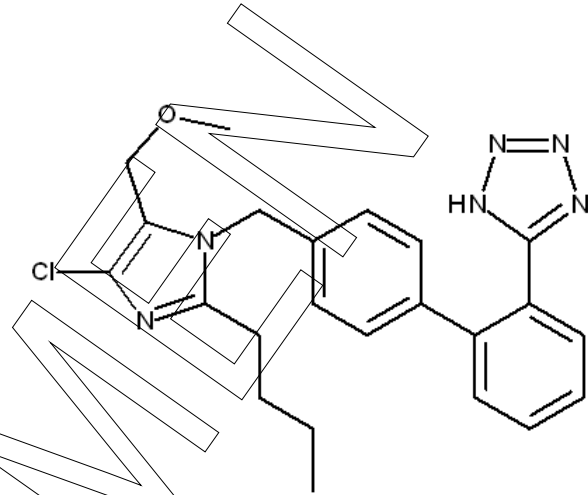
light yellow solid

Melting point (DSC)

163 °C

Long-term storage

2 to 8 °C, dark



Assay "as is"
97.0 %

Date of shipment:

05 Nov 2021

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:		Product Release
Dr. Sabine Schröder	Luckenwalde, 09 Sep 2021		



Mikromol™

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

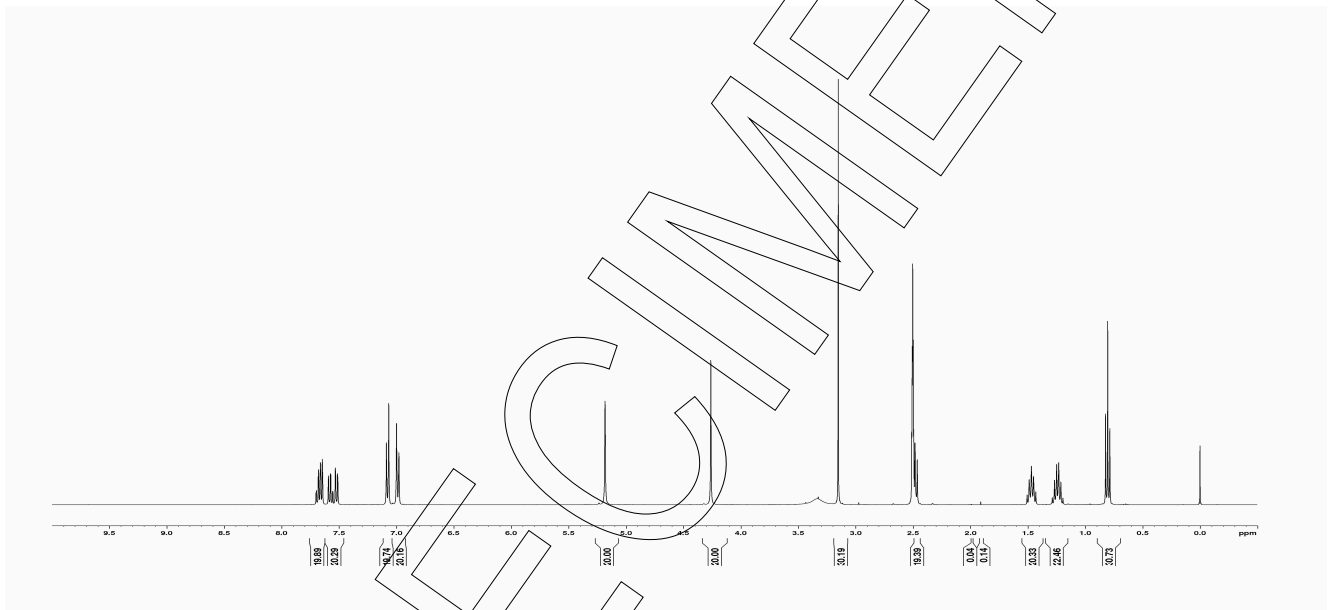
SPECIMEN



Identity

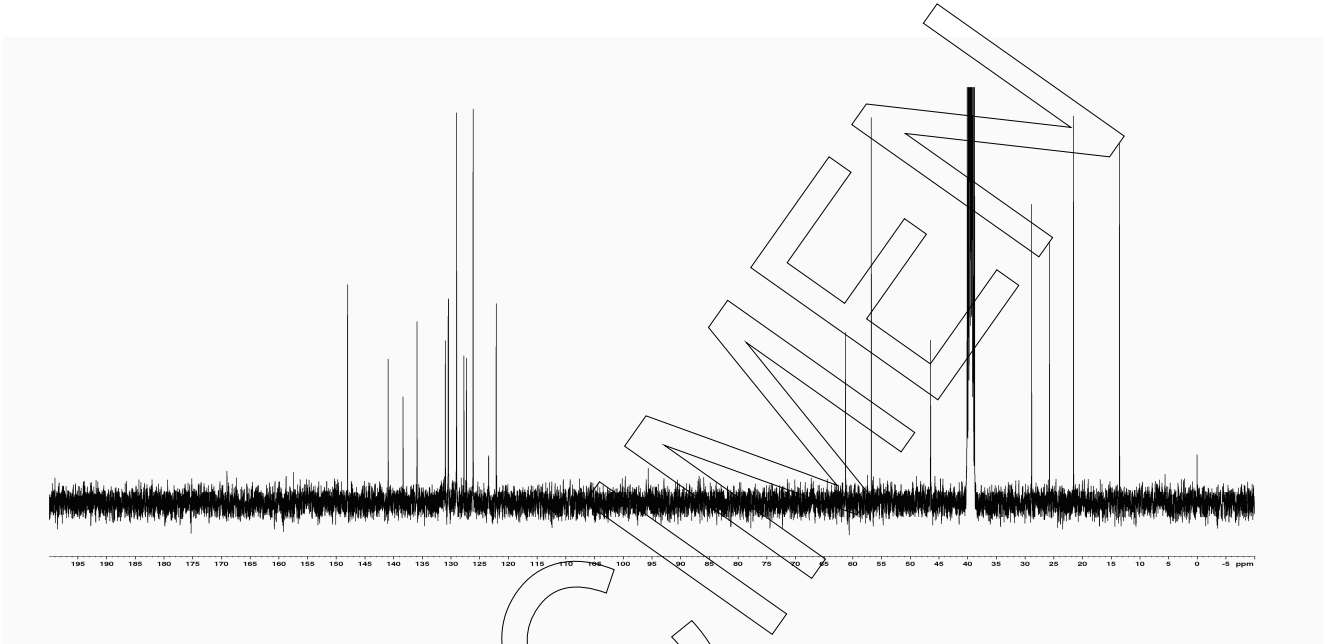
The identity of the reference material was established by following analyses.

Method	Conditions	Result
¹ H-NMR	400 MHz, DMSO-d ₆	Structure confirmed





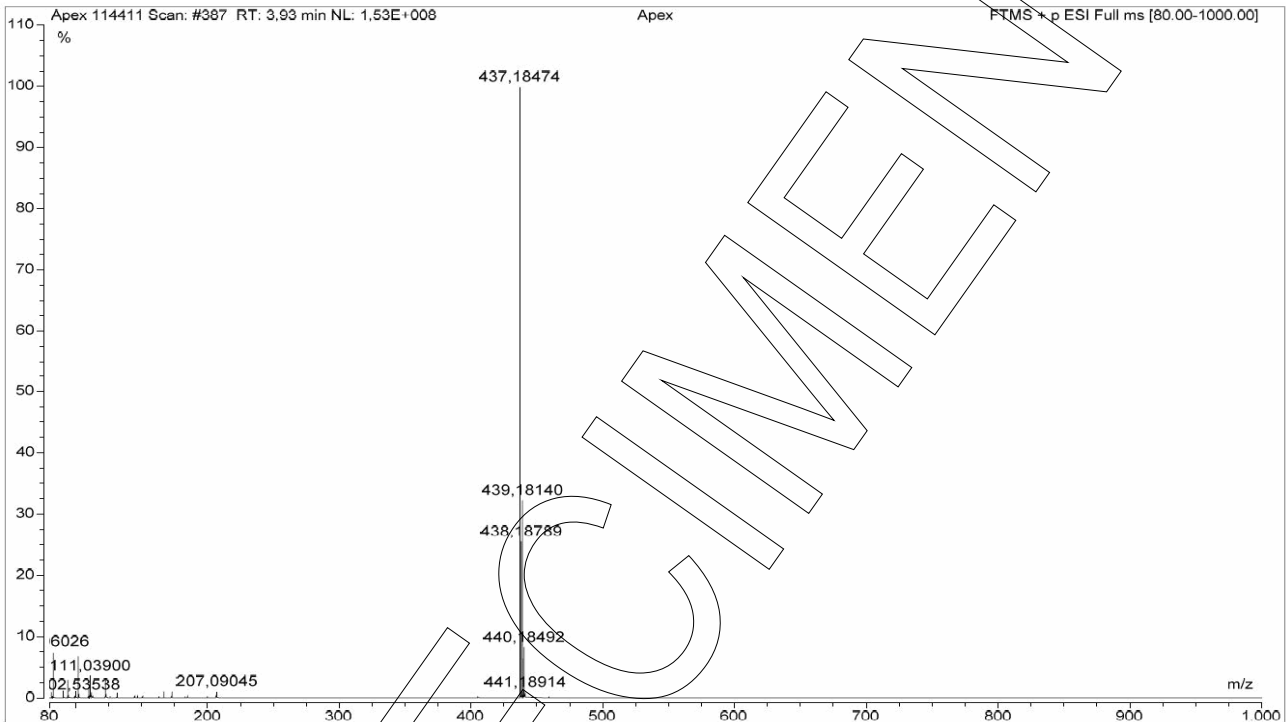
Method	Conditions	Result
¹³ C-NMR	100 MHz, DMSO-d ₆	Structure confirmed



SPECIMEN



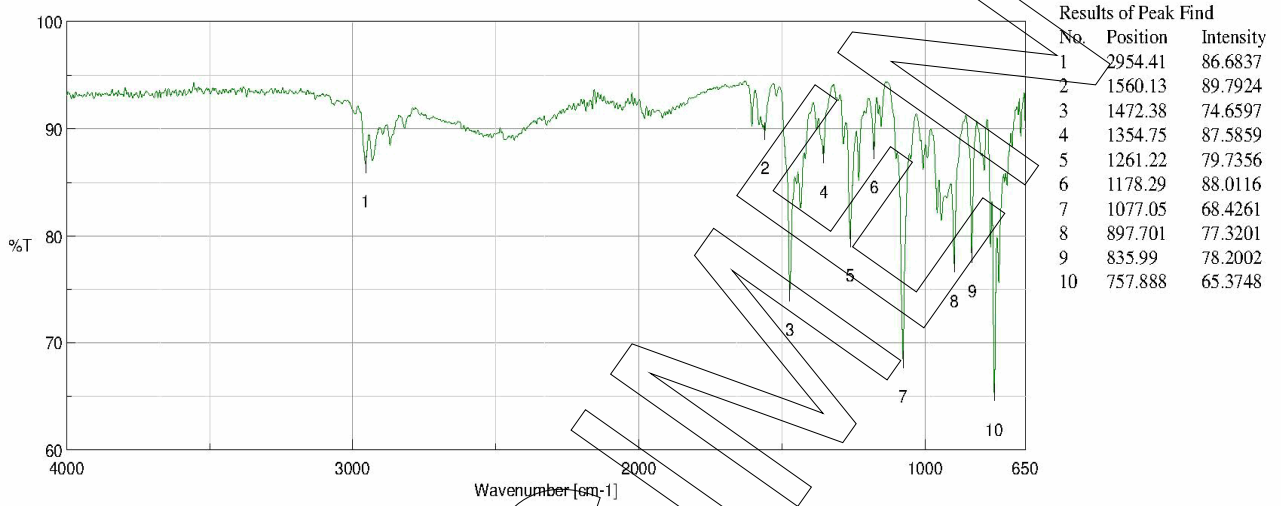
Method	Conditions	Result
MS	3.5 kV ESI+; capillary temperature: 269 °C Theoretical value: 437.18511	Structure confirmed



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



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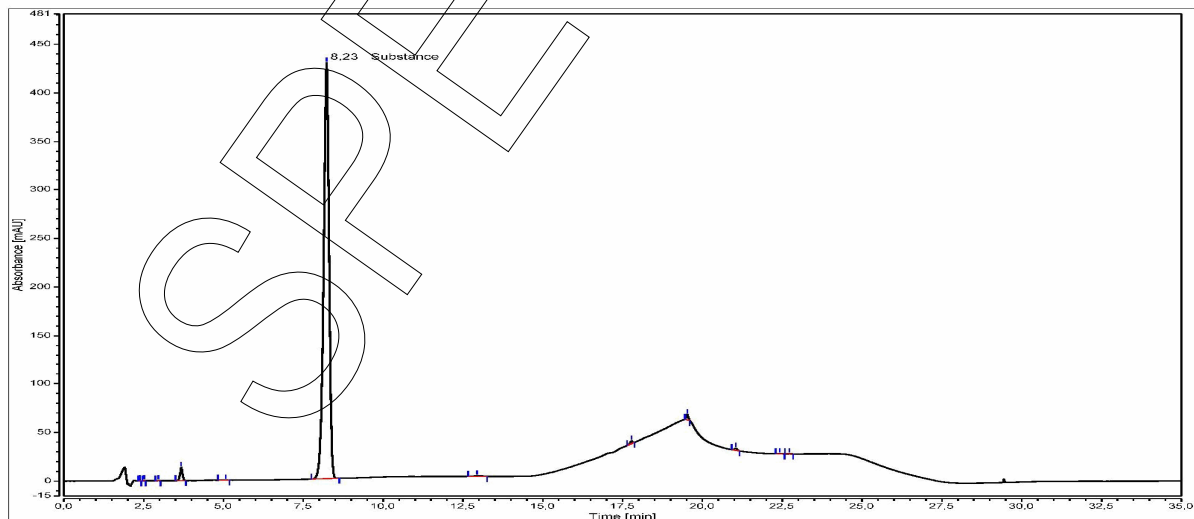
Assay

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

Purity by high performance liquid chromatography (HPLC)

HPLC Conditions:	
Column	Hypersil Gold C18; 5 μ m, 150 x 4.6 mm
Column temperature	40 °C
Detector	DAD, 210 nm
Injector	Auto 3 μ l; 0.0564 mg/ml in Methanol
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	0-12 min A/B 60/40 12-17 min A/B to 30/70 17-22 min A/B 30/70 22-25 min A/B to 60/40 25-35 min A/B 60/40 (v/v)

HPLC chromatogram and peak table





Area percent report - sorted by signal

Pk #	Retention time	Area	Area %
1	2.375	0.0053	0.01
2	2.512	0.0070	0.01
3	2.960	0.0142	0.02
4	3.677	1.1775	1.36
5	5.068	0.0461	0.05
6	8.227	84.4628	97.23
7	12.942	0.2186	0.25
8	17.782	0.2659	0.31
9	19.525	0.4048	0.47
10	21.038	0.2089	0.24
11	22.415	0.0377	0.04
12	22.728	0.0177	0.02
Totals		86.8665	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)

97.22 %; SD = 0.01 %

Volatile content

Water content

Method

Karl Fischer titration

Result (n = 3)

0.10 %; SD = 0.03 %



Residual solvents

Method	¹ H-NMR
Result (n = 1)	Sum: 0.10 % 0.07 % Acetic acid; 0.03 % Ethyl acetate

Final result

Assay "as is": 97.03 %

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:

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

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	09 Sep 2021	Release of the Certificate of Analysis - initial version

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