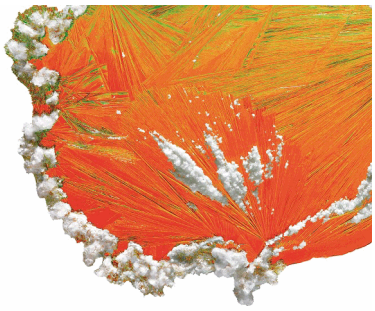


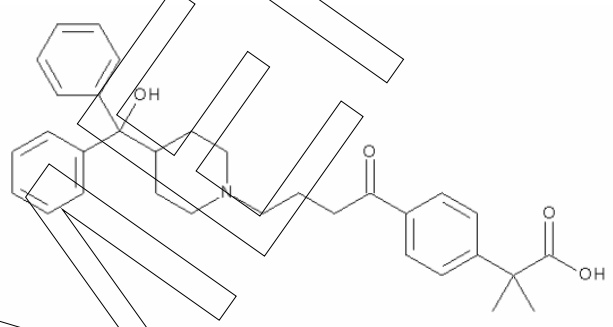
Certificate of Analysis

ISO 9001

Reference Material

Product name

2-[4-[4-[4-(Hydroxydiphenylmethyl)piperidin-1-yl]butanoyl]phenyl]-2-methylpropanoic Acid (Ketofexofenadine)



Product code
MM0507.01

Lot number
1025351

CAS number
76811-98-8

Appearance
white solid

Molecular weight
499.64

Melting point
189 °C (dec)

Molecular formula
$C_{32}H_{37}NO_4$

Long-term storage
2 to 8 °C, dark
hygroscopic

Assay "as is"
94.5 %

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:**		
Dr. Sabine Schröder	Luckenwalde, 04 Sep 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).

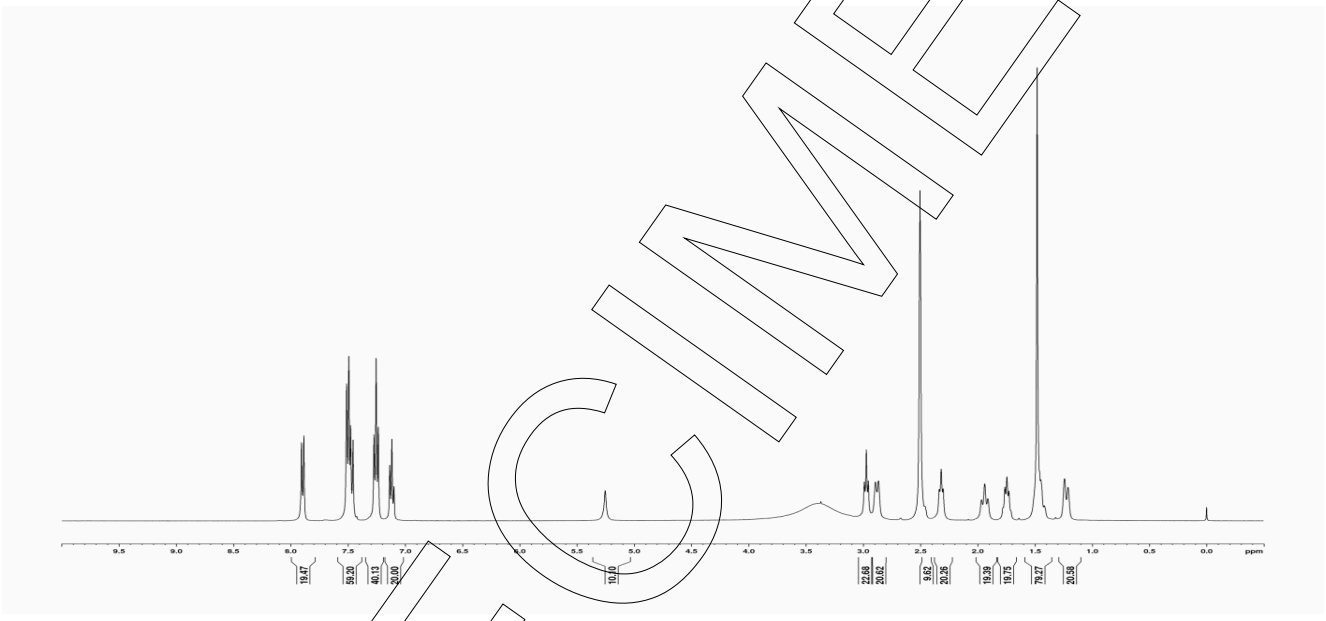
Further content

Identity
Assay
Final result
Revision table

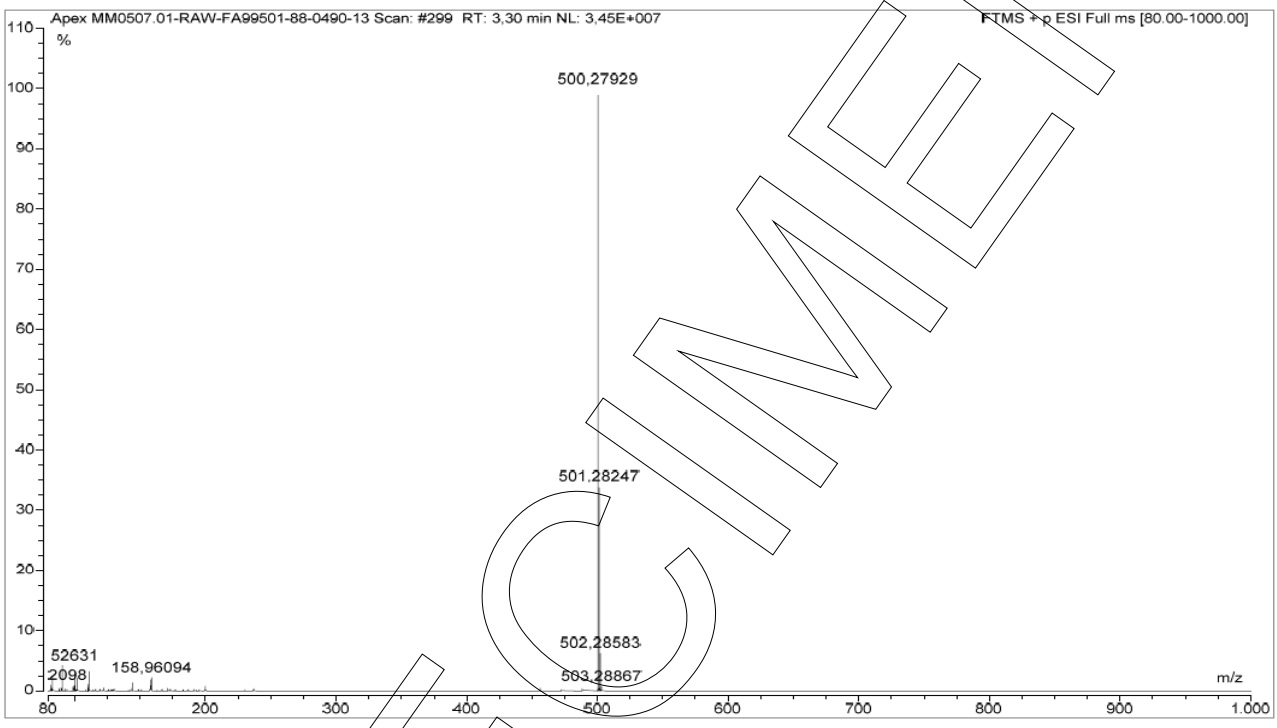
Identity

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

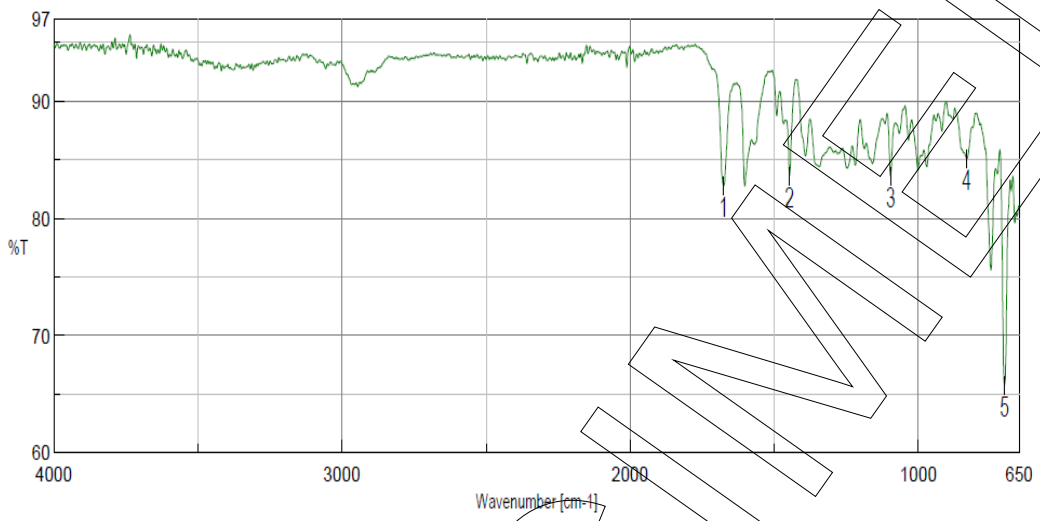
Method	Conditions	Result
^{1}H-NMR	400 MHz, DMSO-d_6	Structure confirmed



Method	Conditions	Result
MS	3.5 kV ESI+; capillary temperature: 269 °C Theoretical value: 500.27954	Structure confirmed



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



Results of Peak Find

No.	Position	Intensity
1	1675.84	82.7373
2	1446.35	83.5772
3	1096.33	83.5637
4	831.169	85.0682
5	700.998	65.7094

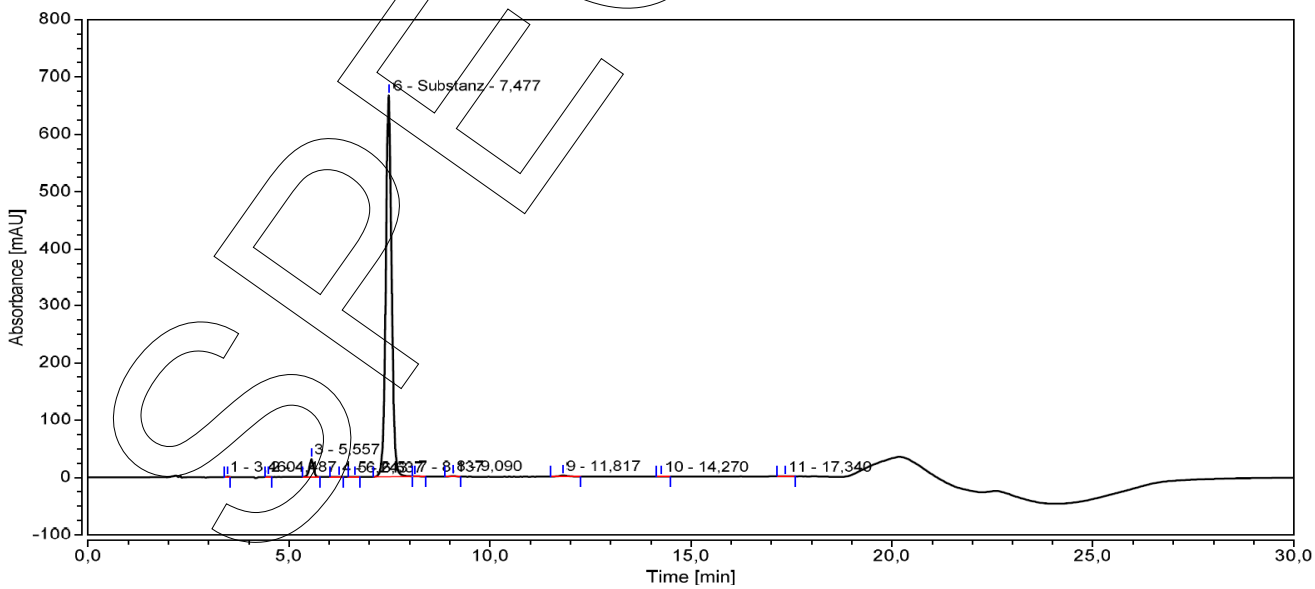
Assay

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

Purity by High Performance Liquid Chromatography (HPLC)

HPLC Conditions:	
Column	ZORBAX Phenyl; 5 µm, 250 x 4.6 mm
Column temperature	22 °C
Detector	DAD, 220 nm
Injector	Auto 5.00 µl; 0.218 mg/ml in mob. phase A without 3 ml Triethylamine
Flow rate	1.0 ml/min
Phase A	6.64 g/l NaH2PO4 + 0.84 g/l NaClO4; pH 2 / Acetonitrile 50/50 (v/v) + 3 ml Triethylamine
Phase B	Acetonitrile
Gradient program	0-15 min A/B 100/0 15-17 min A/B to 50/50 17-19 min A/B 50/50 19-21 min A/B to 100/0 21-30 min A/B 100/0 (v/v)

HPLC chromatogram and peak table



Area percent report - sorted by signal			
Pk #	**Retention time**	**Area**	**Area %**
1	3.460	0.061	0.05
2	4.487	0.038	0.03
3	5.557	3.680	3.14
4	6.243	0.023	0.02
5	6.637	0.020	0.02
6	7.477	112.334	95.84
7	8.137	0.141	0.12
8	9.090	0.236	0.20
9	11.817	0.597	0.51
10	14.270	0.031	0.03
11	17.340	0.047	0.04
Totals		**117.208**	**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)	95.85 %; SD = 0.03 %

Volatile content

Water content	
Method	Karl Fischer titration
Result (n = 3)	1.46 %; SD = 0.13 %

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

Final result

Assay "as is": **94.45 %**

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	04 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.