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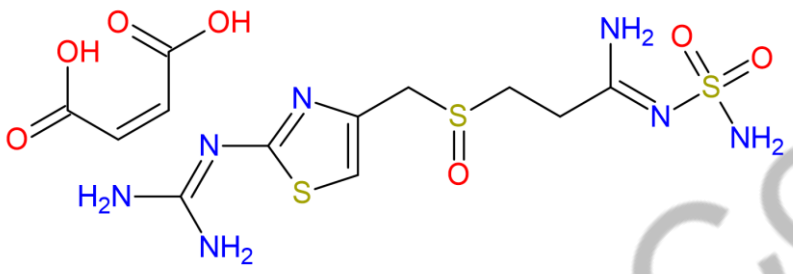
Reference Material Product Information Sheet



Name	Famotidine sulfoxide maleate
Epichem Item #	EPL-AA129 Batch 2
CAS #	109467-06-3
Molecular Formula	$C_8H_{15}N_7O_3S_3$. $C_4H_4O_4$
Molecular Weight	469.52 g/mol
Appearance	Off-white powder
Melting Point	171.0 - 177.7 °C (decomposition)
Combustion Analysis	Required (%): C: 30.7, H: 4.1, N: 20.9 Found (%): C: 29.3, H: 4.3, N: 19.8
Purity	92.8%
Date of Manufacture	8 April 2015
Storage Requirements	Protect from heat, light and moisture.
Special Precautions	**This compound is for laboratory use only. Its toxicological properties may not have been fully established. It should be handled only by suitably qualified personnel.**
Intended Use	This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
Date of Shipment	TBA
	This certificate is valid for one year from the date of shipment provided the substance is unopened and stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

Epichemistry Pty Limited, Suite 11, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
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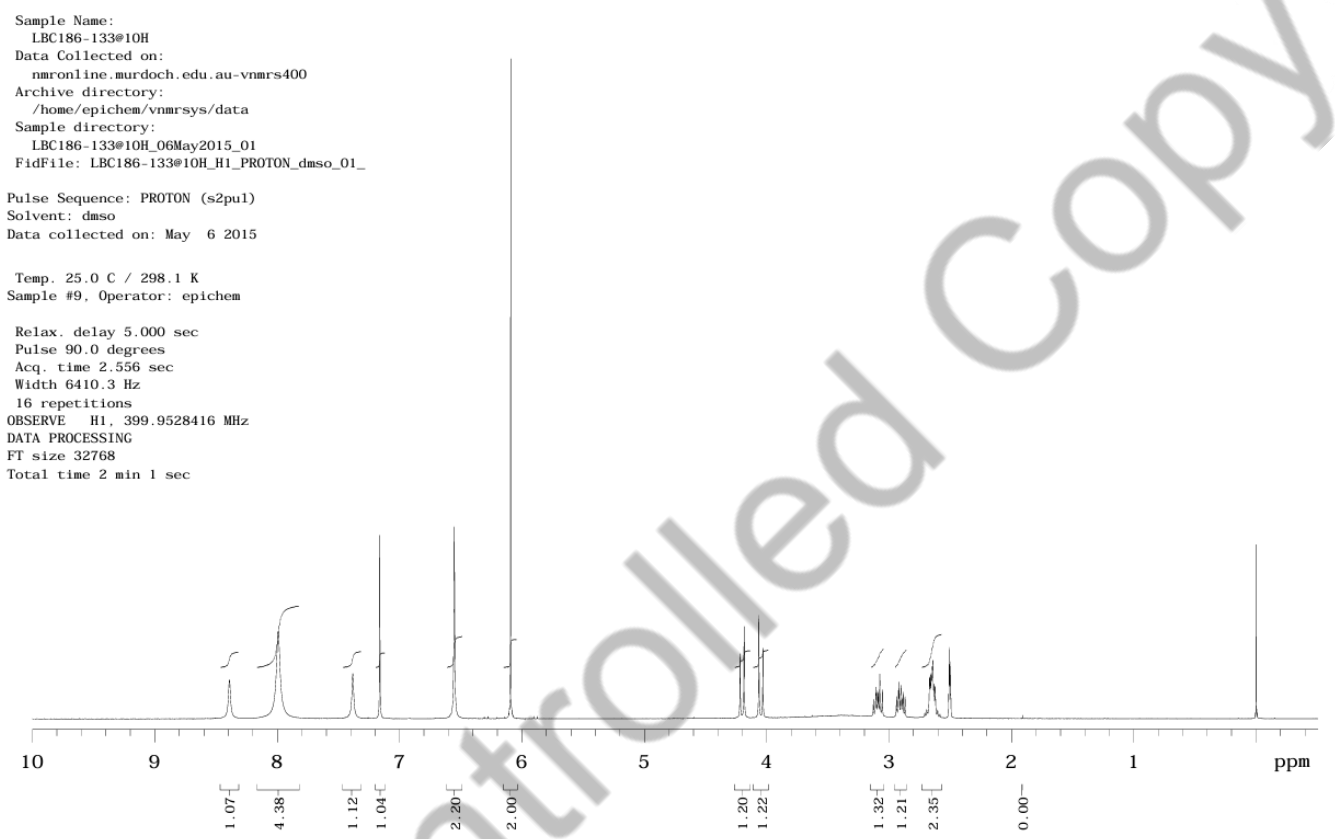
I. Identity

The identity of this product was established using the following analyses:

Ia. ^{1}HNMR Spectrum

Conditions: 400 MHz, DMSO-d_6

^{1}HNMR spectrum consistent with chemical structure.



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Ib. Mass Spectrum

The mass spectrum of this material was analysed by Liquid Chromatography Mass Spectroscopy (LCMS) using in-house EM005.WI08.

Method: ACN/water gradient (+ 0.1% formic acid).

Poroshell 120 EC-C18, 4.6 x 30 mm, 3.5 micron

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0.445        457965        376.05 I
                           356.10 I
                           355.10 I
                           354.20 I
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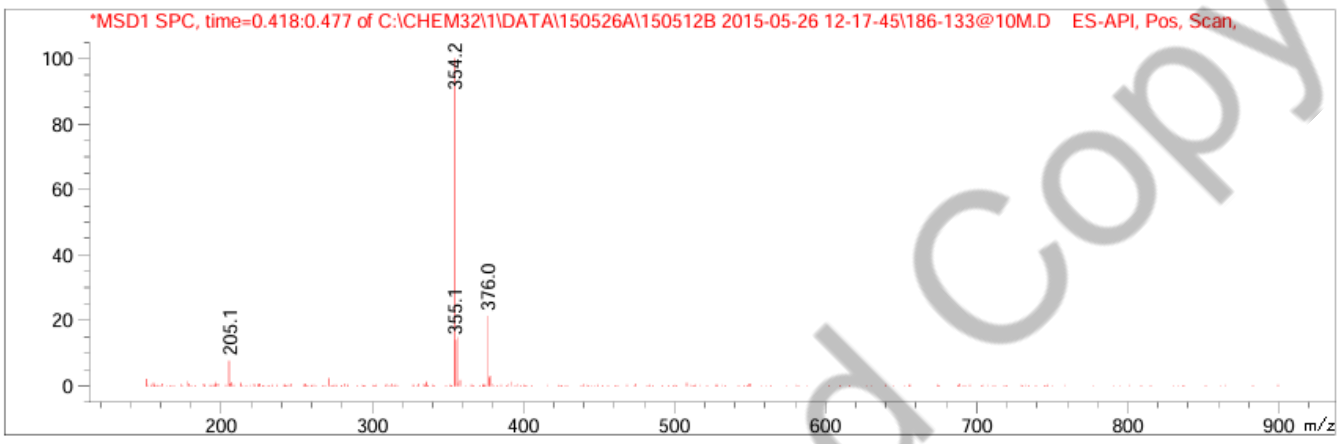
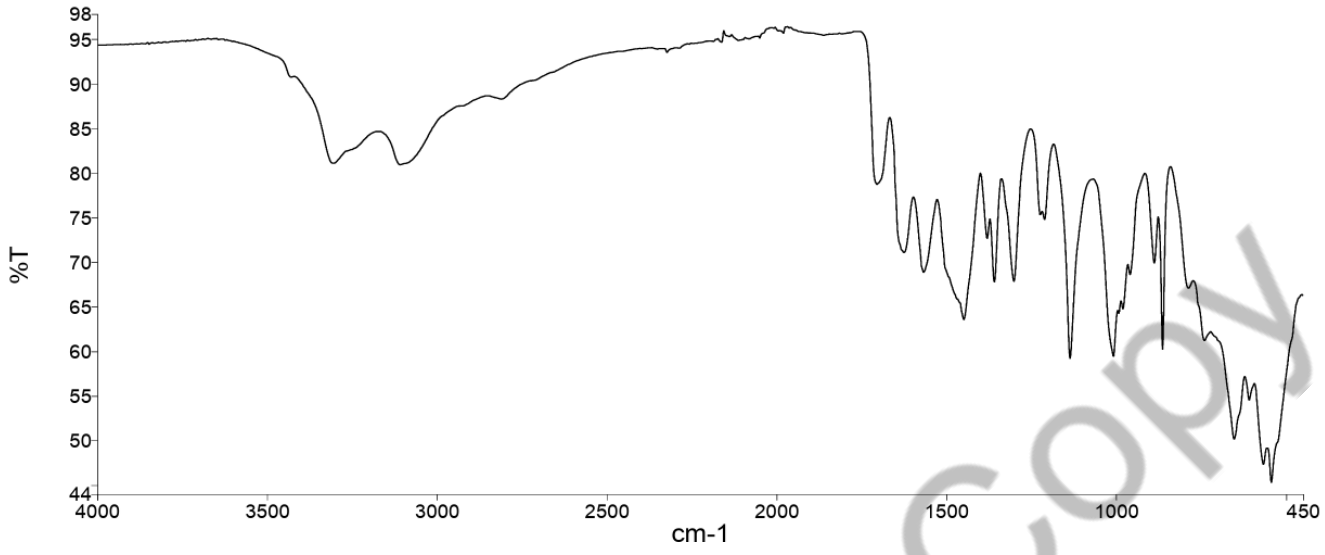


Theoretical value: 354.0 $[M+H]^+$

The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform Infrared Spectroscopy (FTIR) using in-house EM005.WI09.



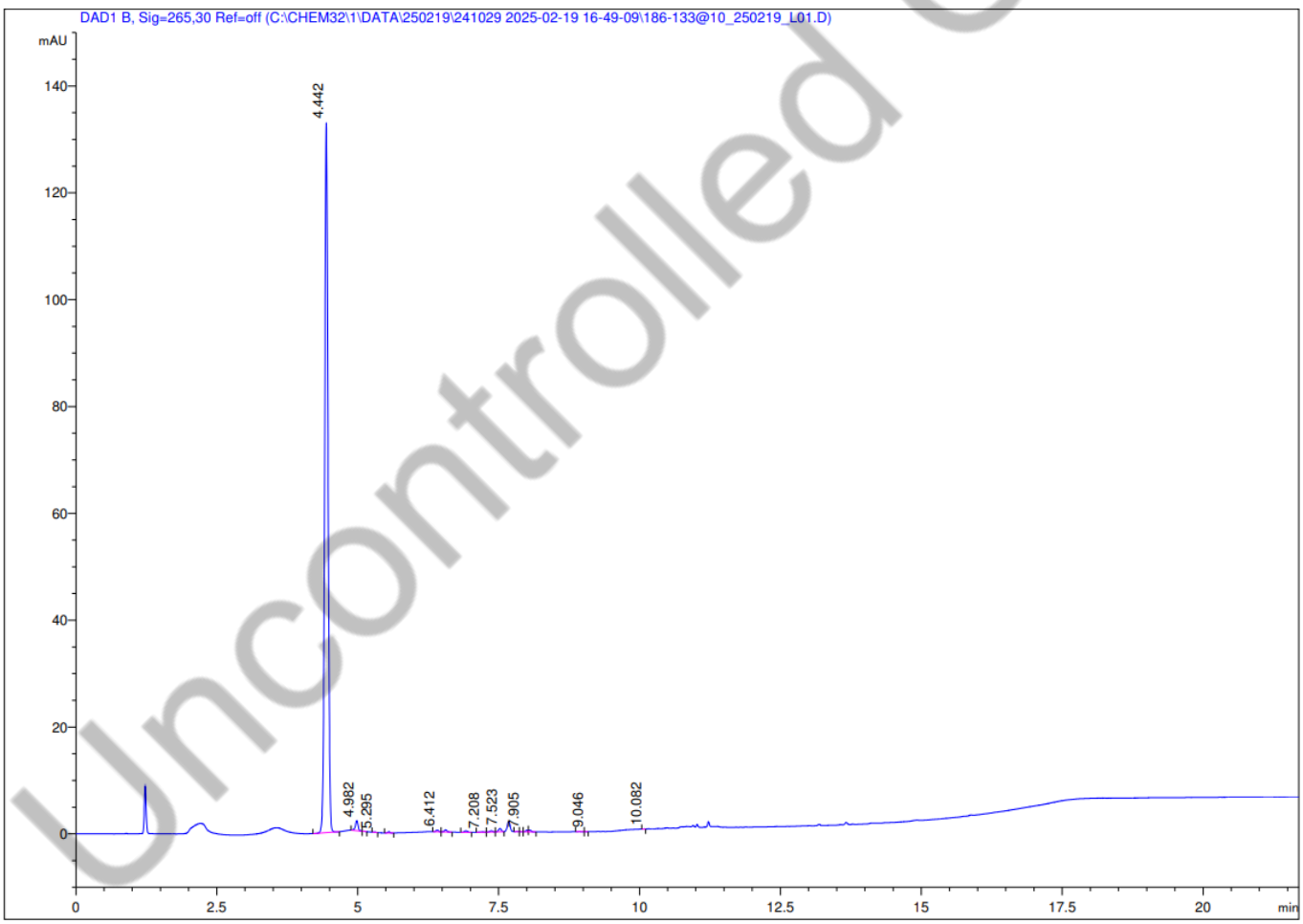
The interpretation of the signals of the Fourier Transform Infrared Spectrum is consistent with the structural formula.

II. Purity

The purity of this material was analysed by high performance liquid chromatography (HPLC) using in-house EM005.WI07.

HPLC Conditions:

Column	Conditions				Detector	Injector
Agilent Poroshell 120 EC-C18 4.6 x 50mm 3 micron	25ºC				DAD 265 nm	Auto 1.0 µL 0.35 mg/mL in 100% water (NO MODIFIERS)
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
	0.00	99.5	0.5	1.0		
	8.00	87.5	12.5	1.0		
	16.25	5	95	1.0		
	21.25	5	95	1.0		
	22.25	99.5	0.5	1.0		
	28.25	99.5	0.5	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.44	548.24	97.24
2	4.98	6.10	1.08
3	5.11	0.12	0.02
4	5.30	0.14	0.03
5	5.55	0.49	0.09
6	6.41	0.97	0.17
7	6.56	1.28	0.23
8	6.92	1.02	0.18
9	7.21	0.30	0.05
10	7.37	0.84	0.15
11	7.52	2.14	0.38
12	7.84	0.09	0.02
13	7.91	0.04	0.01
14	8.01	0.89	0.16
15	8.05	0.88	0.16
16	8.93	0.15	0.03
17	9.05	0.04	0.01
18	10.08	0.03	0.01
Total			100 (rounded)

For the calculation the system peaks were ignored. The content of the analyte was determined as a ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100%.

Results:

Average 97.2% (average of duplicate analyses)

III. Water Content

Method: Karl-Fischer titration using in-house EM005.WI04.

Results:

Average 4.5%

IV. Ash Content

Method: Current BP (Appendix XI J, Method II); Current Ph Eur (2.4.16)

Results:

Contains <0.1% ash

V. Residual Solvents

Method: ^{1}HNMR

Result:

No significant impurities detected by ^{1}H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	97.2%
Water content	4.5%
Ash content	<0.1%
Residual solvents	<0.1%
Purity	92.8%

This purity is assessed to be 92.8%.

Product Reviewed By:

Sandy San Carlos
Associate Chemist

Product Released By:

James Rixson, PhD
General Manager

Release Date: 26th February 2025

The calculation of the purity follows the formula:

$$\text{Purity}(\%) = \frac{((\text{Chromatographicpurity[HPLC]})x(100 - (\text{watercontent} + \text{ashcontent} + \text{volatilecontents})))}{100}$$