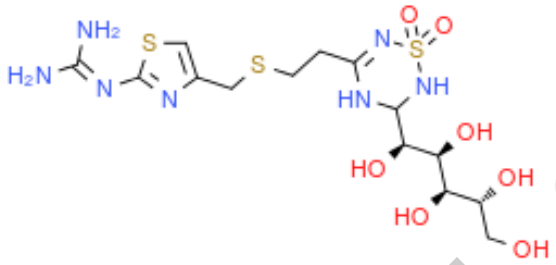
Our Formula. Your Success.

Reference Material Product Information Sheet

Epichem's Quality System conforms to ISO9001:2015 as certified by ECAAS Pty Ltd - Certification number 616061.



Name	Famotidine glucose adduct
BP/EP Name	Not applicable.
USP Name	Not applicable.
Synonym(s)	Not applicable.
Epichem Item #	EPL-AA288 Batch 1
CAS #	Not available.
Molecular Formula	$C_{14}H_{25}N_7O_7S_3$
Molecular Weight	499.59 g/mol
Appearance	Pale-yellow powder
Melting Point	89.5-128.5°C (decomposition)
Combustion Analysis	Required (%): C:33.7; H:5.0; N:19.6. Found (%): C:32.6; H:5.2; N:18.7.
Purity	86.0%
Date of Manufacture	30 September 2022
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)

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

I. Identity

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

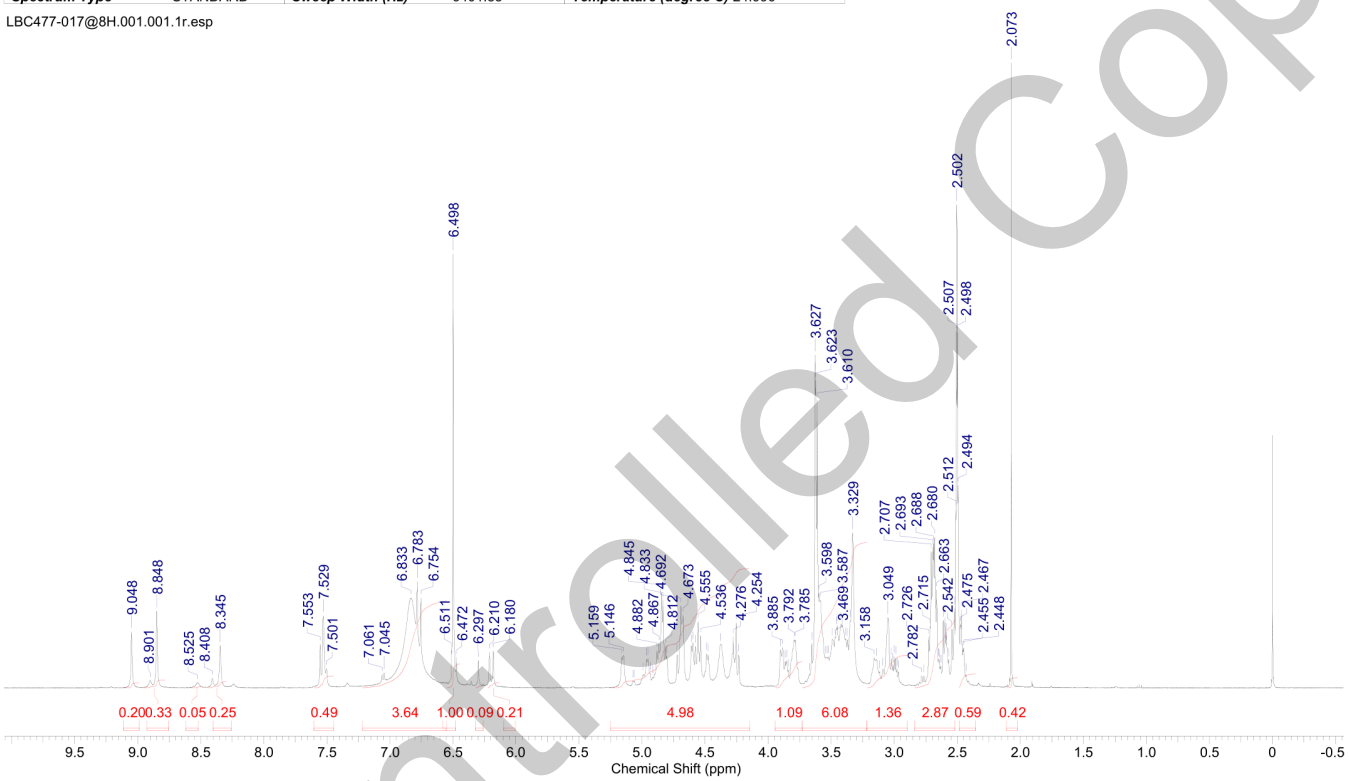
Ia. [1]HNMR Spectrum

Conditions: 400 MHz, DMSO-d_6

[1]H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	***Comment***	LBC477-017@8H 1H DMSO {E:\dataexternal\epichem} cygoh 4			***Date***	07 Sep 2022 17:46:40
Date Stamp	07 Sep 2022 17:46:40			***File Name***	\\NAPHTHALENE\Company\NMR files\LBC477\LBC477-017@8H\1\pdata\1\1r		
Frequency (MHz)	400.13	***Nucleus***	1H	***Number of Transients***	8	***Origin***	spect
Original Points Count	24038	***Owner***	nmr	***Points Count***	32768	***Pulse Sequence***	zg
Receiver Gain	114.00	***SW(cyclical) (Hz)***	6402.05	***Solvent***	DMSO-d6	***Spectrum Offset (Hz)***	2798.8450
Spectrum Type	STANDARD	***Sweep Width (Hz)***	6401.85	***Temperature (degree C)***	24.996		

LBC477-017@8H.001.001.1r.esp



EPL-AA288 Batch 1

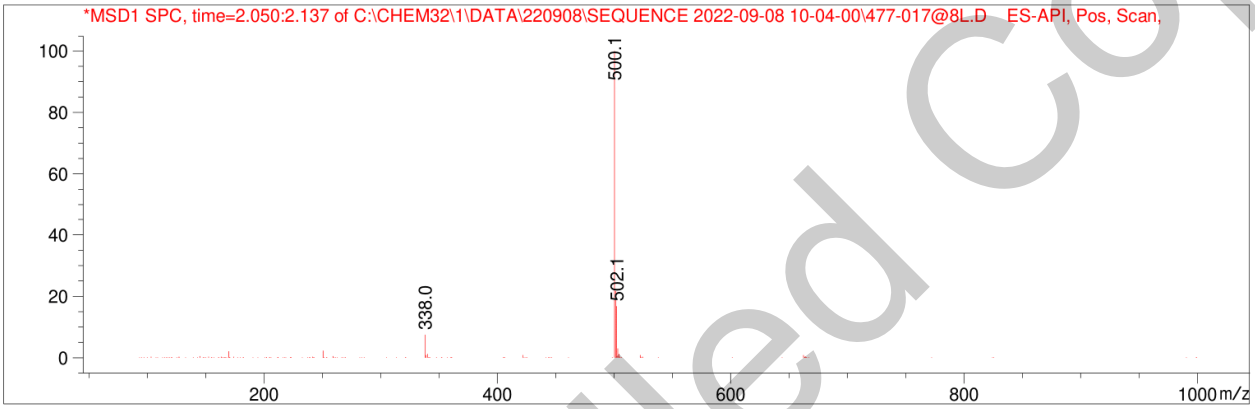
Ib. Mass Spectrum

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).

ZORBAX SB-C8, 4.6 x 30 mm, 3.5 micron.

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.085	4558734	502.15 I 501.15 I 500.10 I



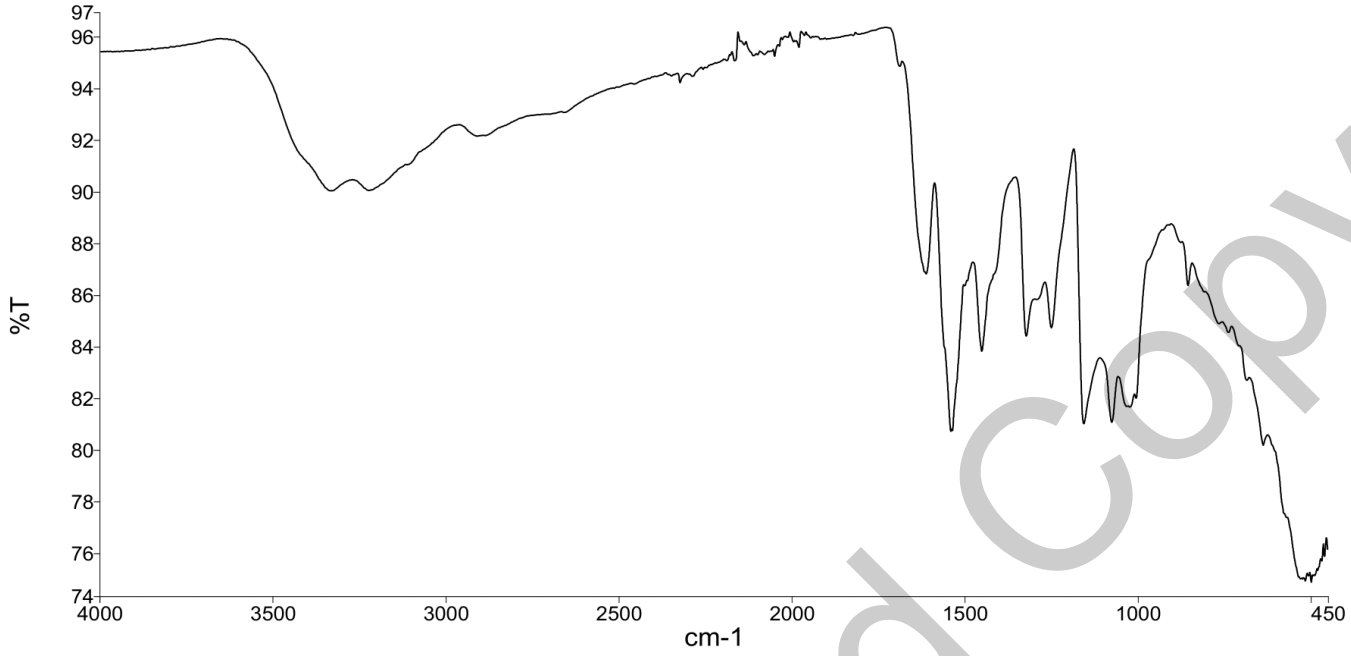
Theoretical value: 500.1 [M+H]+.

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

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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.

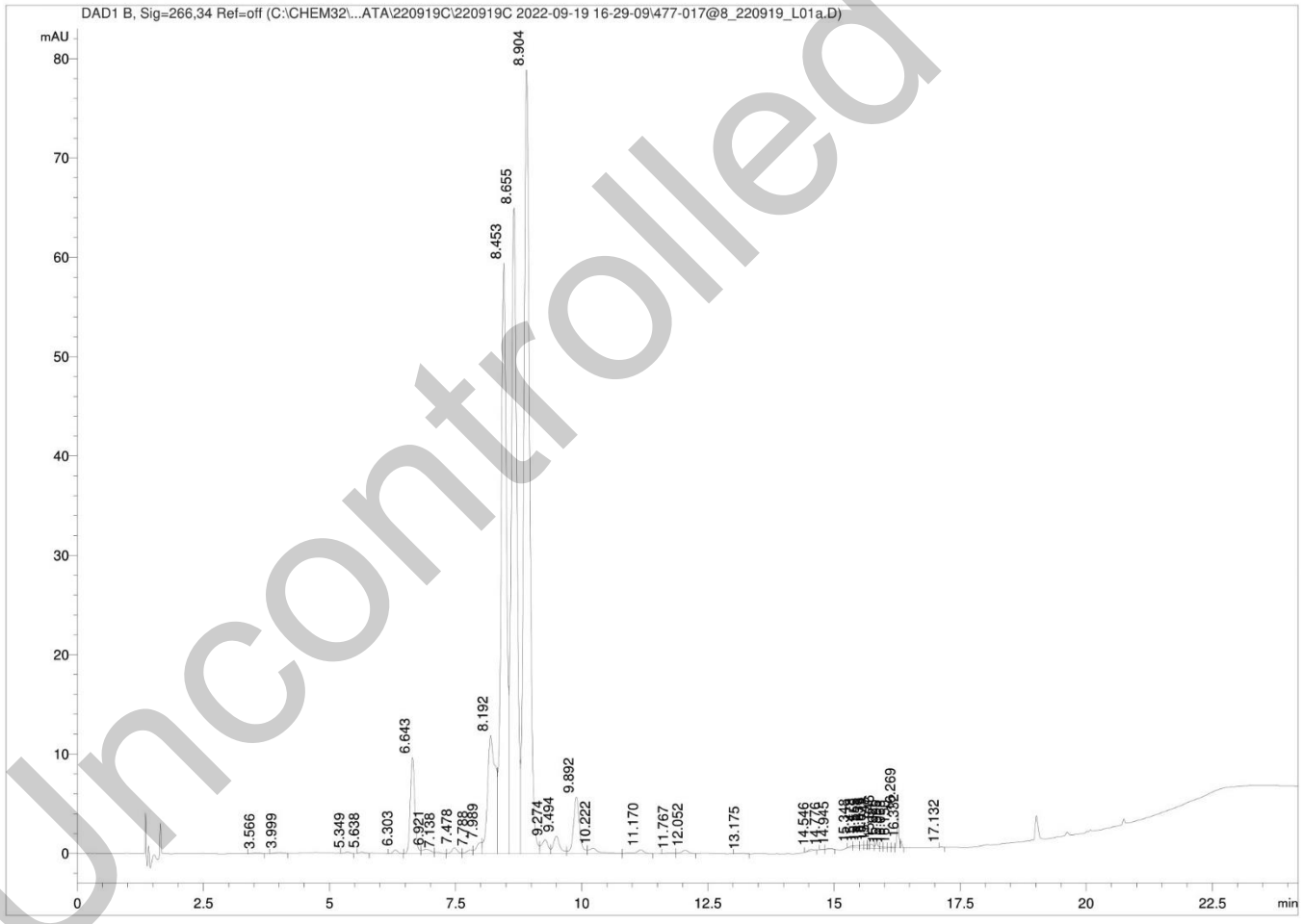
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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
Fortis H2o 4.6 x 100mm 3 micron	25ºC				DAD 266nm	Auto 2.0 µL 1.0 mg/mL in 100% methanol (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	96	4	1.0		
	12.00	90	10	1.0		
	20.50	5	95	1.0		
	22.50	5	95	1.0		
	23.50	96	4	1.0		
	29.50	96	4	1.0		



EPL-AA288 Batch 1

Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	3.57	0.75	0.04
2	4.00	1.16	0.06
3	5.35	0.85	0.04
4	5.64	0.88	0.05
5	6.30	2.33	0.12
6	6.64	60.72	3.16
7	6.92	5.36	0.28
8	7.14	1.34	0.07
9	7.48	4.56	0.24
10	7.79	3.16	0.16
11	7.99	8.22	0.43
12	8.19	132.26	6.89
13	8.45	441.82	23.03
14	8.66	504.23	26.28
15	8.90	633.84	33.03
16	9.27	12.65	0.66
17	9.49	15.80	0.82
18	9.89	47.26	2.46
19	10.22	7.82	0.41
20	11.17	4.12	0.21
21	11.77	0.60	0.03
22	12.05	3.06	0.16
23	13.18	0.57	0.03
24	14.55	1.19	0.06
25	14.78	0.24	0.01
26	14.95	0.86	0.04
27	15.35	1.05	0.05
28	15.48	1.84	0.10
29	15.56	1.54	0.08
30	15.64	1.24	0.06
31	15.68	0.85	0.04
32	15.75	2.05	0.11
33	15.85	2.19	0.11
34	15.93	0.68	0.04
35	15.99	0.54	0.03

EPL-AA288 Batch 1

36	16.07	0.46	0.02
37	16.15	0.28	0.01
38	16.27	8.64	0.45
39	16.33	1.46	0.08
40	17.13	0.24	0.01
Totals			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 89.3% (average of 10 duplicate runs)
Result calculated as the sum of four major close eluting peaks (Peaks 12 to 15).

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

III. Water Content

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

Results:

Average 1.9%

IV. Ash Content

Method: BP 2022 Appendix XI J. Ash Method II

Result:

Contains 0.7% ash.

V. Residual Solvents

Method: ^{1}HNMR

Result:

Contains 1.1% acetonitrile by ^{1}H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	89.3%
Water content	1.9%
Ash content	0.7%
Residual solvents	1.1%
Purity	86.0%

This purity is assessed to be 86.0%.

Product Reviewed By:

James Rixson, PhD
Head of Production

Product Released By:

Carol Worth, PhD
Quality Manager

Release Date: 2 November 2022

The calculation of the purity follows the formula:

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

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902