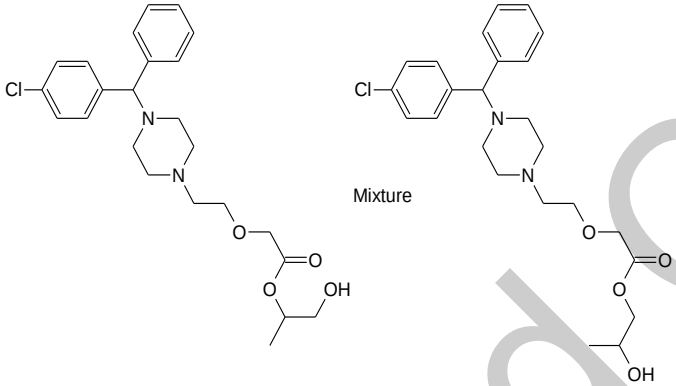
Reference Material Product Information Sheet

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



Name	Cetrizine 1,2-propylene glycol esters
USP Name	Propylene glycol ester of cetirizine
Epichem Item #	EPL-AA96 Batch 2
CAS #	2576325-35-2
Molecular Formula	$C_{24}H_{31}ClN_2O_4$
Molecular Weight	446.98 g/mol
Appearance	Amber syrup
Melting Point	Not applicable.
Combustion Analysis	Required (%): C:64.5; H:7.0; N:6.3. Found (%): C:62.9; H:7.1; N:6.0.
Purity	98.0%
Date of Manufacture	9 February 2021
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

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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:

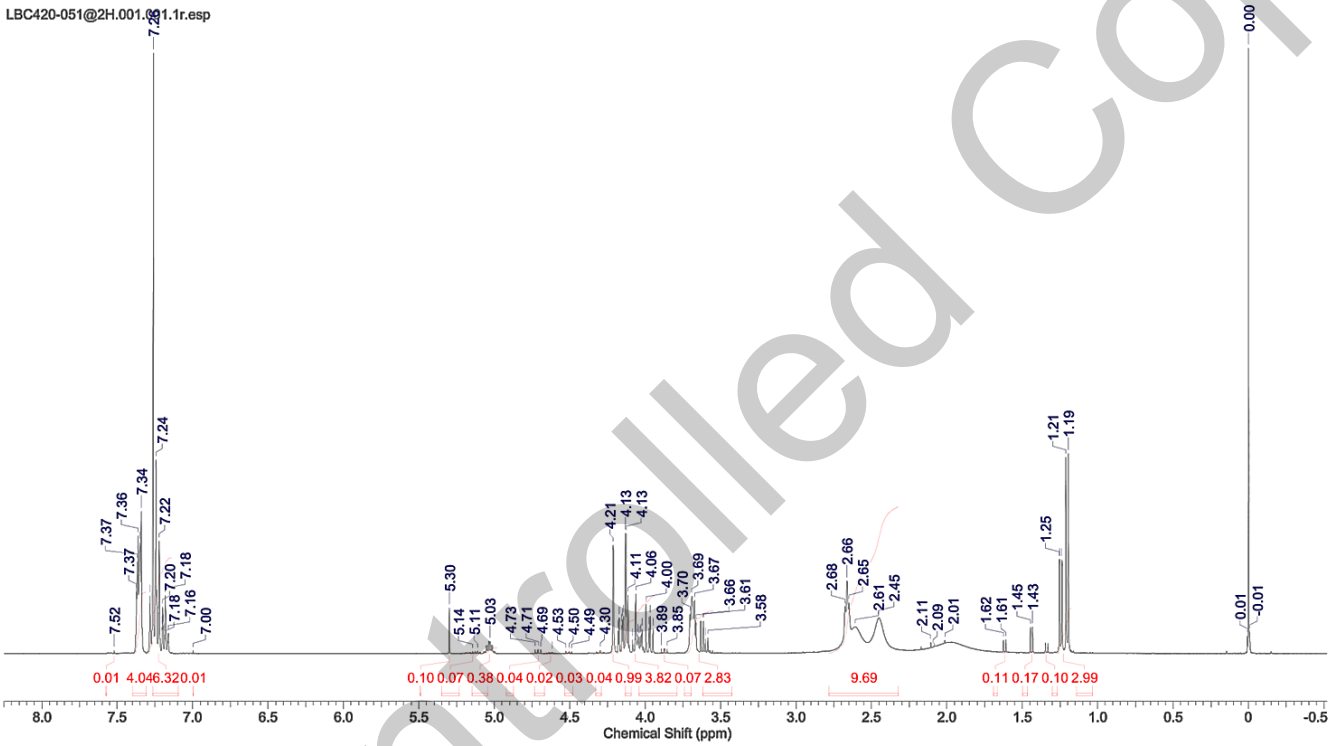
Ia. ^{1}HNMR Spectrum

Conditions: 400 MHz, DMSO-d_6

^{1}HNMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	*Comment*	LBC420-051@2H 1H CDCl3 {E:\dataexternal\epichem} cygoh 14				
Date	12 Jan 2021 17:50:56			*Date Stamp*	12 Jan 2021 17:50:56		
File Name	\\naphthalene\company\NMR files\LBC420-051@2H\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*	128.00
SW(cyclical) (Hz)	6402.05	*Solvent*	CHLOROFORM-d			*Spectrum Offset (Hz)*	2791.7827
Spectrum Type	STANDARD	*Sweep Width (Hz)*	6401.85	*Temperature (degree C)*	24.671		

LBC420-051@2H.001.1r.esp



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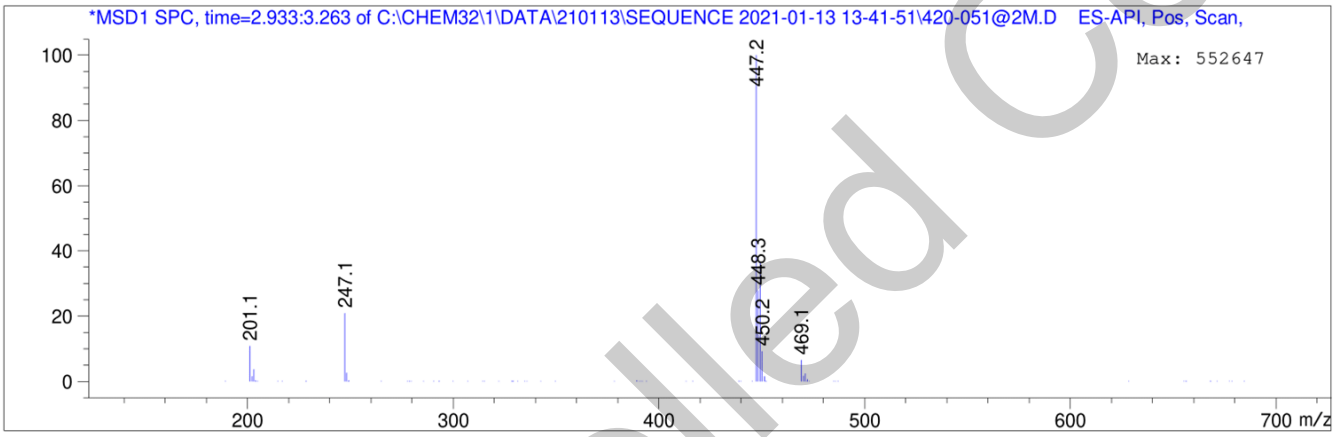
Ib. Mass Spectrum

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).

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

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.995	33223074	449.20 I
		448.25 I
		447.20 I
		247.15 I
		201.10 I



Theoretical value: 447.2 $[M+H]^+$.

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

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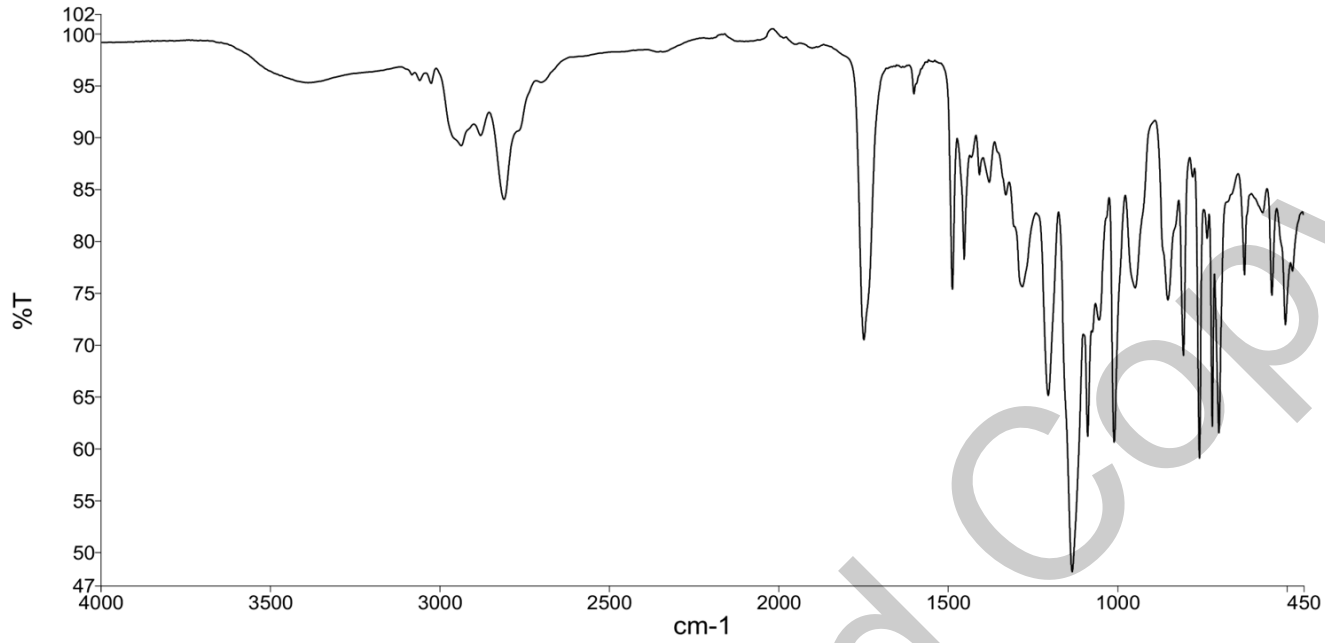
Ic. IR Spectrum

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



The interpretation of the signals of the Fourier Transform Infra-red Spectrum is consistent with the structural formula.

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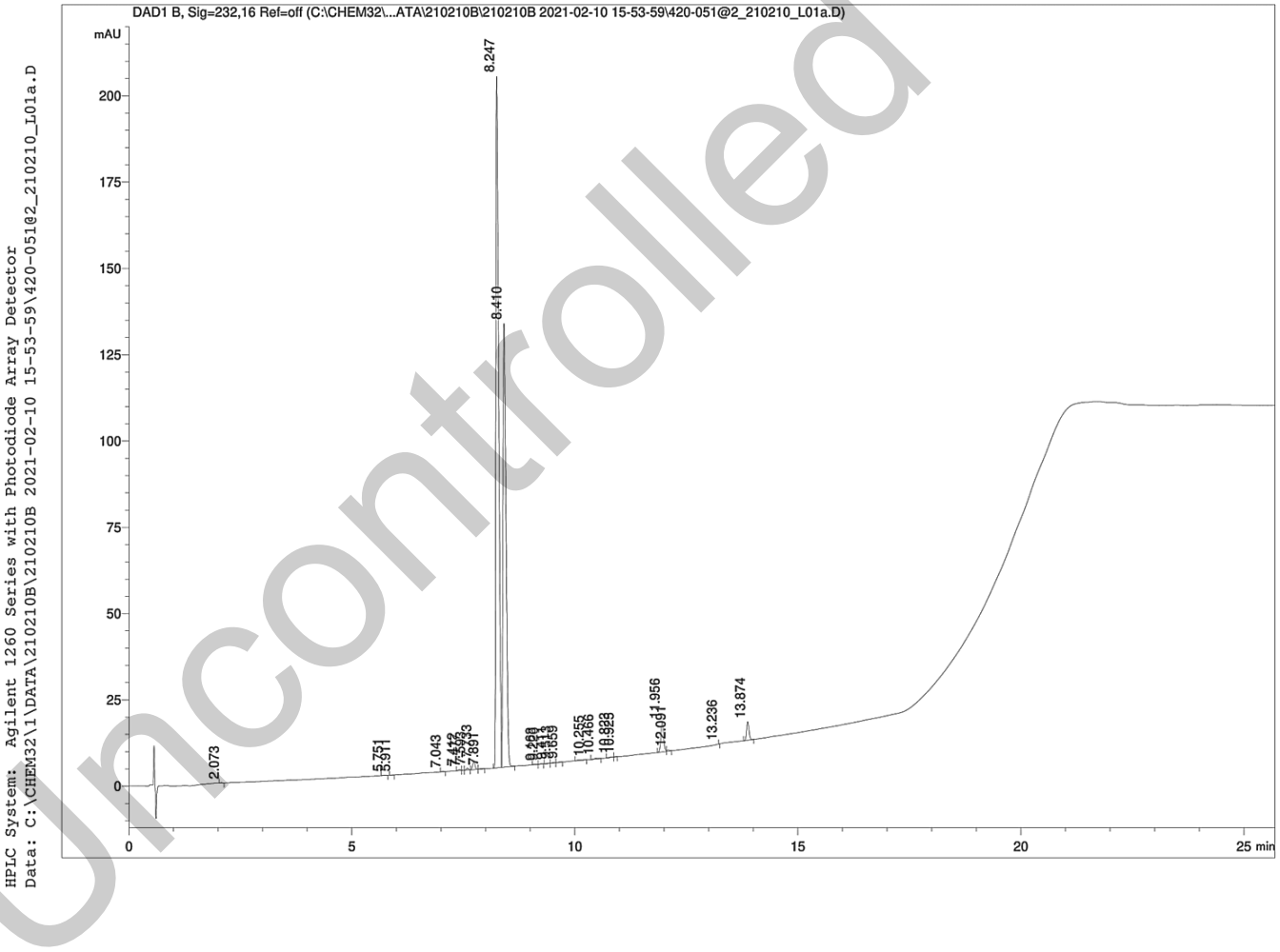
II. Purity

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 2.7 micron	25ºC				DAD 232nm	Auto 1.0 µL 1.0 mg/mL in 100% acetonitrile (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	80	20	1.0		
	16.00	40	60	1.0		
	19.50	5	95	1.0		
	24.50	5	95	1.0		
	25.50	80	20	1.0		
	28.50	80	20	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.07	0.27	0.02
2	5.75	0.28	0.02
3	5.91	0.08	0.01
4	7.04	0.30	0.02
5	7.41	1.04	0.07
6	7.48	0.28	0.02
7	7.59	1.96	0.13
8	7.73	8.69	0.57
9	7.89	0.54	0.04
10	8.25	856.64	55.76*
11	8.41	603.16	39.26*
12	9.17	0.35	0.02
13	9.23	0.35	0.02
14	9.41	0.51	0.03
15	9.51	0.67	0.04
16	9.66	0.51	0.03
17	10.26	0.91	0.06
18	10.47	1.10	0.07
19	10.82	0.82	0.05
20	10.93	0.25	0.02
21	11.96	36.75	2.39*
22	12.09	1.44	0.09
23	13.24	0.02	0.00
24	13.87	19.49	1.27*
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 98.7% (average of 10 duplicate analyses)
*Calculated from sum of peaks 10,11,21 and 24.

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III. Ash Content

Method: BP 2021 Appendix XI J Method II

Result:

Contains <0.1% ash.

IV. Residual Solvents

Method: ^{1}HNMR

Result:

0.7% dichloromethane by ^{1}H NMR analysis.

V. Final Result

Chromatographic purity (HPLC)	98.7%
Ash content	<0.1%
Residual solvents	0.7%
Purity	98.0%

This purity is assessed to be 98.0%.

Product Reviewed By:

James Rixson, PhD
Head of Production

Product Released By:

Boon Tan
Quality Manager

Release Date: 19 February 2021

The calculation of the purity follows the formula:

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

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