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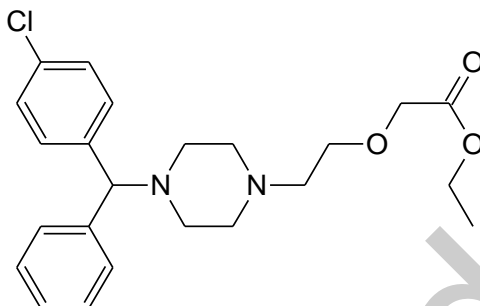
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Reference Material Product Information Sheet

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



Name	Cetirizine ethyl ester
Synonym(s)	ethyl (RS)-(2-(4-((4-chlorophenyl)phenylmethyl)-1-piperazinyl)ethoxy)acetate
Epichem Item #	EPL-AA94 Batch 3
CAS #	246870-46-2
Molecular Formula	C ₂₃ H ₂₉ ClN ₂ O ₃
Molecular Weight	416.95 g/mol
Appearance	Light orange viscous oil
Combustion Analysis	Required (%): C:66.3; H:7.0; N:6.7. Found (%): C:65.9; H:6.8; N:7.1.
Purity*	99.5%
Date of Manufacture	3 December 2018
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)

* NATA accreditation does not cover the performance of this service

EPL-AA94 Batch 3

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:

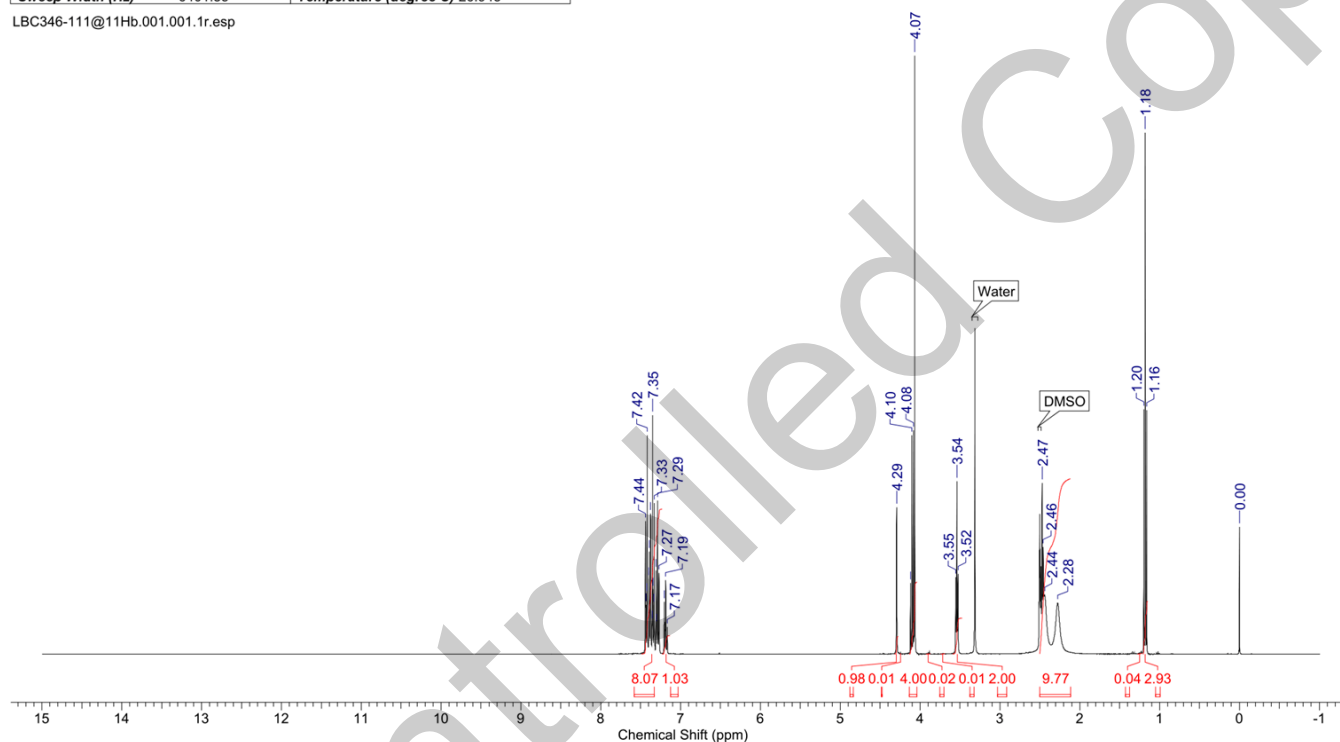
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, CDCl₃

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC346-111@11H 1H DMSO (E:\data\external\epichem) cygoh 11		
Date	29 Nov 2018 18:01:36	Date Stamp	29 Nov 2018 18:01:36		
File Name	\naphthalene\company\NMR files\LBC346\LBC346-111@11Hb\1\data\11r		Frequency (MHz)	400.13	
Nucleus	1H	Number of Transients	8	Origin	spect
Owner	nmr	Points Count	32768	Original Points Count	24038
SW(cyclical) (Hz)	6402.05	Pulse Sequence	zg	Receiver Gain	90.50
Sweep Width (Hz)	6401.85	Solvent	DMSO-d6	Spectrum Offset (Hz)	2798.5049
		Temperature (degree C)	26.945	Spectrum Type	STANDARD

LBC346-111@11Hb.001.001.1r.esp



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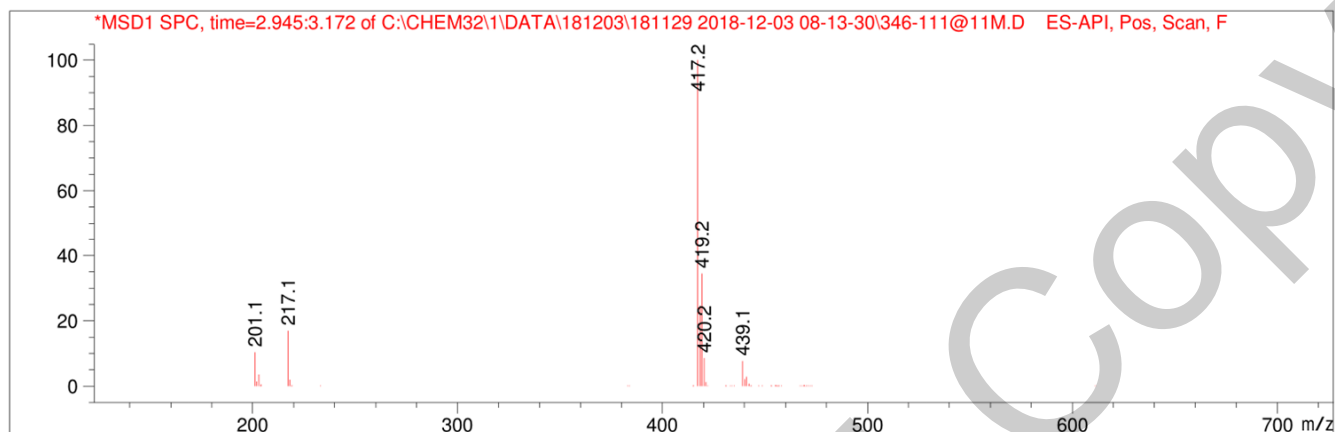
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Ib. Mass Spectrum

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.



Theoretical value: 417.2 [M+H]⁺.

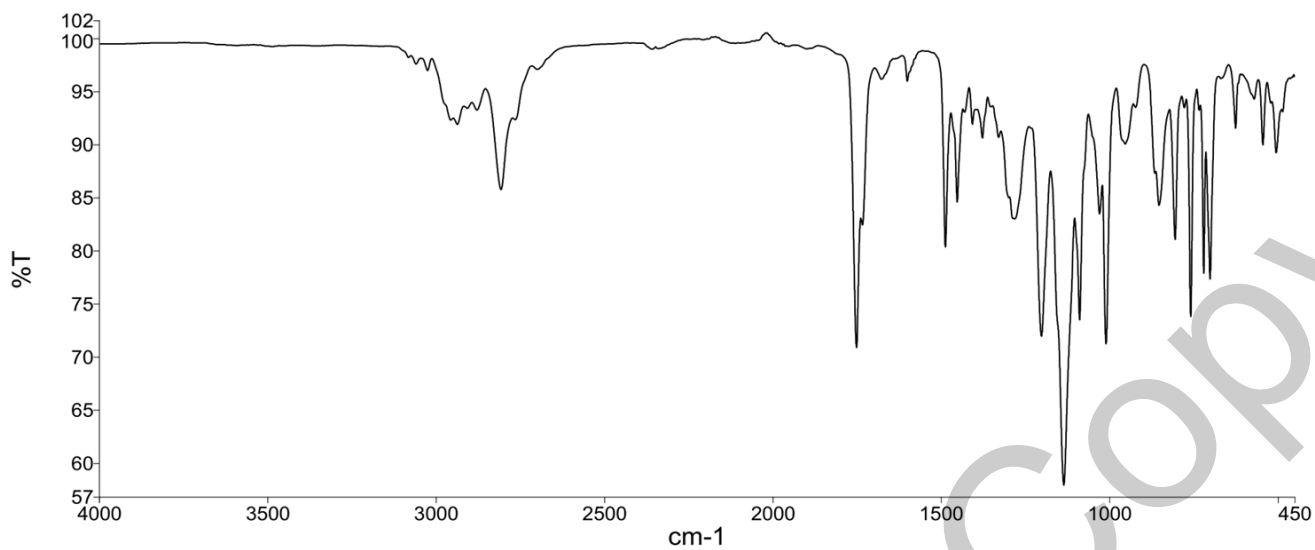
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform 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.

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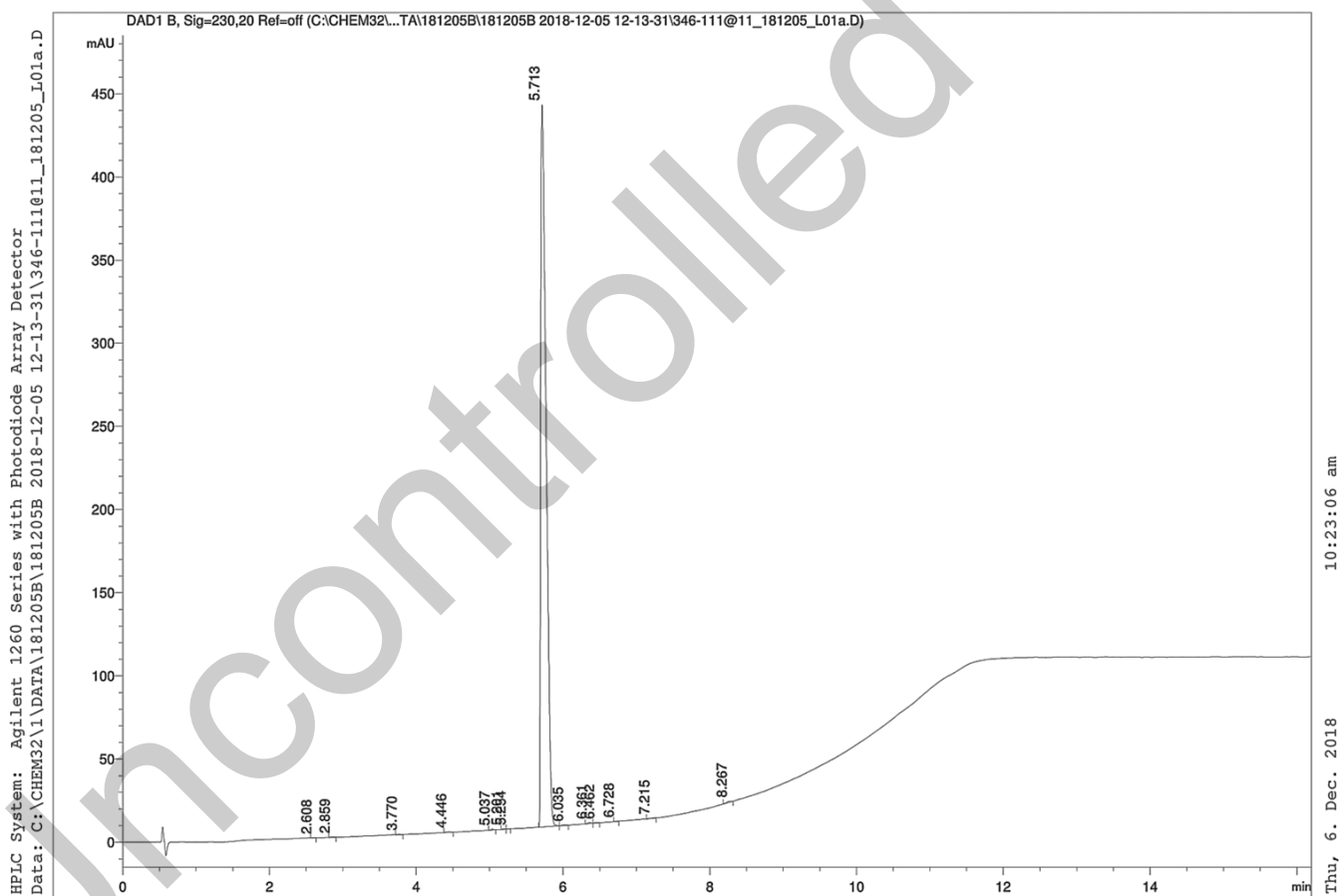
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II. Purity

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	25°C				DAD 230nm	Auto 1.0 µL 1.4 mg/mL 100% acetonitrile
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
	0.00	75	25	1.0		
	6.00	45	55	1.0		
	10.00	5	95	1.0		
	15.00	5	95	1.0		
	16.00	75	25	1.0		
	19.00	75	25	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.61	0.20	0.01
2	2.86	0.78	0.04
3	3.77	0.59	0.03
4	4.45	1.07	0.05
5	5.04	1.19	0.05
6	5.20	0.54	0.02
7	5.25	0.35	0.02
8	5.71	2204.24	99.53
9	6.03	0.76	0.03
10	6.36	1.52	0.07
11	6.46	0.49	0.02
12	6.73	0.17	0.01
13	7.21	0.48	0.02
14	8.27	2.28	0.10
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 99.6% (average of 10 duplicate analyses)

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III. Water Content

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

Results:

Average 0.1%

IV. Ash Content

Method: BP 2018 Ash (Appendix XI J) Method II

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹HNMR

Result:

No significant impurities detected by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.6%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	99.5%

This purity is assessed to be 99.5%.

Product Reviewed By:

Product Released By:

John Moursounidis, PhD
Head Reference Standards

Boon Tan
Quality Manager

Release Date: 13 December 2018

*NATA accreditation does not cover the performance of this service.

The calculation of the purity follows the formula:

$$\text{Purity(\%)} = \frac{((\text{Chromatographic purity[HPLC]}) \times (100 - (\text{water content} + \text{ash content} + \text{volatile contents})))}{100}$$

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