



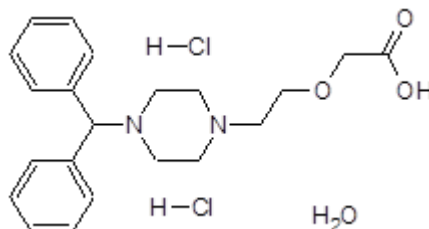
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## Reference Material Product Information Sheet

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



<b>Name</b>	2-(2-(4-(diphenylmethyl)piperazin-1-yl)ethoxy)acetic acid dihydrochloride monohydrate
<b>BP/EP Name</b>	Cetirizine Impurity F dihydrochloride monohydrate
<b>USP Name</b>	Deschlorocetirizine
<b>Synonym(s)</b>	Deschloro Cetirizine dihydrochloride monohydrate; 1-((diphenyl)methyl)-4-(2-(carboxymethoxy)ethyl)piperazine dihydrochloride monohydrate; 2-(2-(4-(diphenylmethyl)-1-piperazinyl)ethoxy)acetic acid dihydrochloride monohydrate; (2-(4-(diphenylmethyl)-1-piperazinyl)ethoxy)acetic acid dihydrochloride monohydrate; 2-(2-(4-benzhydrylpiperazin-1-yl)ethoxy)acetic acid dihydrochloride monohydrate; Cetirizine Deschloro Impurity dihydrochloride monohydrate.
<b>Epichem Item #</b>	EPL-AA29 Batch 2
<b>CAS #</b>	2575516-48-0 (Related CAS# 83881-54-3 for anhydrous product)
<b>Molecular Formula</b>	C <sub>21</sub> H <sub>26</sub> N <sub>2</sub> O <sub>3</sub> ·2HCl·H <sub>2</sub> O
<b>Molecular Weight</b>	445.39 g/mol
<b>Appearance</b>	White powder
<b>Melting Point</b>	201.1-210.2°C (decomposition)
<b>Combustion Analysis</b>	Required (%): C:56.6; H:6.8; N:6.3. Found (%): C:56.8; H:6.8; N:6.2.
<b>Purity*</b>	98.9%
<b>Date of Manufacture</b>	9 December 2015
<b>Storage Requirements</b>	Protect from heat, light and moisture.
<b>Special Precautions</b>	<b>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.</b>
<b>Intended Use</b>	This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
<b>Date of Shipment</b>	TBA This certificate is valid for one year from the date of shipment provided the substance is unopened and stored under the recommended conditions.
<b>Retest Date</b>	TBA (Proper Storage and Handling Required)

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

EPL-AA29 Batch 2

Revision 4

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ABN 80 106 769 902

## I. Identity

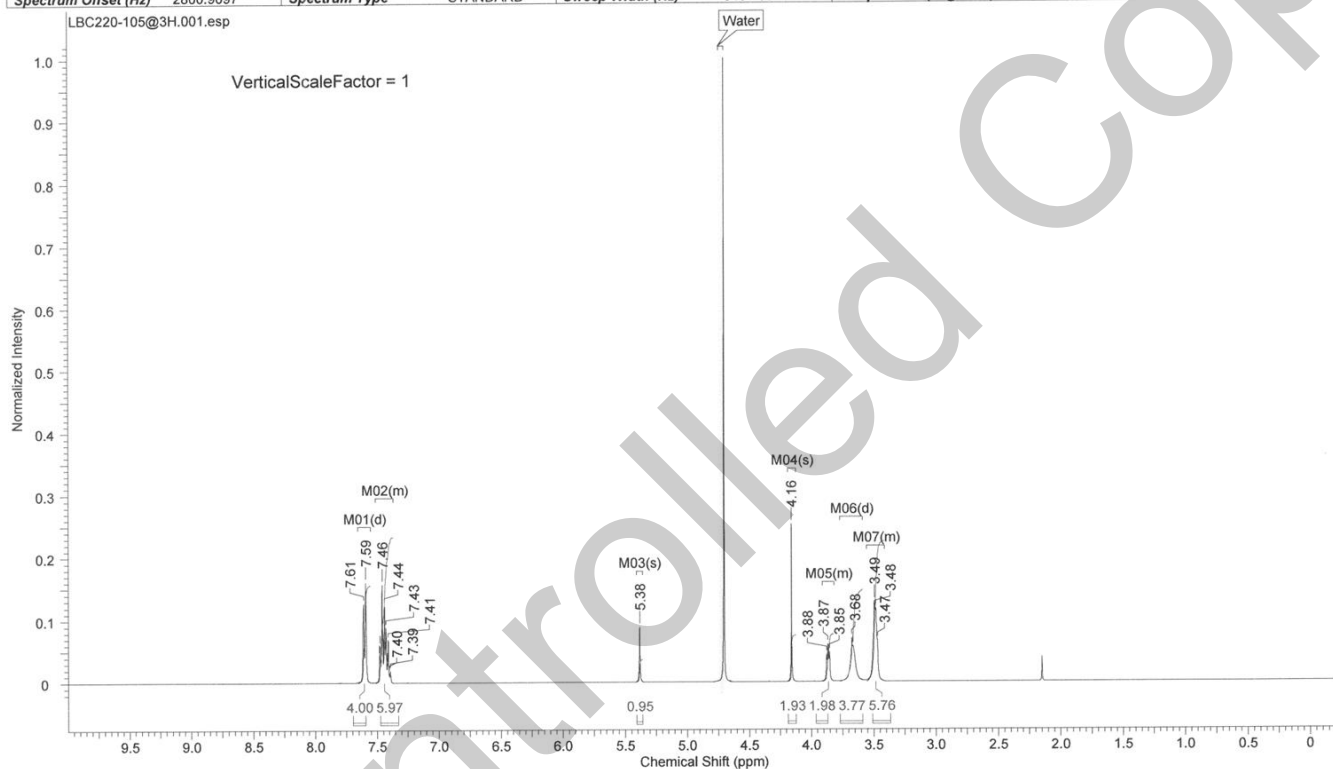
The identity of this product was established using the following analyses:

### Ia. <sup>1</sup>H NMR Spectrum

Conditions: 400 MHz, D<sub>2</sub>O

<sup>1</sup>H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC220-105@3H	1H D2O (E:\data\external\epichem) cygoh 6	Date	01 Dec 2015 17:59:28	
Date Stamp	01 Dec 2015 17:59:28	File Name	\\NAPHTHALENE\Company\NMR files\LBC220-105@3H\1fid				
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	90.50	SW(cyclical) (Hz)	6402.05	Solvent	DEUTERIUM OXIDE		
Spectrum Offset (Hz)	2800.9097	Spectrum Type	STANDARD	Sweep Width (Hz)	6401.85	Temperature (degree C)	26.836



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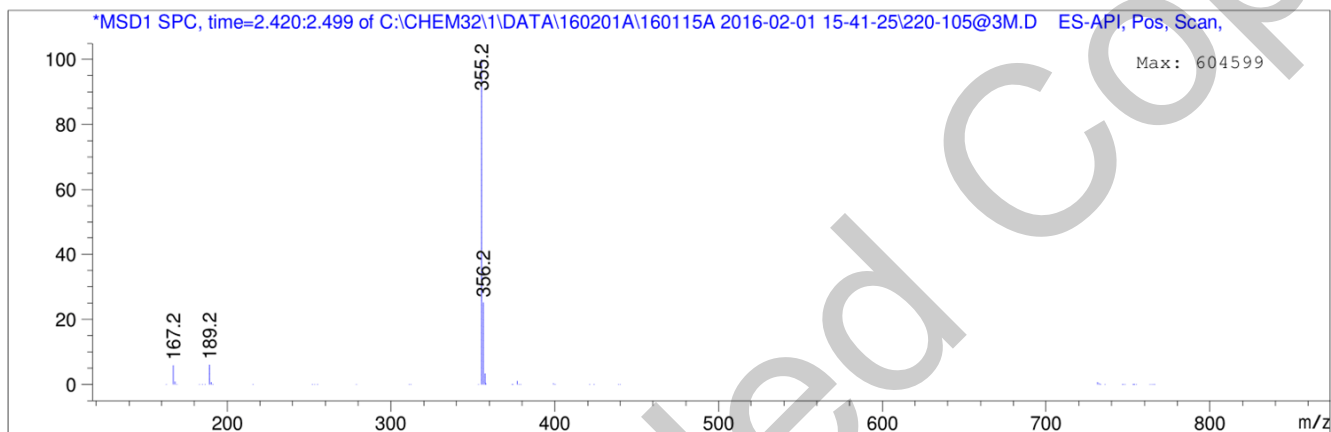
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## Ib. Mass Spectrum

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

Method: 5% to 100% ACN in water gradient (+0.1% formic acid)  
Poroshell 120 EC-C18, 4.6 x 50 mm, 2.7 micron

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.447	7264073	356.20 I 355.20 I

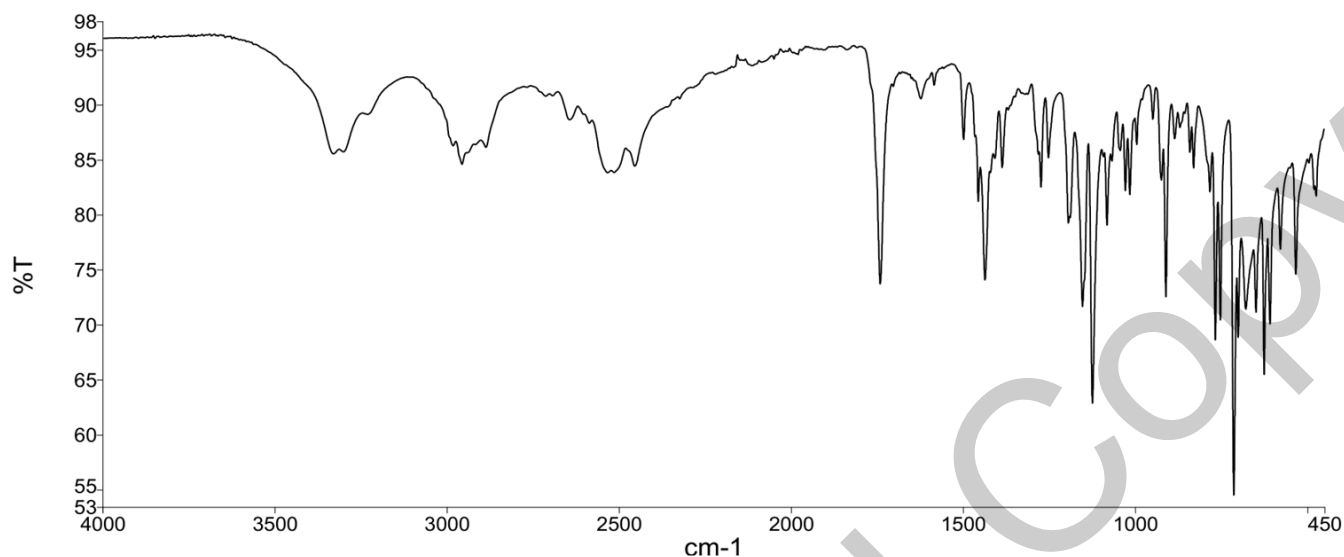


Theoretical values: 355.2 [M+H]<sup>+</sup>.

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.

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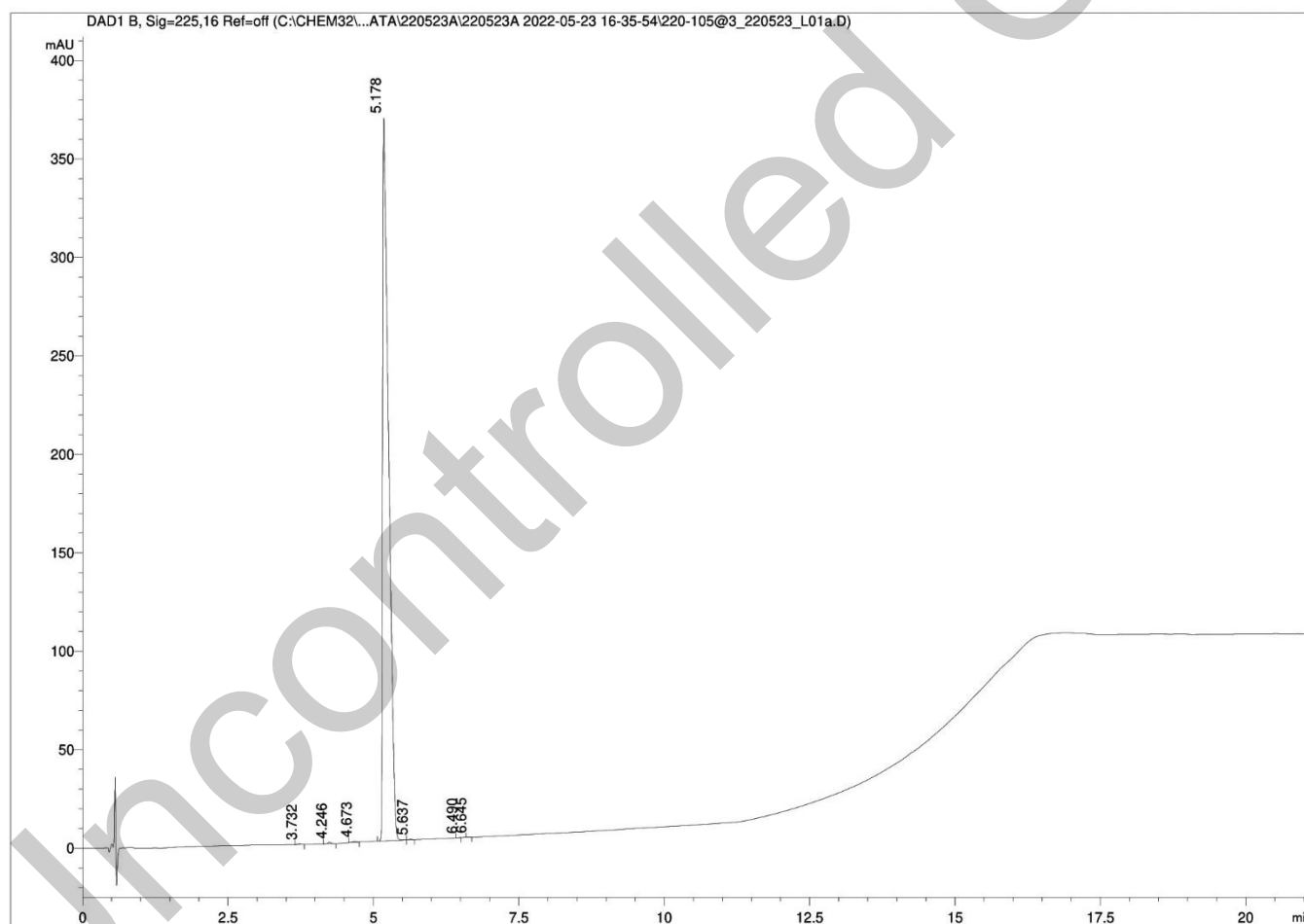
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## II. Purity

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

### HPLC Conditions:

Column	Conditions				Detector	Injector
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
Agilent Poroshell 120 EC-C18	40°C				DAD 225nm	Auto
4.6 x 50mm	0.00	80	20	1.0		2.0 µL
	3.00	75.5	24.5	1.0		1.2 mg/mL in
2.7 micron	10.00	54.5	45.5	1.0		50% acetonitrile
	14.95	5	95	1.0		50% water
	19.95	5	95	1.0		(+0.1% TFA)
	20.95	80	20	1.0		
	23.95	80	20	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	3.73	1.30	0.05
2	4.25	2.92	0.11
3	4.67	2.08	0.08
4	5.18	2622.80	99.70
5	5.64	1.37	0.05
6	6.49	0.14	0.01
7	6.65	0.18	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 99.7% (average of 10 duplicate runs)

### III. Water Content

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

**Results:**

Average 4.5%

### IV. Ash Content

Method: BP2016 Ash (Appendix XI J) as per WS001/27424

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>H NMR

**Result:**

Contains 0.3% 1,4-dioxane by <sup>1</sup>H NMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	99.7%
Water content	0.5% (Total water = 4.5%, Water of Hydration = 4.0%)
Ash content	<0.1%
Residual solvents	0.3%
Purity*	98.9%

This purity is assessed to be 98.9%.

Product Reviewed By:

Product Released By:

James Rixson, PhD  
Head of Production

Carol Worth, PhD  
Quality Manager

Release Date: 5 July 2023

*\*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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