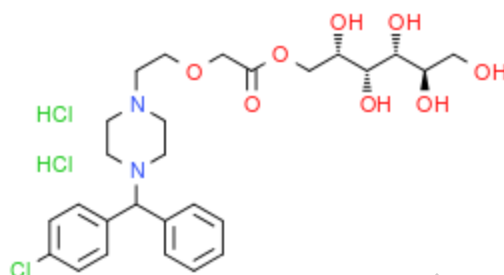


Reference Material Product Information Sheet

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



Name	Cetirizine sorbitol ester dihydrochloride
BP/EP Name	Not applicable.
USP Name	Not applicable.
Synonym(s)	Not applicable.
Epichem Item #	EPL-AA289 Batch 1
CAS #	Not available.
Molecular Formula	C ₂₇ H ₃₇ ClN ₂ O ₈ .HCl.HCl
Molecular Weight	625.98 g/mol
Appearance	White powder
Melting Point	86.1-103.2°C (Decomposes)
Combustion Analysis	Required (%): C:51.8; H:6.3; N:4.5. Found (%): C:52.6; H:6.7; N:4.6.
Purity by HPLC	94.3% at 232nm by HPLC (assuming all components detected with the same response factor). Purity is the combined integration of the five close-eluting major peaks taken to be regio-isomers based on structure and review of analytical data.
Date of Manufacture	20 August 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 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)

EPL-AA289 Batch 1

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:

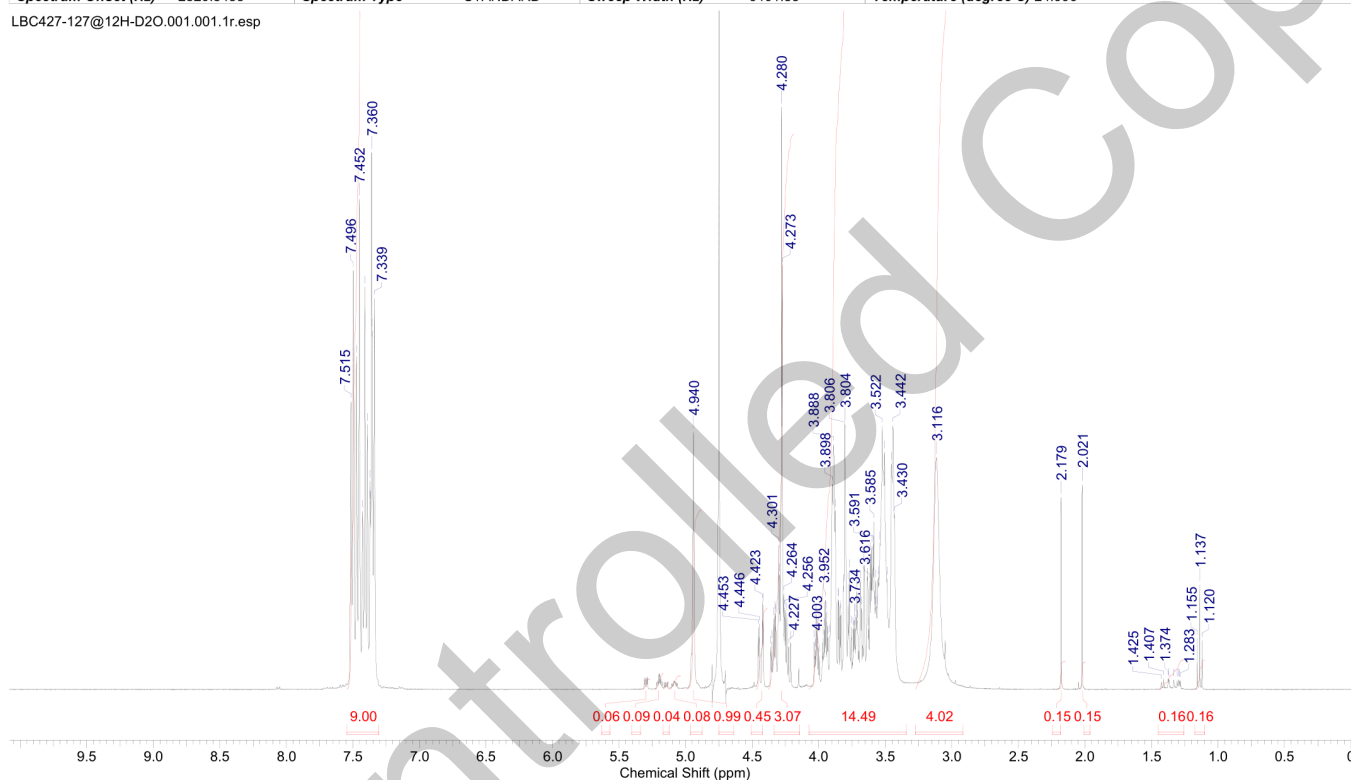
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, D₂O

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC427-127@11H 1H D2O (E:\data\external\epichem) cygoh 12	Date	30 Jul 2021 18:16:32				
Date Stamp	30 Jul 2021 18:16:32	Nucleus	1H	File Name	\naphthalene\company\NMR files\LBC427\LBC427-127@12H-D2O\1\data\11r				
Frequency (MHz)	400.13	Owner	nmr	Number of Transients	8	Origin	spect		
Original Points Count	24038	SW(cyclical) (Hz)	6402.05	Points Count	32768	Pulse Sequence	zg		
Receiver Gain	71.80	Spectrum Type	STANDARD	Solvent	DEUTERIUM OXIDE	Sweep Width (Hz)	6401.85	Temperature (degree C)	24.996
Spectrum Offset (Hz)	2820.3455								

LBC427-127@12H-D2O.001.001.1r.esp



EPL-AA289 Batch 1

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

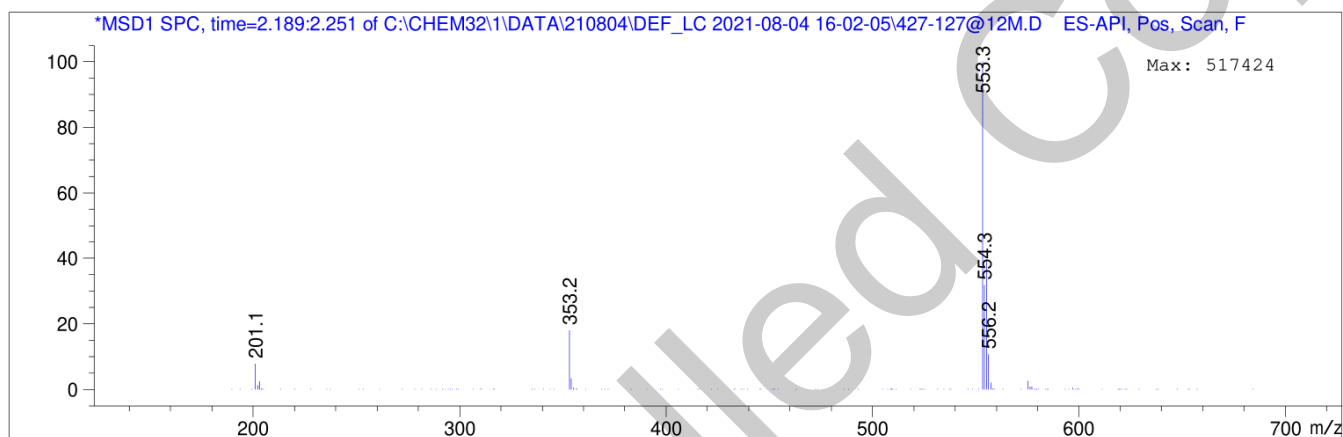
ABN 80 106 769 902

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
2.215	8443666	556.20
		555.20
		554.25
		553.25
		353.20



Theoretical value: 553.3 [M+H]⁺.

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

EPL-AA289 Batch 1

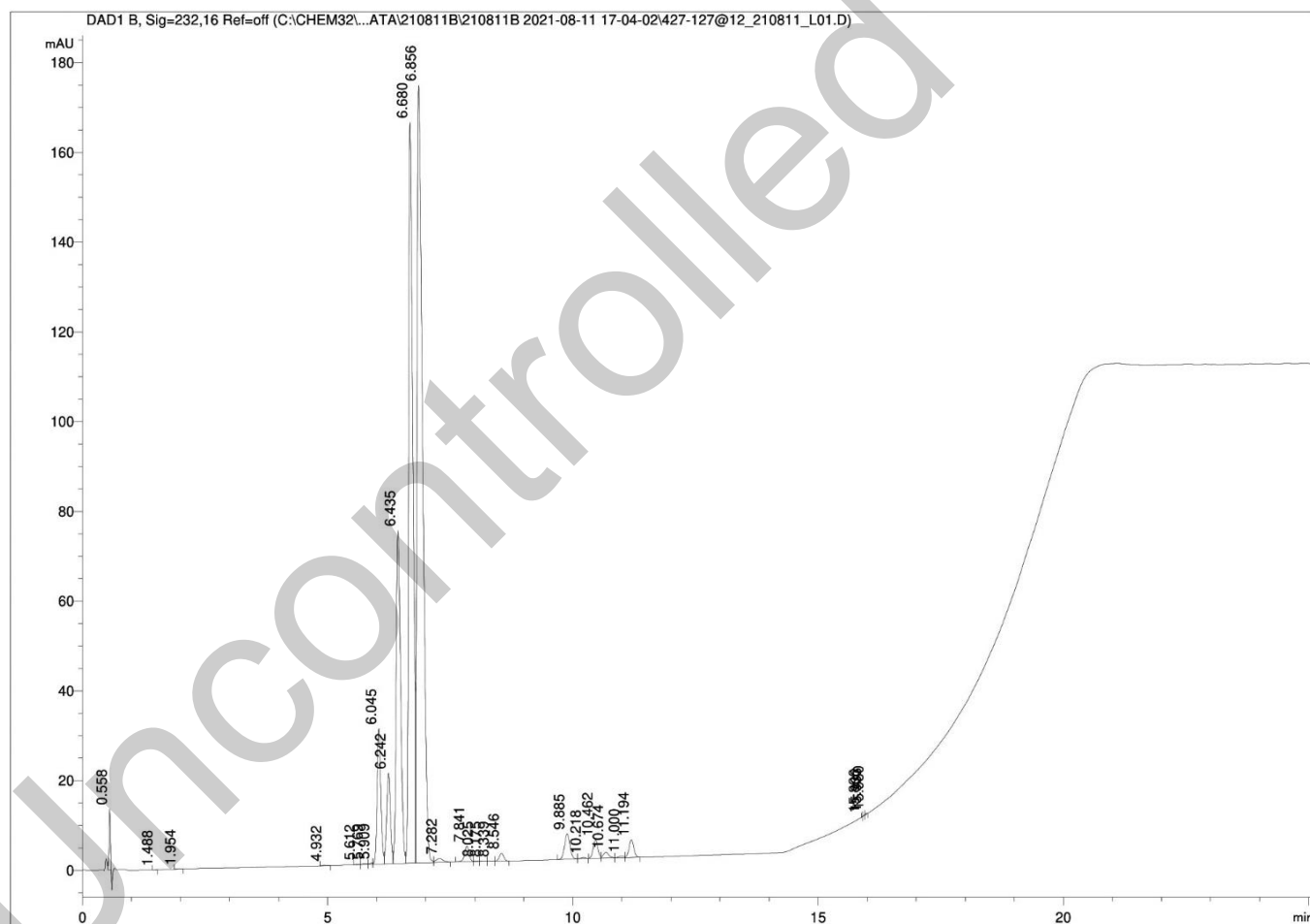
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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
Agilent Poroshell 120 EC-C18 4.6 x 50mm 2.7 micron	25°C				DAD 232nm	Auto 2.0 µL 1.50 mg/mL in 50% acetonitrile 50% 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	77	23	1.0		
	13.00	64	36	1.0		
	18.90	5	95	1.0		
	23.90	5	95	1.0		
	24.90	77	23	1.0		
	27.90	77	23	1.0		



EPL-AA289 Batch 1

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

Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	0.56	25.49	0.78
2	1.49	0.11	0.00
3	1.95	0.23	0.01
4	4.93	0.73	0.02
5	5.61	0.67	0.02
6	5.77	1.54	0.05
7	5.91	1.31	0.04
8	6.05	156.94	4.79
9	6.24	107.12	3.27
10	6.43	460.40	14.05
11	6.68	995.11	30.38
12	6.86	1370.17	41.83
13	7.28	9.06	0.28
14	7.84	22.16	0.68
15	8.02	0.69	0.02
16	8.18	0.51	0.02
17	8.34	0.34	0.01
18	8.55	10.89	0.33
19	9.89	43.47	1.33
20	10.22	1.94	0.06
21	10.46	27.24	0.83
22	10.67	9.86	0.30
23	11.00	2.60	0.08
24	11.19	26.55	0.81
25	15.90	0.07	0.00
26	15.93	0.18	0.01
27	15.98	0.53	0.02
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

94.3% (average of duplicate)

Peaks 8 to 12 are integrated together for purity determination and are assumed to be regio-isomers based on structure and review of analytical data.

EPL-AA289 Batch 1

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 0.3%

IV. Residual Solvents

Method: ¹HNMR

Result:

Contains 0.3% ether, 0.3% acetonitrile, 0.2% acetone by ¹H NMR analysis.

V. Final Result

Chromatographic purity (HPLC)	94.3%
Water content	0.3%
Residual solvents	0.8%
Purity by HPLC	94.3% at 232nm by HPLC (assuming all components detected with the same response factor). Purity is the combined integration of the five close-eluting major peaks taken to be regio-isomers based on structure and review of analytical data.

This purity is assessed to be 94.3% at 232nm by HPLC (assuming all components detected with the same response factor). Purity is the combined integration of the five close-eluting major peaks taken to be regio-isomers based on structure and review of analytical data.

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Carol Worth, PhD
Quality Manager

Release Date: 11 January 2023

EPL-AA289 Batch 1

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