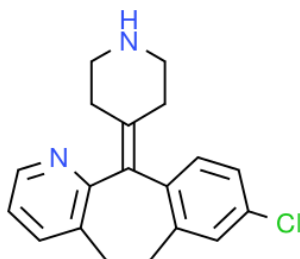


Reference Material Product Information Sheet



Name	Desloratadine
BP/EP Name	Loratadine Impurity D
USP Name	Loratadine Related Compound A
Synonym(s)	8-chloro-11-(piperidin-4-ylidene)-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine
Epichem Item #	EPL-AA270 Batch 1
CAS #	100643-71-8
Molecular Formula	C ₁₉ H ₁₉ ClN ₂
Molecular Weight	310.83 g/mol
Appearance	Off-white solid
Melting Point	156.0-157.6°C
Combustion Analysis	Required (%): C:73.4; H:6.2; N:9.0. Found (%): C:73.5; H:6.3; N:17.8.
Purity	99.8%
Date of Manufacture	24 June 2020
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-AA270 Batch 1

Epichemistry Pty Limited, Suite 11, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 8 9363 7888 www.epichem.com ABN 50 670 849 377

I. Identity

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

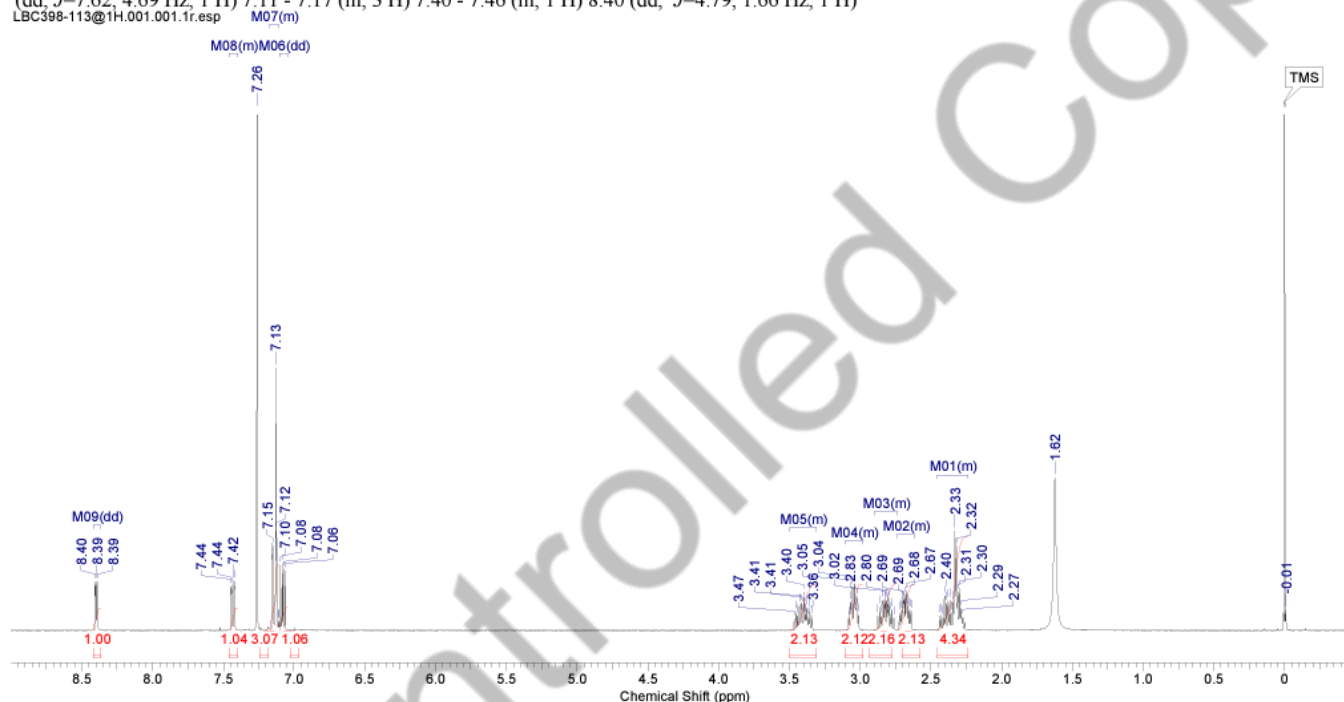
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, CDCl₃

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC398-113@1H 1H CDCl ₃ (E:\data\external\epichem) cygoh	Date	24 Jun 2020 17:44:32
Date Stamp	24 Jun 2020 17:44:32	Nucleus	1H	File Name	\\naphthalene\company\NMR files\LBC398-113@1H\1\data\1\1r
Frequency (MHz)	400.13	Owner	nmr	Number of Transients	8
Original Points Count	24038	SW(cyclical) (Hz)	6402.05	Points Count	32768
Receiver Gain	181.00	Spectrum Type	STANDARD	Solvent	CHLOROFORM-d
Spectrum Offset (Hz)	2792.3311			Sweep Width (Hz)	6401.85
				Temperature (degree C)	24.996

¹H NMR (400 MHz, CHLOROFORM-d) δ ppm 2.24 - 2.45 (m, 5 H) 2.62 - 2.74 (m, 2 H) 2.74 - 2.90 (m, 2 H) 2.98 - 3.10 (m, 2 H) 3.31 - 3.49 (m, 2 H) 7.08 (dd, *J*=7.62, 4.69 Hz, 1 H) 7.11 - 7.17 (m, 3 H) 7.40 - 7.46 (m, 1 H) 8.40 (dd, *J*=4.79, 1.66 Hz, 1 H)



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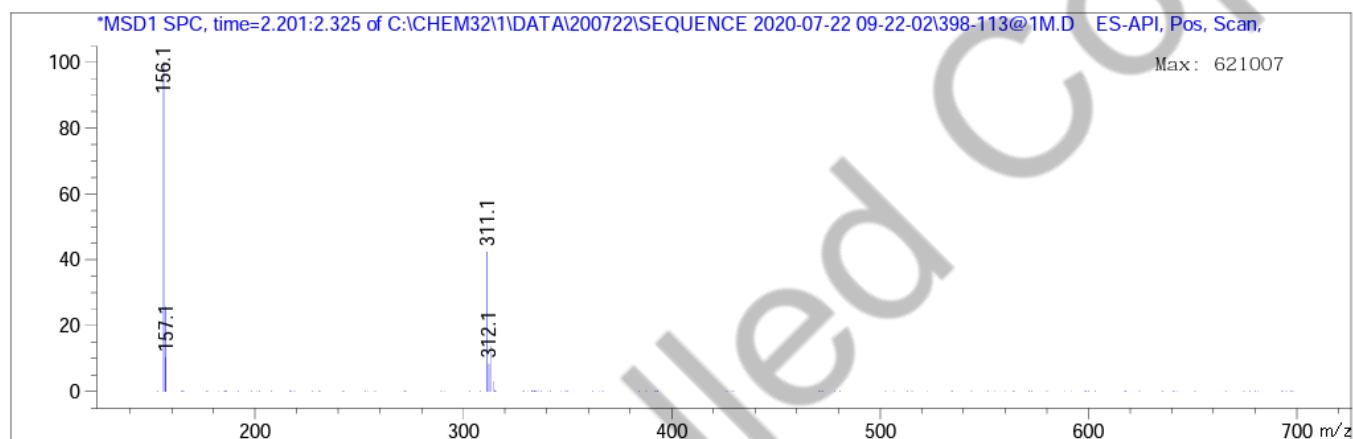
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Ib. Mass Spectrum

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.

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.246	15678692	313.10 I
		311.10 I
		157.10 I
		156.90 I
		156.10 I



Theoretical value: 313.10 [M+H]⁺.

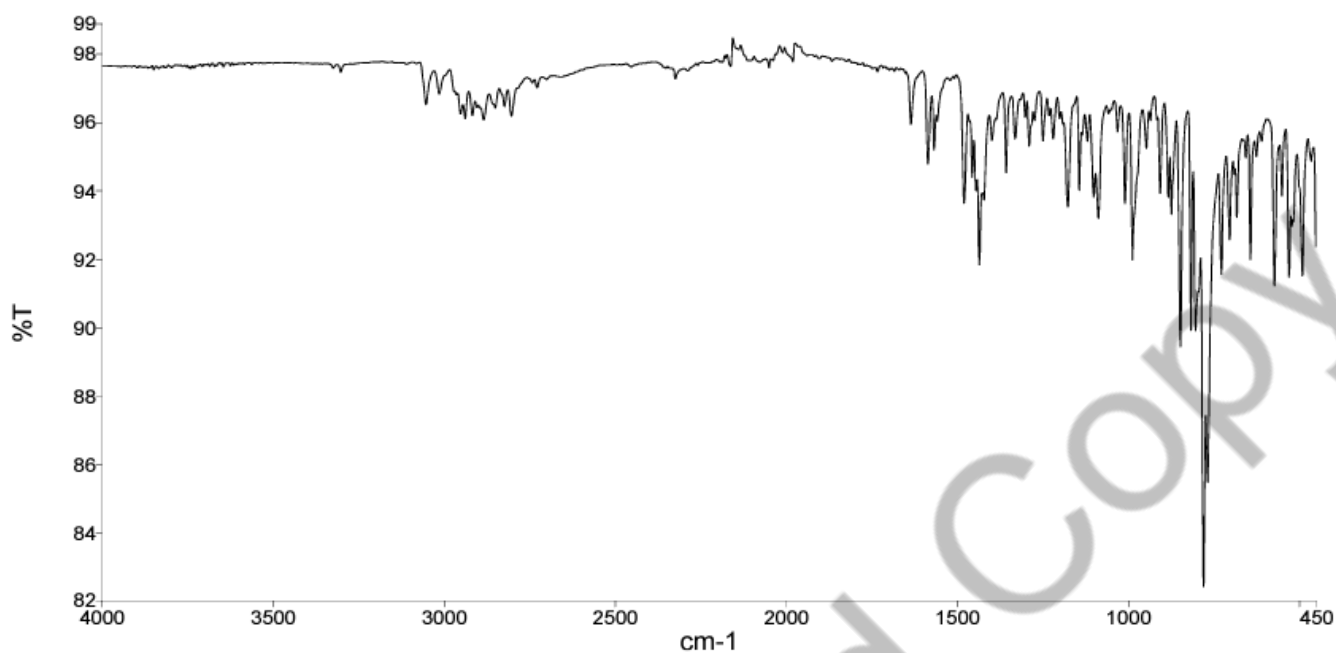
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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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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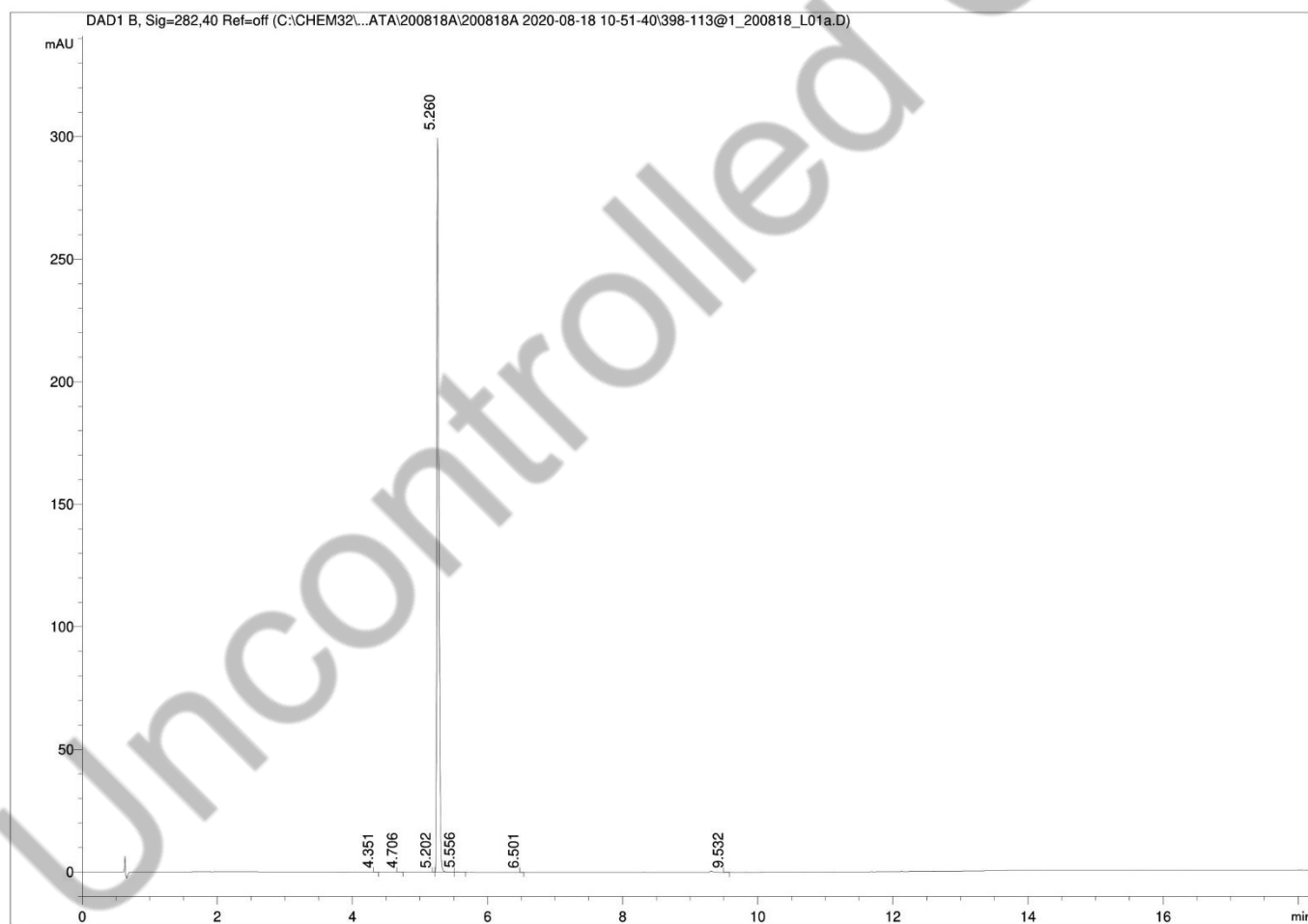
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II. Purity

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 282nm	Auto 1.0 µL 0.4 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	95	5	1.0		
	6.00	65	35	1.0		
	12.00	5	95	1.0		
	17.00	5	95	1.0		
	18.00	95	5	1.0		
	21.00	95	5	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.35	0.04	0.01
2	4.71	0.04	0.01
3	5.20	0.08	0.01
4	5.26	656.99	99.89
5	5.26	0.43	0.07
6	6.50	0.02	0.00
7	9.53	0.09	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 99.9% (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 2020 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)	99.9%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity	99.8%

This purity is assessed to be 99.8%.

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Carol Worth, PhD
Quality Manager

Release Date: 7 October 2022

The calculation of the purity follows the formula:

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

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