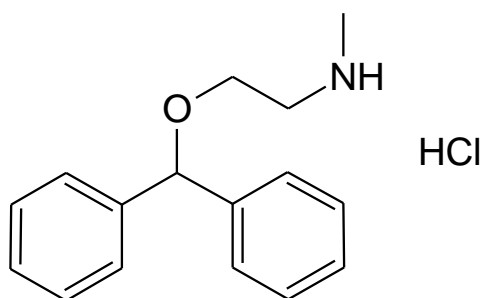


Reference Material Product Information Sheet

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



Name	desmethyldiphenhydramine hydrochloride
BP Name	Diphenhydramine Impurity A hydrochloride
Synonym(s)	<i>N</i> -(2-(benzhydryloxy)ethyl)- <i>N</i> -methylamine hydrochloride; 2-(benzhydryloxy)- <i>N</i> -methylethanaminium chloride; 2-(diphenylmethoxy)- <i>N</i> -methyl)ethanaminium chloride
Epichem Item #	EPL-AA11 Batch 16
CAS #	53499-40-4
Molecular Formula	C ₁₆ H ₁₉ NO.HCl
Molecular Weight	277.80 g/mol
Appearance	White powder
Melting Point	157.4-160.4°C
Combustion Analysis	Required (%): C:69.2; H:7.3; N:5.0. Found (%): C:69.1; H:7.3; N:5.1.
Purity*	99.8%
Date of Manufacture	10 August 2015
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-AA11 Batch 16

Revision 4

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

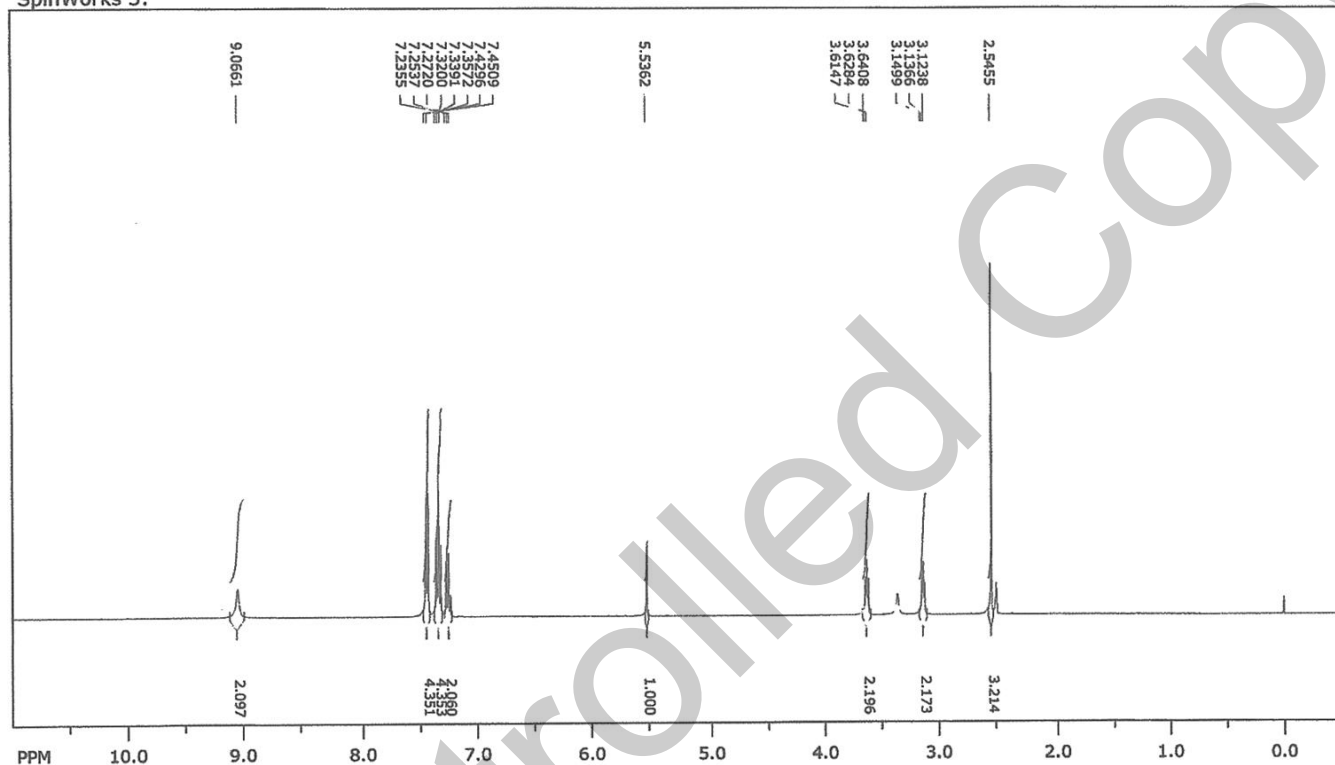
The identity of this product was established using the following analyses:

Ia. ¹H NMR Spectrum

Conditions: 400 MHz, DMSO-d₆

¹H NMR spectrum consistent with chemical structure.

SpinWorks 3:



file: ...nth\NMR data\
transmitter freq.: 400.177726 MHz
time domain size: 26232 points
width: 6402.56 Hz = 15.9993 ppm = 0.244074 Hz/pt
number of scans: 64

freq. of 0 ppm: 400.175305 MHz
processed size: 65536 complex points
LB: 0.000 GF: 0.0000
Hz/cm: 164.358 ppm/cm: 0.41071

EPL-AA11 Batch 16

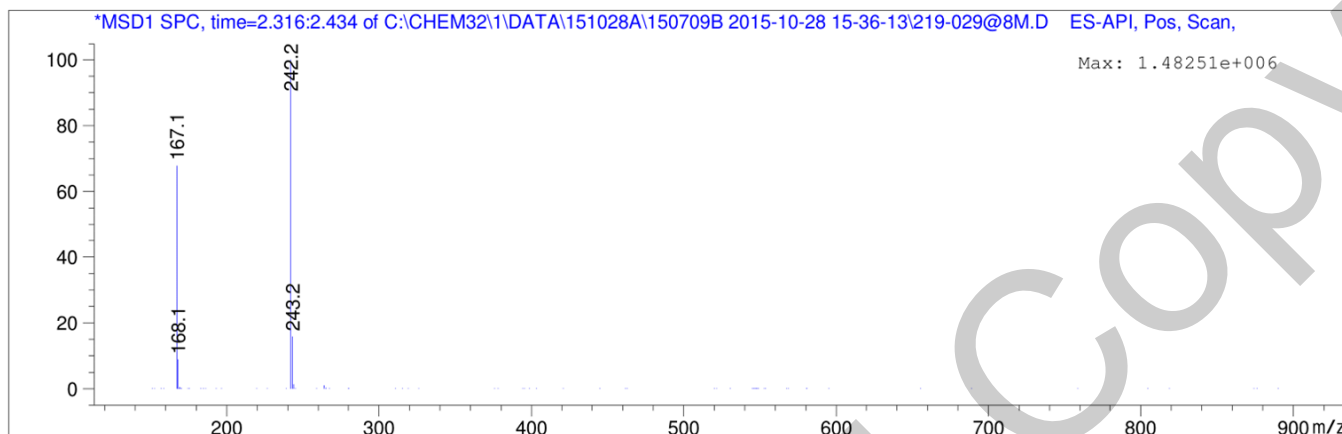
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Ib. Mass Spectrum

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

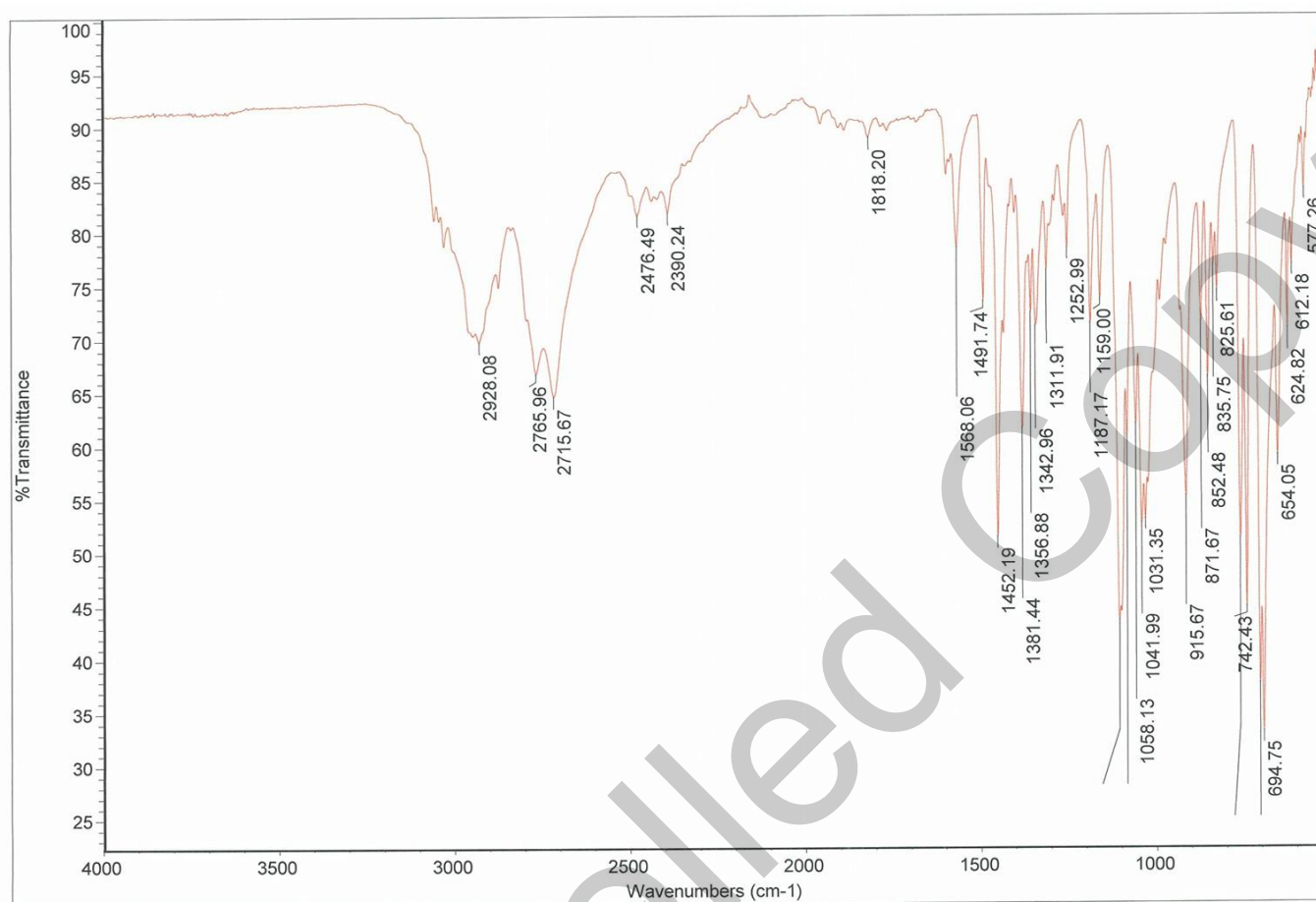


Theoretical value: 242.2 [M+H]⁺.

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 Infra-red Spectroscopy (FTIR) using in-house EM005.WI09.



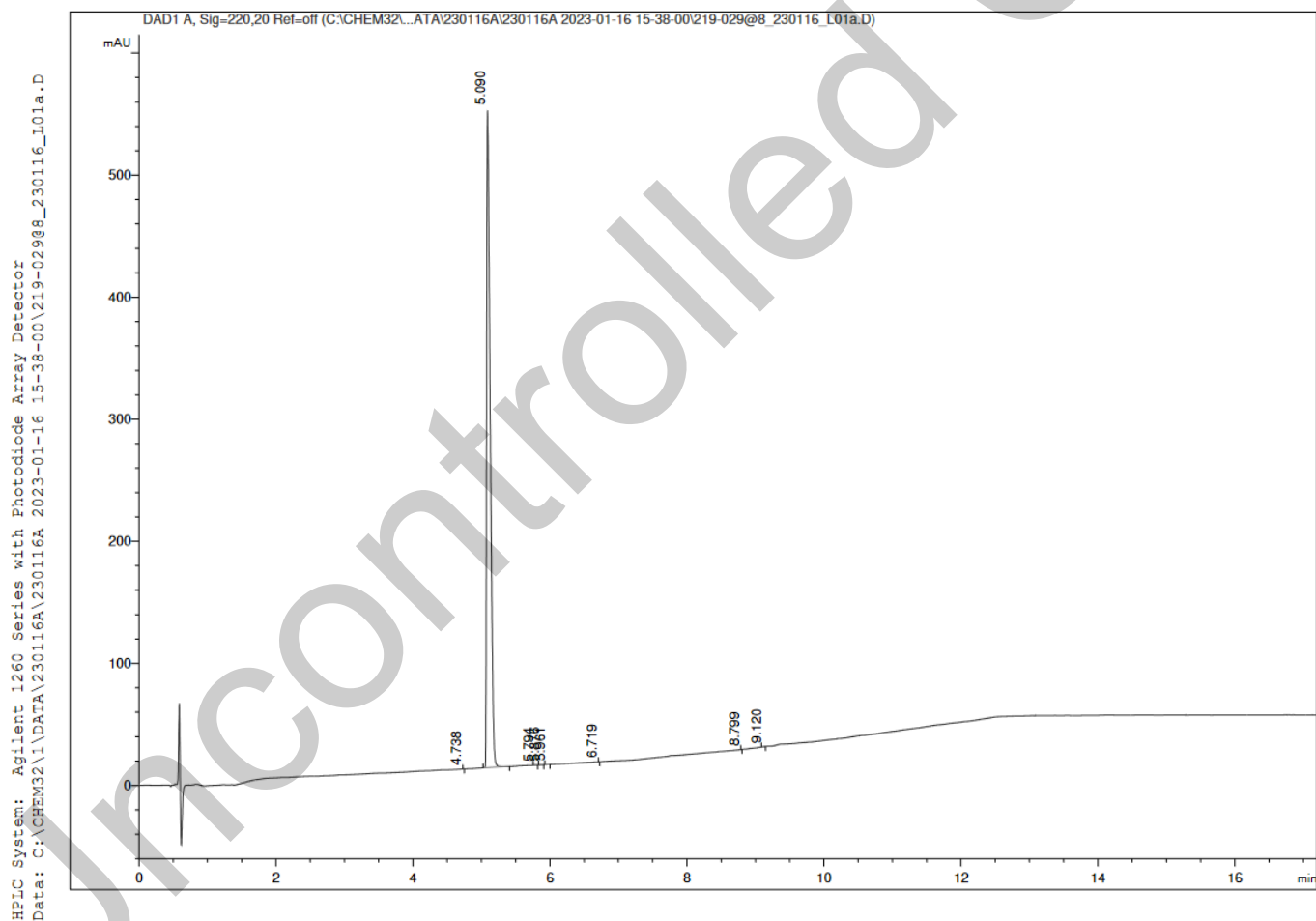
The interpretation of the signals of the Fourier Transform Infra-red Spectrum is consistent with the structural formula.

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 50 mm 2.7 micron	25°C				DAD 220nm	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	85	15	1.0		
	6.00	55	45	1.0		
	11.00	5	95	1.0		
	16.00	5	95	1.0		
	17.00	85	15	1.0		
	20.00	85	15	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	3.65	0.10	0.00
2	5.08	2055.15	99.95
3	5.78	0.19	0.01
4	5.87	0.29	0.01
5	5.95	0.27	0.01
6	9.12	0.23	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)

III. Water Content

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

Results:

Average 0.1%

IV. Ash Content

Method: BP2015 Ash (Appendix XI J) as per WS001/26397

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 Reference Standards

Carol Worth
Quality Manager

Release Date: 25 January 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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