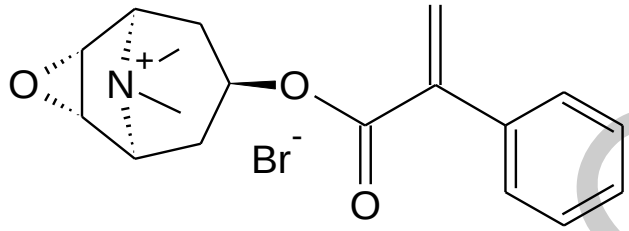
Our Formula. Your Success.

Reference Material Product Information Sheet

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



Name	Apomethylscopolamine bromide
Synonym(s)	3*endo*-atropoyloxy-6*exo*,7*exo*-epoxy-8,8-dimethyl-nortropanium bromide
Epichem Item #	EPL-AA134 Batch 1
CAS #	109668-57-7
Molecular Formula	$C_{18}H_{22}BrNO_3$
Molecular Weight	380.28 g/mol
Appearance	Colourless microcrystals
Melting Point	208.4-212.5°C (decomposition)
Combustion Analysis	Calculated for $C_{18}H_{22}BrNO_3$ (%): C:56.8; H:5.8; N:3.7; Br: 21.0. Found (%): C:54.4; H:6.1; N:3.6; Br:20.2 (consistent with water content).
Purity*	98.1%
Date of Manufacture	26 March 2013
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-AA134 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

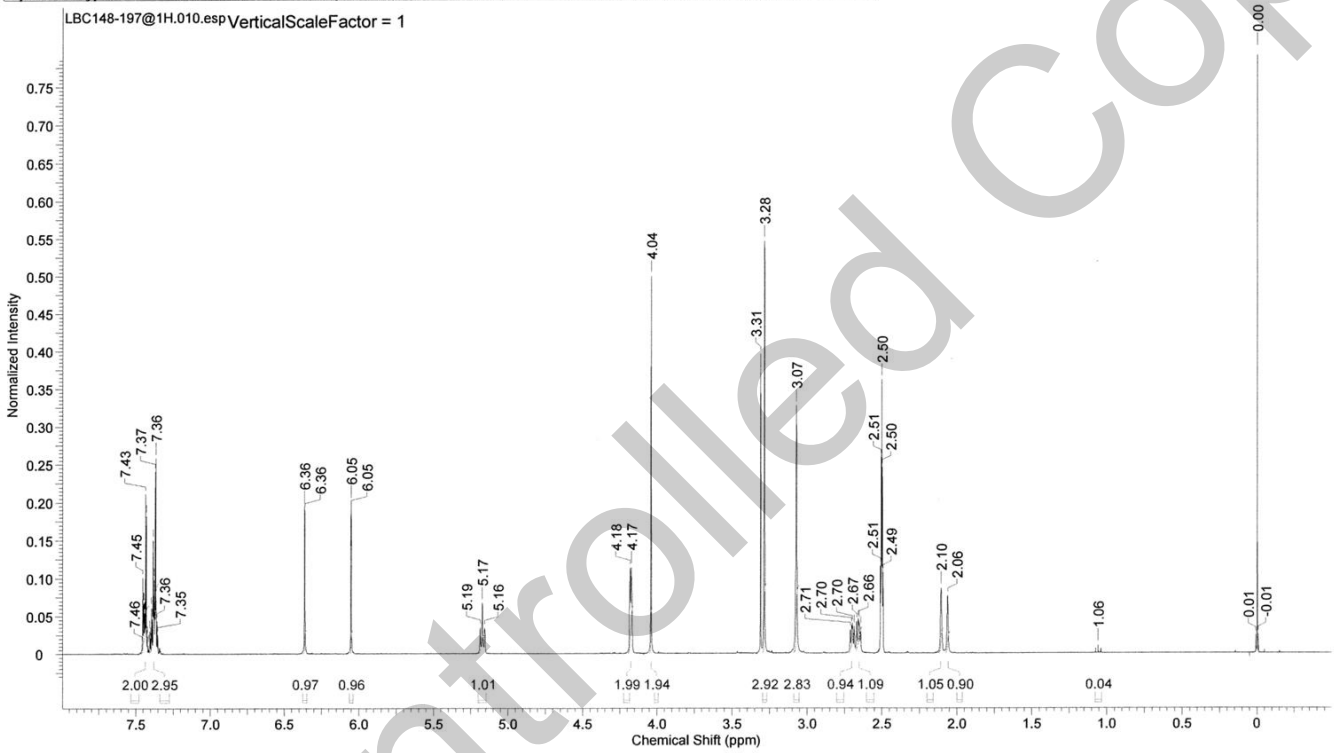
The identity of this product was established using the following analyses:

Ia. ^{1}HNMR Spectrum

Conditions: 400 MHz, DMSO-d_6

^{1}HNMR spectrum consistent with chemical structure.

Acquisition Time (sec)	4.9999	*Comment*	1H DMSO {E:\data\epichem} epichem 3			*Date*	27 Mar 2013 13:24:16
Date Stamp	27 Mar 2013 13:24:16						
File Name	\\benzene\company\Working file folders\R&D012\CRD projects\CRD022 - Apomethylscopolamine bromide\NMR Data\LBC148-197@1H\10\fid						
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	114.00	*SW(cyclical) (Hz)*	4807.69	*Solvent*	DMSO-d6	*Spectrum Offset (Hz)*	2197.5688
Spectrum Type	STANDARD	*Sweep Width (Hz)*	4807.55	*Temperature (degree C)*	26.836		



EPL-AA134 Batch 1

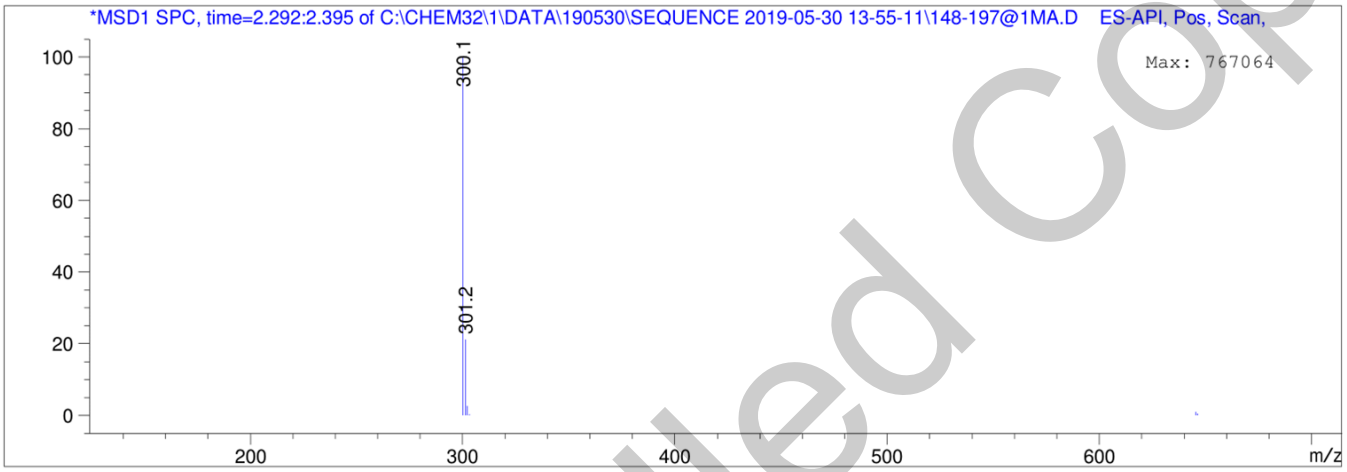
Ib. Mass Spectrum

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
2.322	10834378	301.20 I 300.10 I



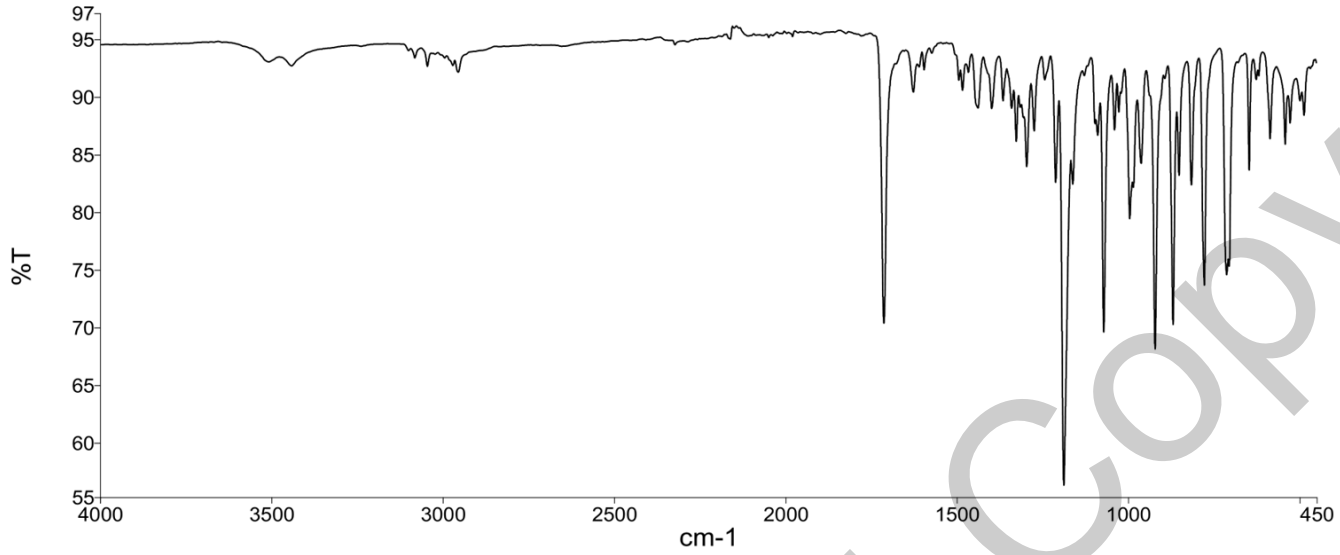
Theoretical value: 300.1 $[M\text{-}Br]^+$.

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

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

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.

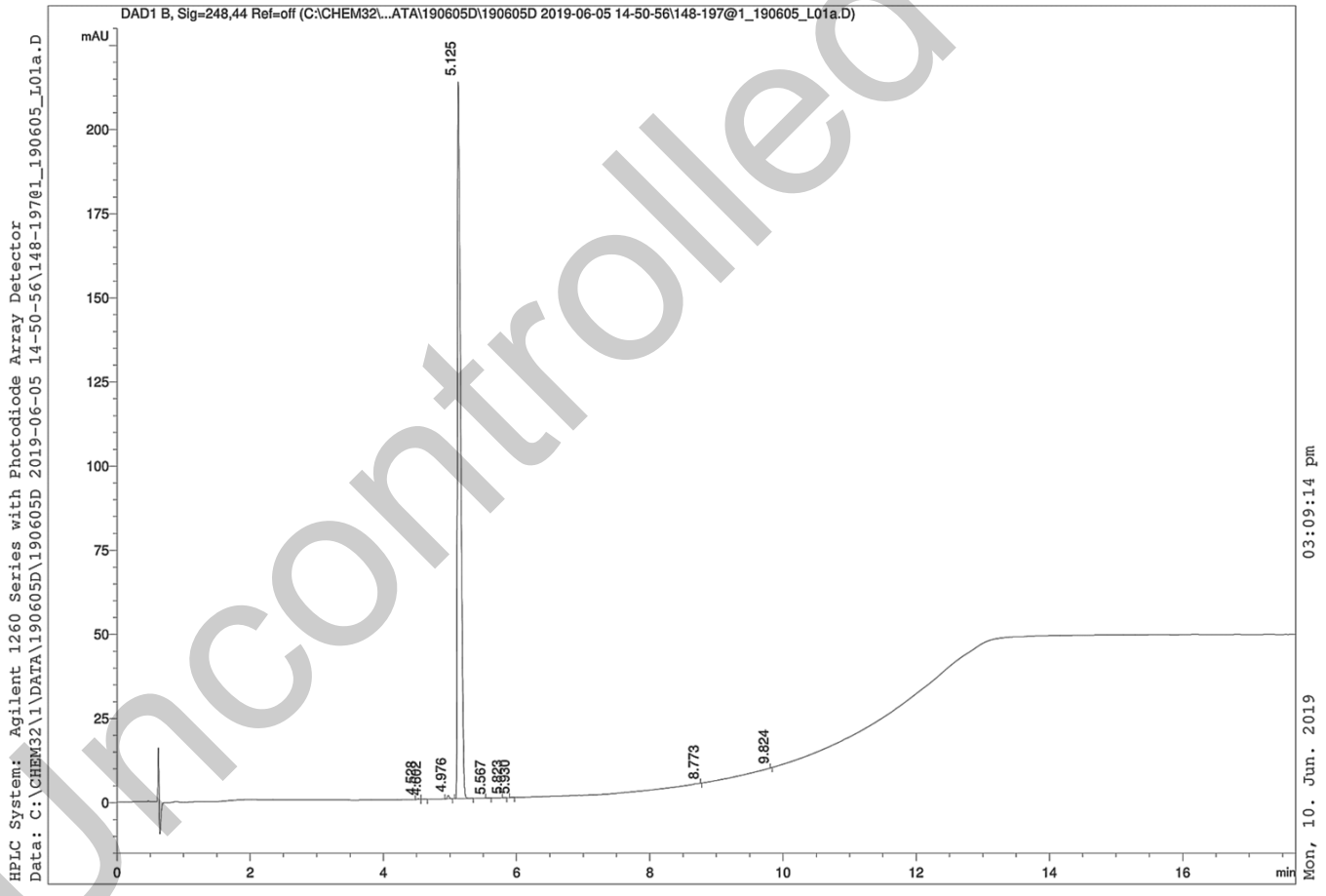
EPL-AA134 Batch 1

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	25ºC				DAD 248nm	Auto 1.0 µL 1.40 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	90	10	1.0		
	6.00	60	40	1.0		
	11.50	5	95	1.0		
	16.50	5	95	1.0		
	17.50	90	10	1.0		
	20.50	90	10	1.0		



EPL-AA134 Batch 1

Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.53	0.40	0.06
2	4.60	0.20	0.03
3	4.98	2.11	0.29
4	5.12	719.01	99.60
5	5.57	0.04	0.01
6	5.82	0.03	0.00
7	5.93	0.06	0.01
8	8.77	0.01	0.00
9	9.82	0.04	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 99.6% (average of 10 duplicate analyses)

EPL-AA134 Batch 1

III. Water Content

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

Results:

Average 1.3%

IV. Ash Content

Method: BP2013 Ash

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ^{1}HNMR

Result:

0.2% Ethanol by ^{1}H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.6%
Water content	1.3%
Ash content	<0.1%
Residual solvents	0.2%
Purity*	98.1%

This purity is assessed to be 98.1%.

Product Reviewed By:

John Moursounidis, PhD
Head Reference Standards

Product Released By:

Boon Tan
Quality Manager

Release Date: 26 July 2019

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

The calculation of the purity follows the formula:

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

EPL-AA134 Batch 1