



Accredited for compliance with ISO 17034  
This document shall not be reproduced except in full.  
Accreditation Number: 20126  
Corporate Site Number: 24143

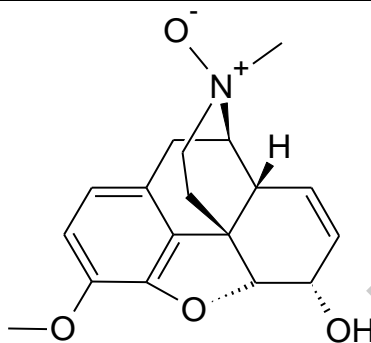
The results of the tests, calibrations and/or measurements included in this document are traceable to Australia/national standards.  
NATA is a signatory to the APLAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of reference materials certificates.



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.



<b>Name</b>	codeine- <i>N</i> -oxide
<b>Synonym(s)</b>	(5 $\alpha$ )-7,8-didehydro-4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol- <i>N</i> -oxide; genocodeine.
<b>Epichem Item #</b>	EPL-AA35 Batch 21
<b>CAS #</b>	3688-65-1
<b>Molecular Formula</b>	C <sub>18</sub> H <sub>21</sub> NO <sub>4</sub>
<b>Molecular Weight</b>	315.36 g/mol
<b>Appearance</b>	Beige crystals
<b>Melting Point</b>	217.5-220.4°C (decomposition)
<b>Combustion Analysis</b>	Required (%): C:68.6; H:6.7; N:4.4. Found (%): C:64.5; H:7.4; N:3.9.
<b>Purity*</b>	95.8%
<b>Date of Manufacture</b>	15 September 2016
<b>Storage Requirements</b>	Hygroscopic. 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>	16 March 2020 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>	18 March 2021 (Proper Storage and Handling Required)

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

EPL-AA35 Batch 21

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

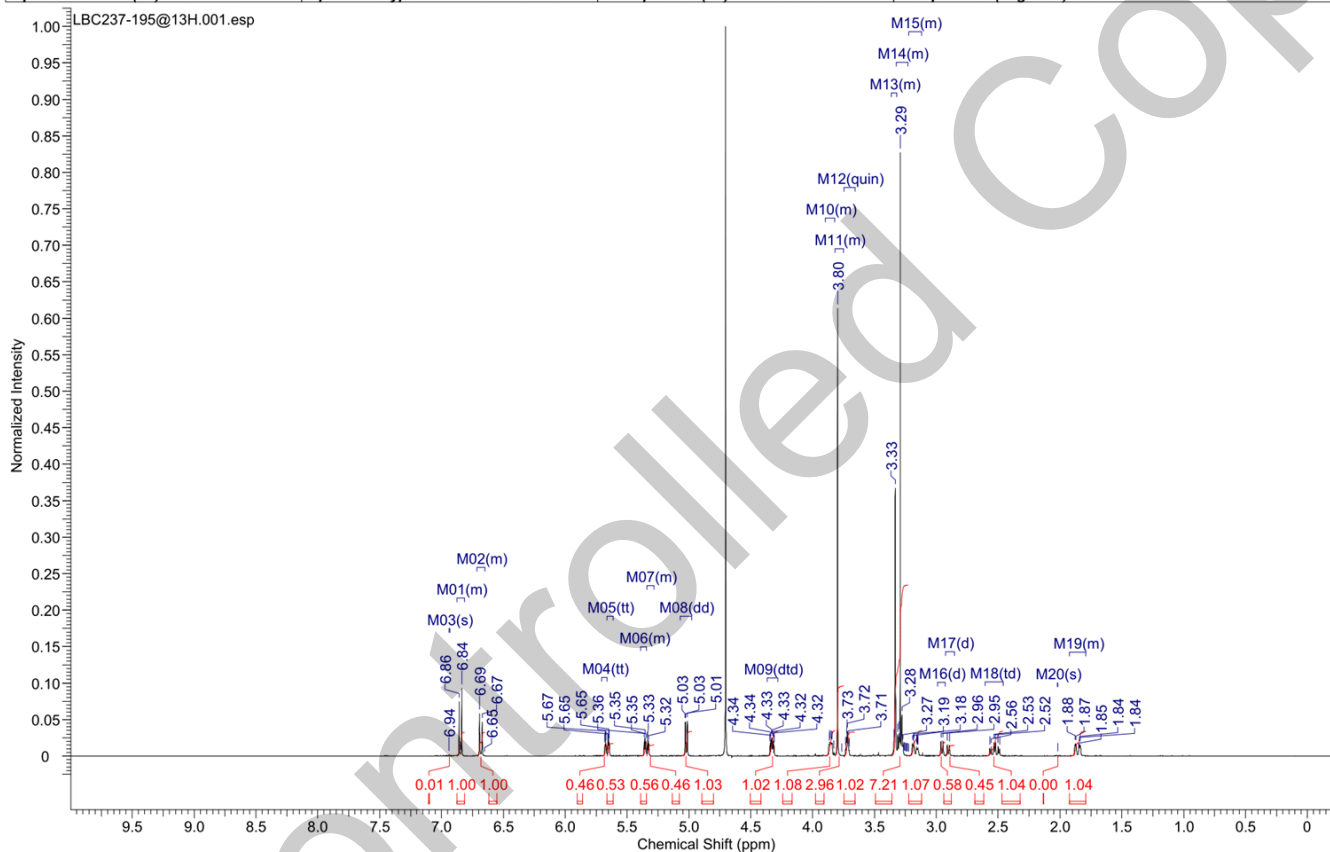
The identity of this product was established using the following analyses:

### Ia. <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	LBC237-195@13H 1H D2O (E:\data\external\epichem) cygoh 7	Date	30 Aug 2016 08:12:48
Date Stamp	30 Aug 2016 08:12:48	File Name	\\NAPHTHALENE\Company\NMR files\LBC237-195@13H\1fid		
Frequency (MHz)	400.13	Nucleus	1H	Number of Transients	8
Original Points Count	24038	Owner	nmr	Points Count	32768
Receiver Gain	128.00	SW(cyclical) (Hz)	6402.05	Solvent	DEUTERIUM OXIDE
Spectrum Offset (Hz)	2800.9097	Spectrum Type	STANDARD	Sweep Width (Hz)	6401.85
				Temperature (degree C)	26.945



EPL-AA35 Batch 21

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

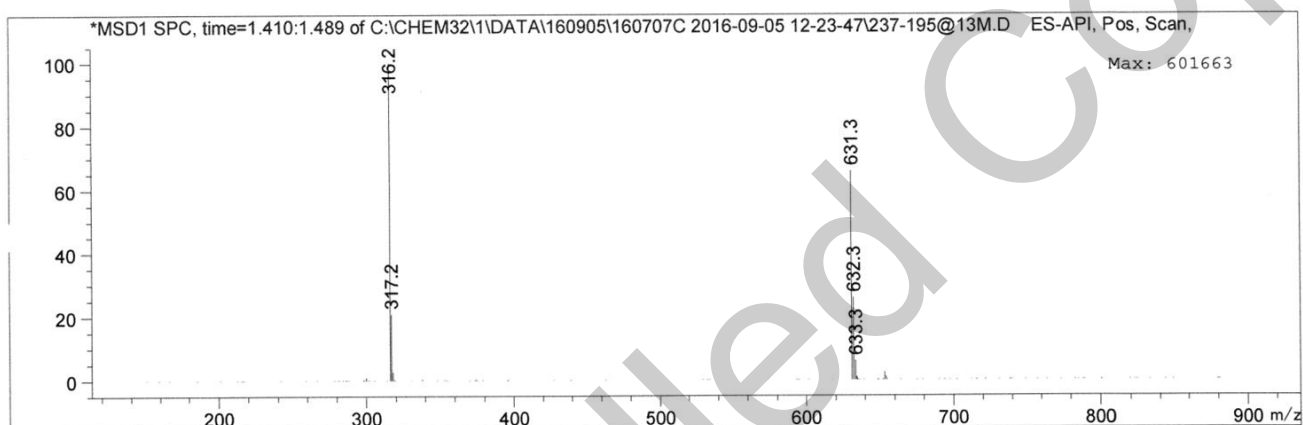
ABN 80 106 769 902

## Ib. Mass Spectrum

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

Method: 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
1.437	10775793	632.30 I
		631.30 I
		317.20 I
		316.20 I



Theoretical value: 316.2 [M+H]<sup>+</sup>.

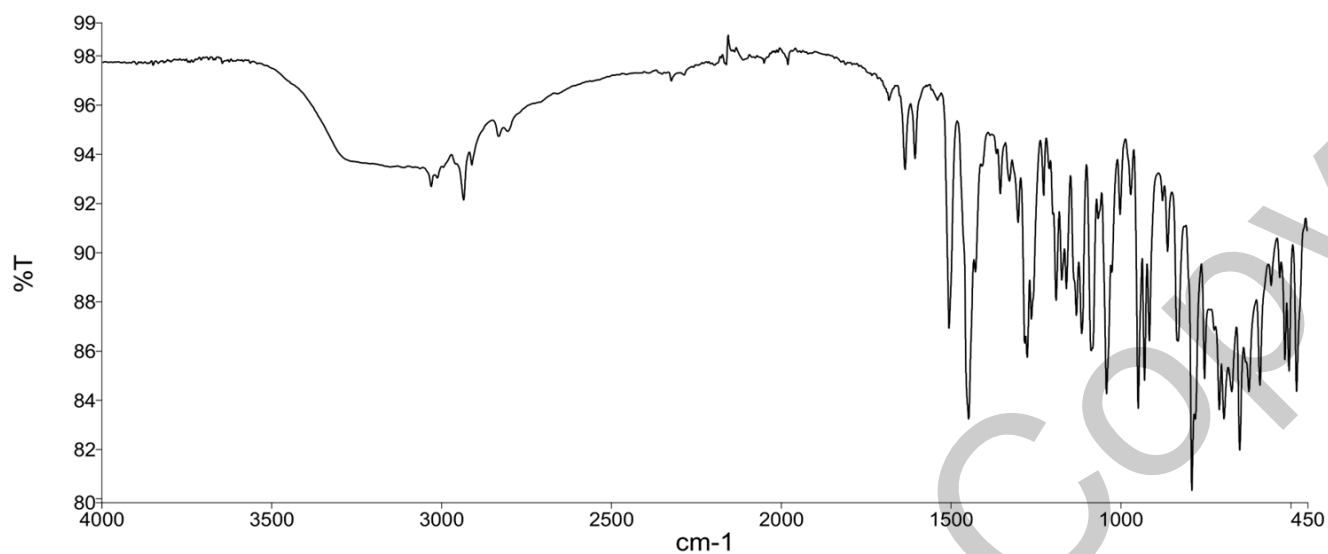
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

EPL-AA35 Batch 21

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-AA35 Batch 21

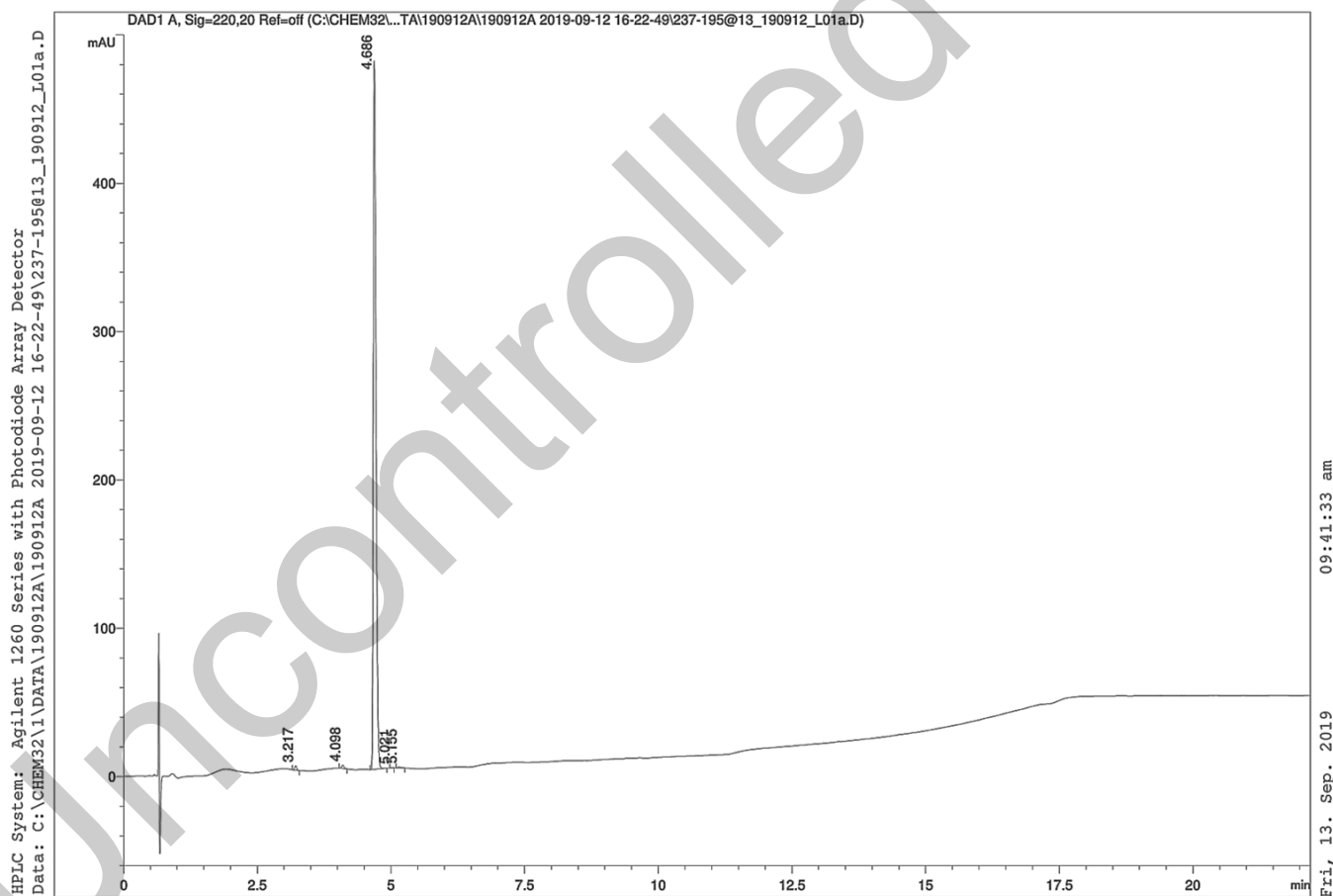
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia  
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

## 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 220nm	Auto 1.0 µL 0.8 mg/mL in 50% water / 50% acetonitrile (+0.1% TFA)
	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		
	5.00	85	15	1.0		
	10.00	65	35	1.0		
	16.00	5	95	1.0		
	21.00	5	95	1.0		
	22.00	95	5	1.0		
	25.00	95	5	1.0		



EPL-AA35 Batch 21

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	3.21	8.90	0.48
2	4.09	7.04	0.38
3	4.68	1833.03	99.00
4	5.01	0.78	0.04
5	5.15	1.77	0.10
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 99.1% (average of 10 duplicate analyses)

EPL-AA35 Batch 21

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 3.3%

### IV. Ash Content

Method: BP2016 Ash (Appendix XI J) as per WS001/C29331

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>HNMR

**Result:**

No significant impurities by <sup>1</sup>H NMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	99.1%
Water content	3.3%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	95.8%

This purity is assessed to be 95.8%.

Product Reviewed By:

Product Released By:

John Moursounidis, PhD  
Head Reference Standards

Boon Tan  
Quality Manager

Release Date: 13 September 2019

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

The calculation of the purity follows the formula:

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

EPL-AA35 Batch 21

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