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epichem

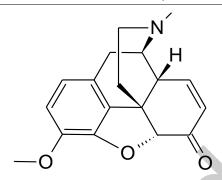
The results of the tests, calibrations and/or measurements included in this document are traceable to Australia/national standards.

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.



Synonym(s) (5α)-7,8-didehydro-4,5-epoxy-3-methoxy-17-methylmorphinan-6-one  Epichem Item # EPL-AA33 Batch 11  CAS # 467-13-0  Molecular Formula C <sub>18</sub> H <sub>19</sub> NO <sub>3</sub> Molecular Weight 297.36 g/mol  Appearance Tan powder  Melting Point 181.4-184.5°C (decomposition)  Combustion Analysis Required (%): C:72.7; H:6.4; N:4.7. Found (%): C:72.5; H:6.6; N:4.7.  Purity* 99.1%  Date of Manufacture 24 August 2018  Storage Requirements Protect from heat, light and moisture.  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.  WARNING: This material is a S8 narcotic. It should not be forwarded on to any third party without citation of an appropriate license to hold.  Intended Use This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.  TBA  This certificate is valid for one year from the date of shipment provided the substance is unopened and stored under the recommended conditions.				
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unopened and stored under the recommended conditions.	Date of Shipment	TBA		
Retest Date TBA (Proper Storage and Handling Required)				
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<sup>\*</sup> NATA accreditation does not cover the performance of this service

EPL-AA33 Batch 11 Revision 1

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
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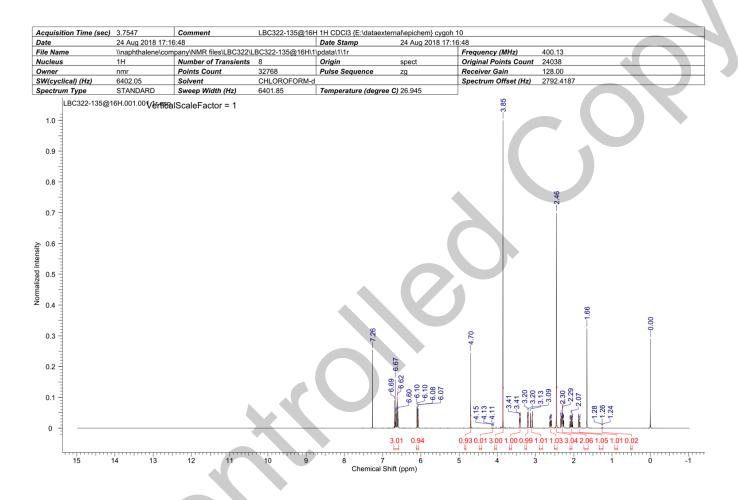
## I. Identity

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

#### Ia. <sup>1</sup>HNMR Spectrum

Conditions: 400 MHz, CDCl<sub>3</sub>

<sup>1</sup>HNMR spectrum consistent with chemical structure.



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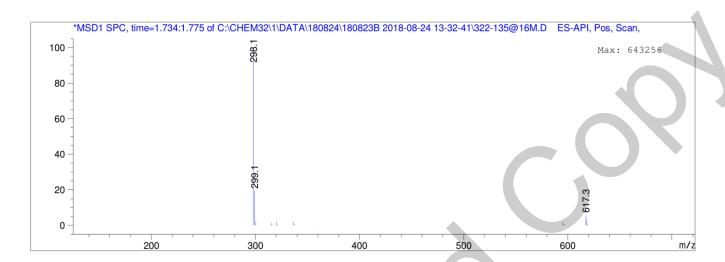
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### **Ib.** Mass Spectrum

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

Method: ACN/water gradient (+ 0.1% formic acid).

ZORBAX SB-C8, 4.6 x 30 mm, 3.5 micron.



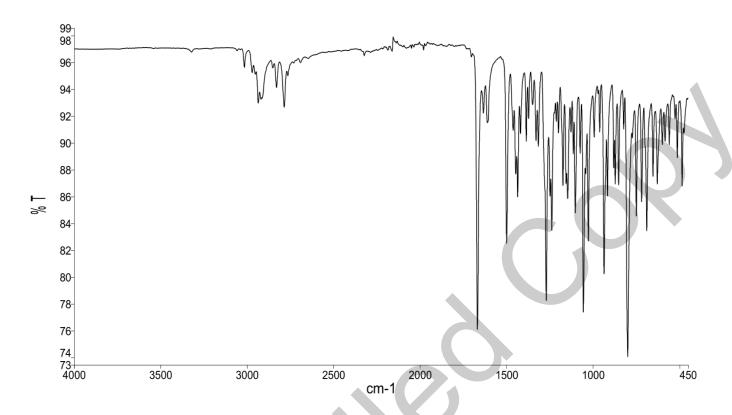
Theoretical value: 298.1 [M+H]+.

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 Infra-red Spectroscopy (FTIR) using inhouse EM005.WI09.



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

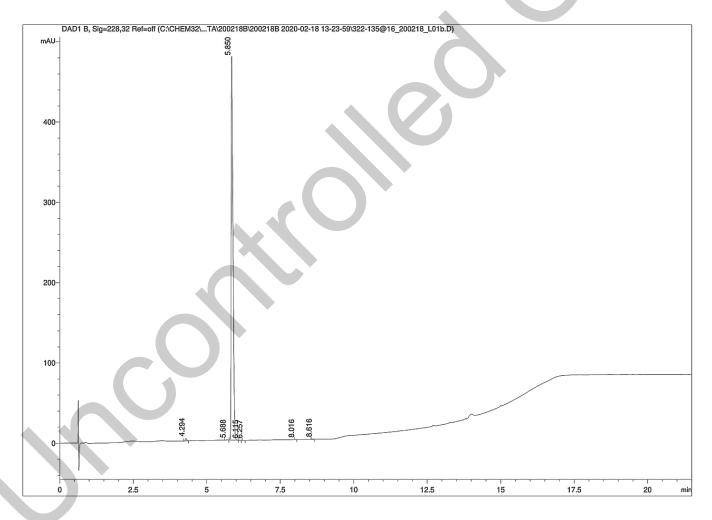
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## II. Purity

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	25°C				DAD	Auto
120 EC-C18	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)	228nm	1.0 µL 0.80 mg/mL in
4.6 x 50mm	0.00	94	6	1.0		50% acetonitrile 50% water
2.7 micron	8.00	78	22	1.0		(NO MODIFIERS)
	15.30	5	95	1.0		
	20.30	5	95	1.0		
	21.30	94	6	1.0		
	24.30	94	6	1.0		



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## Area Percent Report - Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.29	9.12	0.47
2	5.68	0.81	0.04
3	5.84	1937.03	99.44
4	6.08	0.21	0.01
5	6.24	0.26	0.01
6	8.01	0.19	0.01
7	8.63	0.22	0.01
8	9.96	0.03	0.00
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 99.4% (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: BP2018 Ash (Appendix XI J) Method II

**Result:** 

Contains <0.1% ash.

#### V. Residual Solvents

Method: <sup>1</sup>HNMR

**Result:** 

Contains 0.2% ethyl acetate by <sup>1</sup>H NMR analysis.

## VI. Final Result

Chromatographic purity (HPLC)	99.4%
Water content	0.1%
Ash content	<0.1%
Residual solvents	0.2%
Purity*	99.1%

This purity is assessed to be 99.1%.

Product Reviewed By:

Product Released By:

John Moursounidis, PhD Head Reference Standards

Boon Tan Quality Manager 19 February 2020

\*NATA accreditation does not cover the performance of this service. The calculation of the purity follows the formula:

 $Purity(\%) = \frac{((Chromatographic purity[HPLC])x(100 - (water content + ashcontent + volatile contents)))}{100}$ 

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