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Accreditation Number 20126

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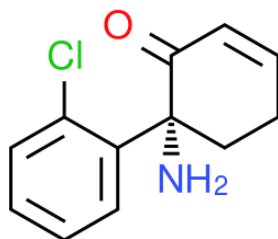
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## Reference Material Product Information Sheet

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



<b>Name</b>	(R)-dehydronorketamine
<b>BP/EP Name</b>	Not Listed
<b>USP Name</b>	Not Listed
<b>Synonym(s)</b>	(6R)-6-amino-6-(2-chlorophenyl)cyclohex-2-en-1-one
<b>Epichem Item #</b>	EPL-AA212 Batch 1
<b>CAS #</b>	153381-93-2
<b>Molecular Formula</b>	C <sub>12</sub> H <sub>12</sub> ClNO
<b>Molecular Weight</b>	221.69 g/mol
<b>Appearance</b>	White powder
<b>Melting Point</b>	75.5-79.6°C
<b>Combustion Analysis</b>	Required (%): C:65.0; H:5.5; N:6.3. Found (%): C:65.0; H:5.6; N:6.6.
<b>Purity*</b>	98.7%
<b>Enantiomeric Purity</b>	99.2% by chiral HPLC.
<b>Date of Manufacture</b>	16 January 2017
<b>Storage Requirements</b>	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>	TBA This certificate is valid for one year from the date of shipment provided the substance is stored under the recommended conditions.
<b>Retest Date</b>	TBA (Proper Storage and Handling Required)

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

EPL-AA212 Batch 1

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## I. Identity

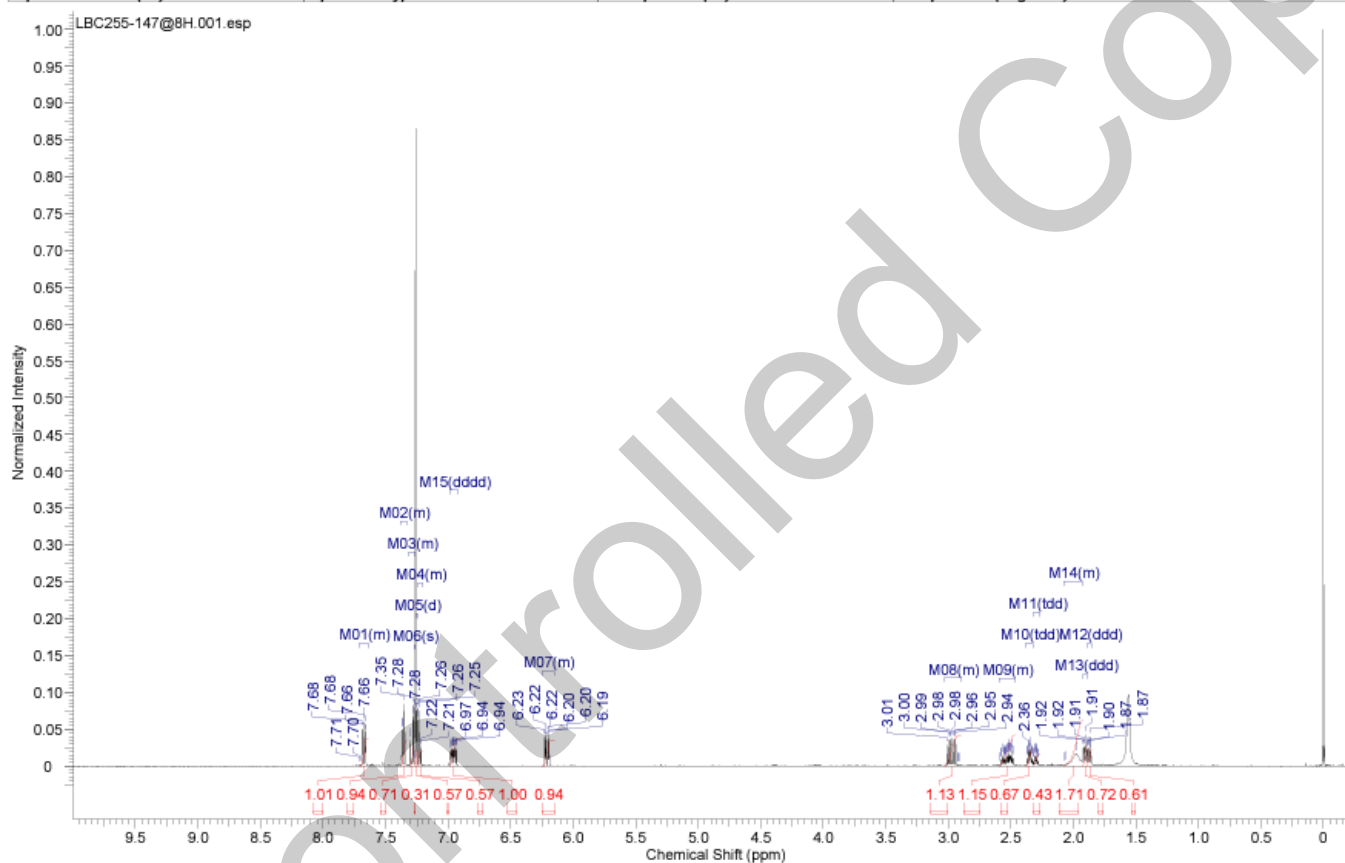
The identity of this product was established using the following analyses:

### Ia. <sup>1</sup>H NMR Spectrum

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

<sup>1</sup>H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	1H CDCl3 (E:\data\external\epichem)\epichem 9	Date	04 Jan 2017 11:35:28		
Date Stamp	04 Jan 2017 11:35:28	File Name	\\NAPHTHALENE\Company\NMR files\170104\LBC255-147@8H\1fid				
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	203.00	SW (cyclical) (Hz)	6402.05	Solvent	CHLOROFORM-d		
Spectrum Offset (Hz)	2791.1824	Spectrum Type	STANDARD	Sweep Width (Hz)	6401.85	Temperature (degree C)	26.836



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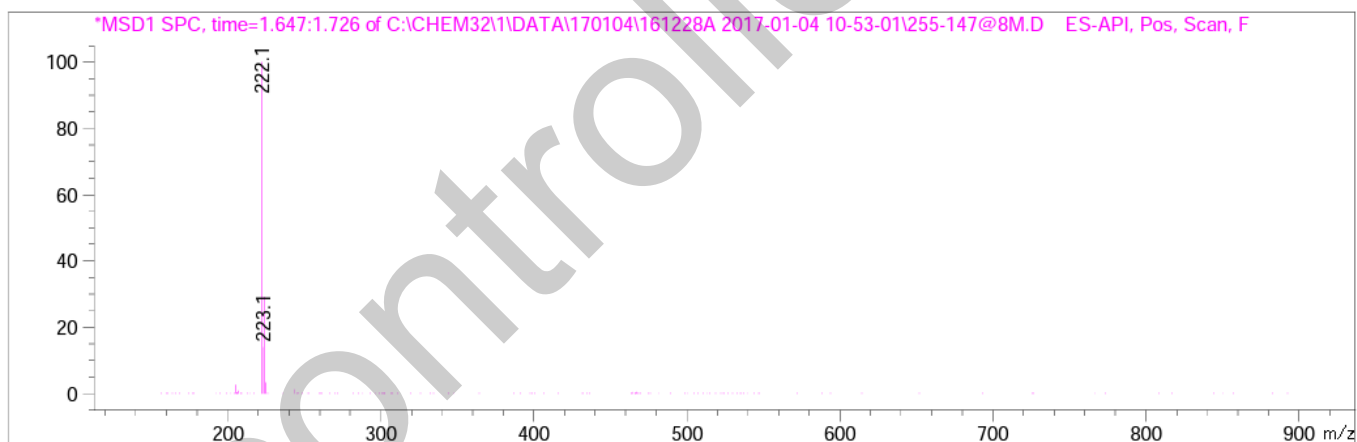
## Ib. Mass Spectrum

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)

LC6: Poroshell 120 EC-C18, 4.6 x 50 mm, 2.7 micron

Retention Time (MS)	MS Area	Mol. Weight or Ion
0.954	53630	279.10 I
1.152	505562	242.20 I 241.10 I 240.10 I
1.471	305326	242.05 I 241.10 I 240.05 I
1.673	11349023	224.20 I 223.10 I 222.10 I
1.835	2322686	224.15 I 223.15 I 222.15 I



Theoretical values: 222.1 [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.

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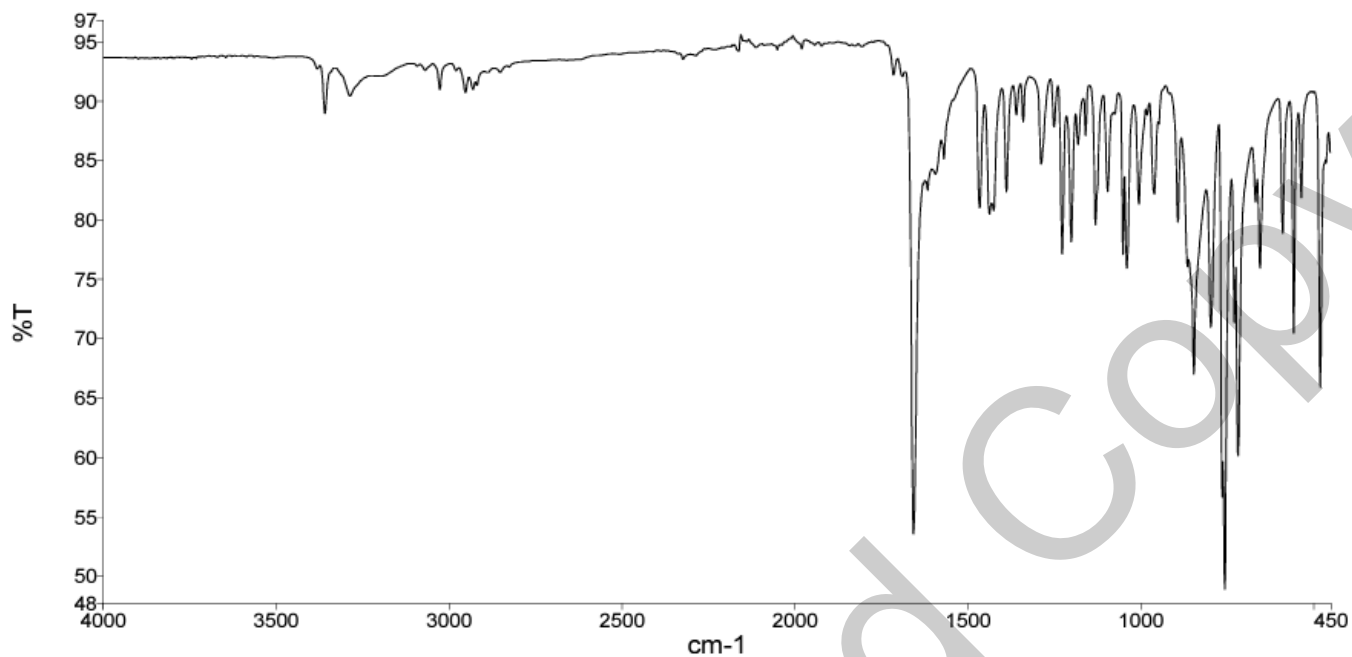
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### Ic. IR Spectrum

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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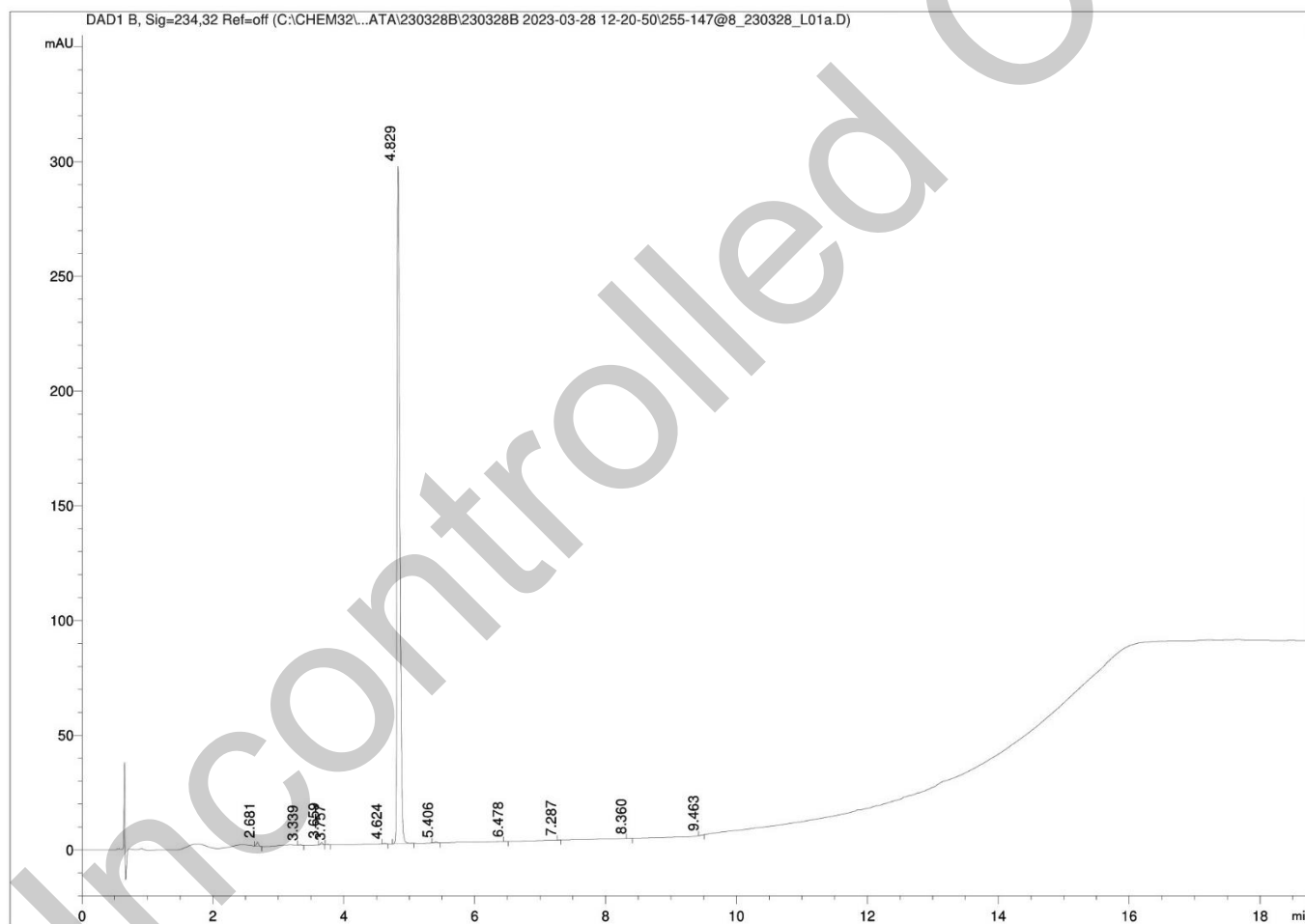
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## II. Purity

The purity of this material was analysed by high performance liquid chromatography (HPLC) using in-house EM005.WI07.

### HPLC Conditions:

Column	Conditions				Detector	Injector
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
Agilent Poroshell 120 EC-C18	25°C				DAD 234nm	Auto
4.6 x 50mm	0.00	95	5	1.0		1.0 µL
2.7 micron	8.00	71	29	1.0		0.50 mg/mL in 50% acetonitrile 50% water (NO MODIFIERS)
	14.60	5	95	1.0		
	17.60	5	95	1.0		
	18.60	95	5	1.0		
	21.60	95	5	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.68	3.98	0.45
2	3.34	0.70	0.08
3	3.66	2.40	0.27
4	3.76	0.42	0.05
5	4.62	0.81	0.09
6	4.83	880.71	98.84
7	5.41	1.38	0.15
8	6.48	0.11	0.01
9	7.29	0.07	0.01
10	8.36	0.30	0.03
11	9.46	0.21	0.02
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 98.8% (average of 10 duplicate runs)

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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 2017 Ash (Appendix XI J) as per WS001/C30139

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>H NMR

**Result:**

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

### VI. Final Result

Chromatographic purity (HPLC)	98.8%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	98.7%

This purity is assessed to be 98.7%.

Product Reviewed By:

Product Released By:

James Rixson, PhD  
Head of Production

Carol Worth, PhD  
Quality Manager

Release Date: 12 April 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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