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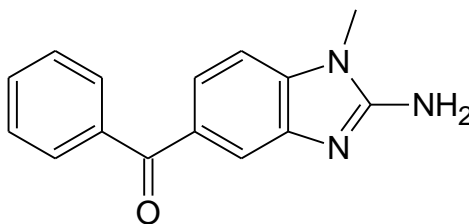
The results of the tests, calibrations and/or measurements included in this document are traceable to Australia/national standards.  
NATA is a signatory to the APLAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of reference materials certificates.



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>	(2-amino-1-methyl-1H-benzimidazol-5-yl)phenylmethanone
<b>Synonym(s)</b>	2-amino-5-benzoyl-1-methylbenzimidazole
<b>BP Name</b>	Mebendazole Impurity C
<b>Epichem Item #</b>	EPL-AA250 Batch 1
<b>CAS #</b>	66066-76-0
<b>Molecular Formula</b>	C <sub>15</sub> H <sub>13</sub> N <sub>3</sub> O
<b>Molecular Weight</b>	251.29 g/mol
<b>Appearance</b>	Orange pink powder
<b>Melting Point</b>	219.3– 221.4°C
<b>Combustion Analysis</b>	Required (%): C: 71.7, H: 5.2, N: 16.7. Found (%): C: 71.4, H: 5.0, N: 16.6.
<b>Purity*</b>	98.8%
<b>Date of Manufacture</b>	14 August 2019
<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 unopened and 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-AA250 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:

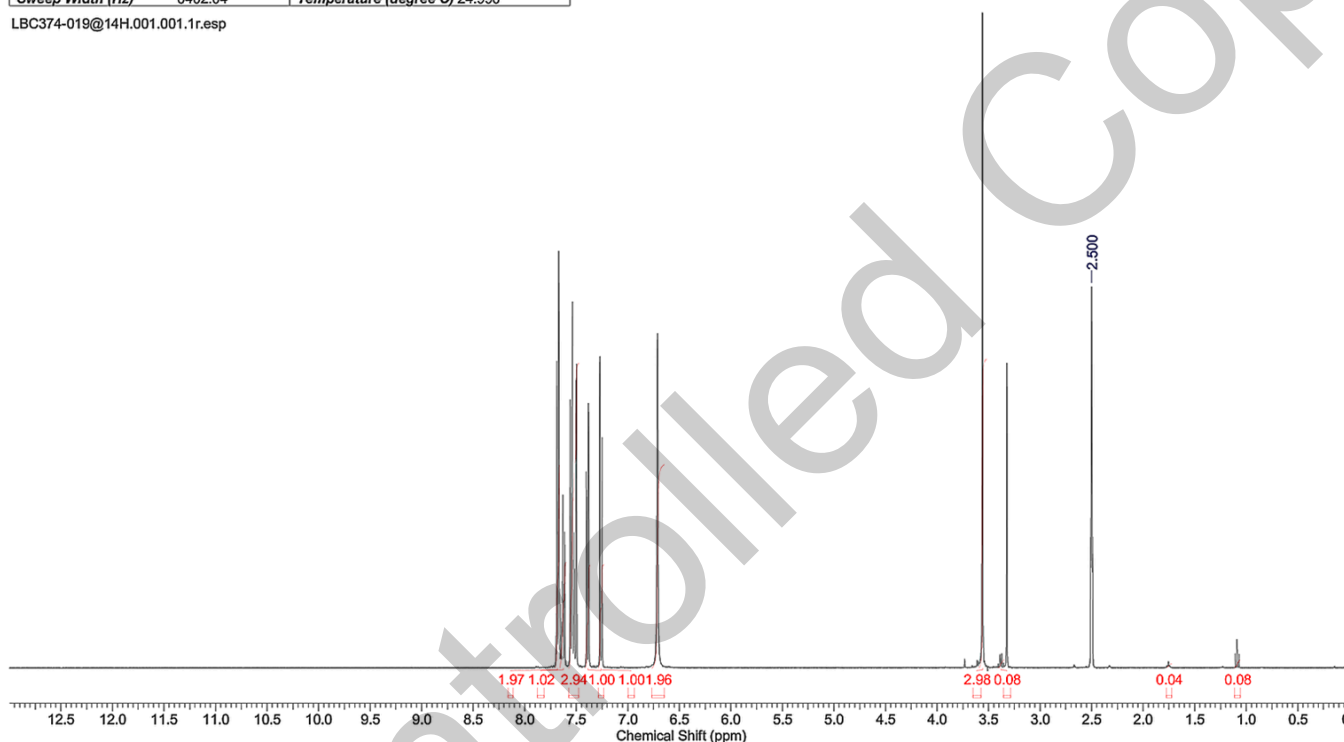
### Ia. <sup>1</sup>H NMR Spectrum

Conditions: 400 MHz, DMSO-d<sub>6</sub>

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

Acquisition Time (sec)	3.7547	Comment	LBC374-019@14H 1H DMSO (E:\dataexternal\epichem) cygoh 5			
Date	13 Aug 2019 17:23:12	Date Stamp	13 Aug 2019 17:23:12			
File Name	\naphthalene\company\NMR files\LBC374\LBC374-019@14H1\data\1r		Frequency (MHz)	400.13		
Nucleus	1H	Number of Transients	8	Origin	spect	
Owner	nmr	Points Count	1048576	Original Points Count	24038	
SW(cyclical) (Hz)	6402.05	Solvent	DMSO-d6	Pulse Sequence	zg	
Sweep Width (Hz)	6402.04	Temperature (degree C)	24.996	Receiver Gain	161.00	
			Spectrum Offset (Hz)	2798.5598	Spectrum Type	STANDARD

LBC374-019@14H.001.001.1r.esp



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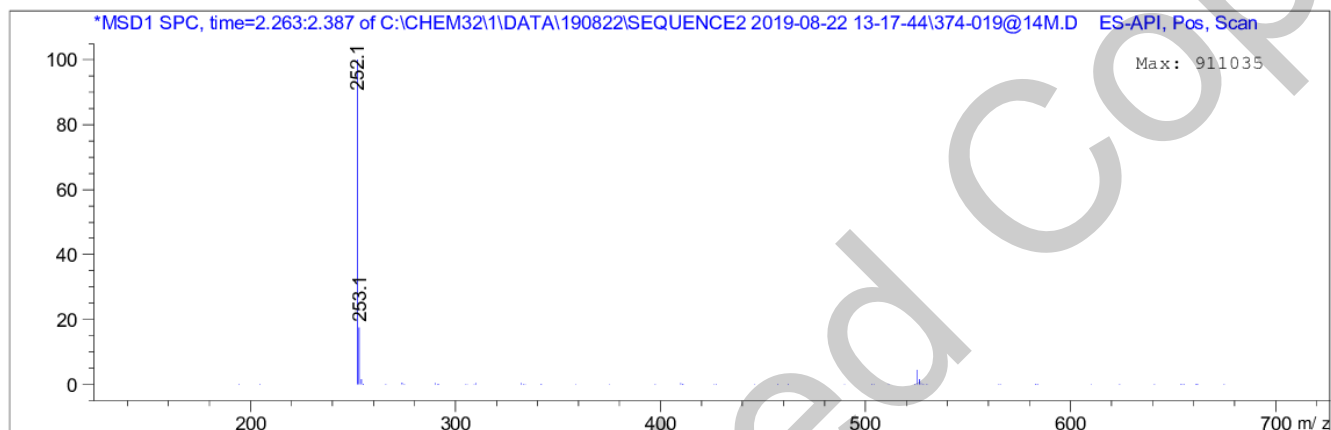
ABN 80 106 769 902

## Ib. Mass Spectrum

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

Method: 5-100% ACN in water gradient (+0.1% formic acid)  
Zorbax Eclipse XDB-C8, 3.0 x 100, 3.5 micron

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.313	12266486	253.10 I
		252.10 I



Theoretical value: 252.1 [M+H]<sup>+</sup>

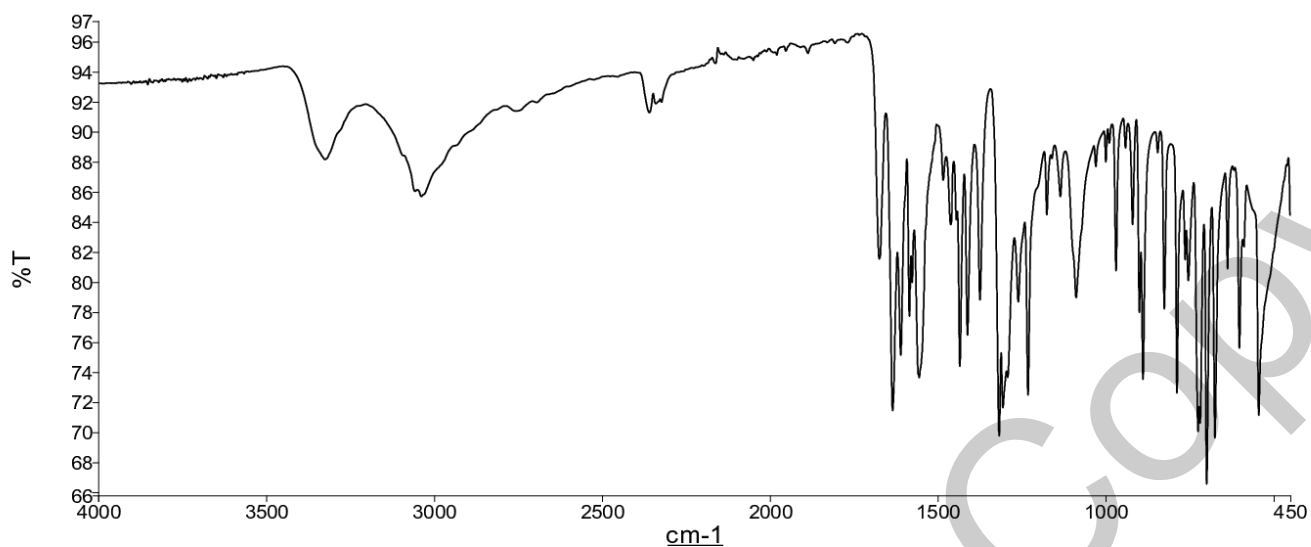
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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### 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.

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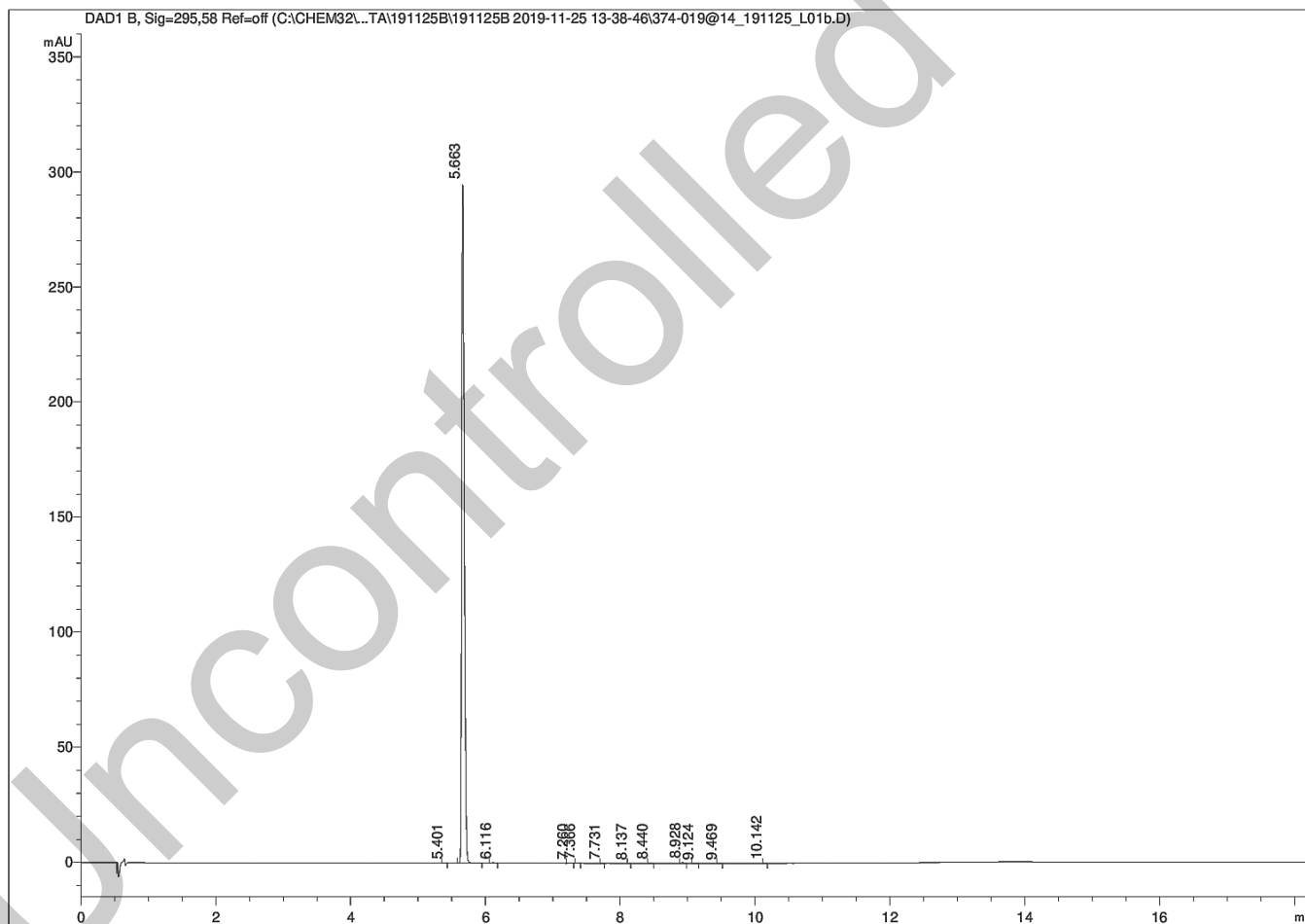
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## II. Purity

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

### HPLC Conditions:

Column	Conditions				Detector	Injector
Agilent Poroshell 120 EC C-18 4.6x50 mm 2.7 micron	25°C				DAD 295nm	Auto 1.0 µL 0.3mg/mL in 90% acetonitrile 10% dimethylsulfoxide (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	90	10	1.0		
	6.00	66	34	1.0		
	12.10	5	95	1.0		
	17.10	5	95	1.0		
	18.10	90	10	1.0		
	21.20	90	10	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	5.41	0.04	0.01
2	5.68	768.87	99.63
3	6.13	0.63	0.08
4	6.70	0.02	0.00
5	7.29	0.34	0.04
6	7.39	0.33	0.04
7	7.75	0.09	0.01
8	8.15	0.03	0.00
9	8.45	0.30	0.04
10	8.94	0.79	0.10
11	9.13	0.08	0.01
12	9.48	0.09	0.01
13	10.15	0.10	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)

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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 2019 Ash Appendix XII Method II

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

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

**Result:**

0.3% tetrahydrofuran; 0.4% diethyl ether by <sup>1</sup>H NMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	99.6%
Water content	0.1%
Ash content	<0.1%
Residual solvents	0.7%
Purity*	98.8%

This purity is assessed to be 98.8%

Product Reviewed By:

Product Released By:

John Moursounidis, PhD  
Head Reference Standards

Boon Tan  
Quality Manager

Release Date: 12 December 2019

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

The calculation of the purity follows the formula:

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

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