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epichem

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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.

$$\bigcap_{O} \bigcap_{N} \bigcap_{N} \bigcap_{O} \bigcap_{N} \bigcap_{N$$

#### Drawn as enol tautomer

Name	5-benzoyl-1,3-dihydro-2 <i>H</i> -benzimidazol-2-one
Synonym(s)	(2-hydroxy-1 <i>H</i> -benzimidazole-5-yl)phenylmethanone
BP Name	Mebendazole Impurity B
Epichem Item #	EPL-AA249 Batch 1
CAS#	21472-33-3
Molecular Formula	$C_{14}H_{10}N_2O_2$
Molecular Weight	238.24 g/mol
Appearance	Cream crystalline powder
<b>Melting Point</b>	315.0°C – 318.4°C (Decomposition)
<b>Combustion Analysis</b>	Required (%): C: 70.6, H: 4.2, N: 11.8. Found (%): C: 69.8, H: 3.9, N: 11.7.
Purity*	99.4%
Date of Manufacture	7 August 2019
<b>Storage Requirements</b>	Protect from heat, light and moisture.
<b>Special Precautions</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>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>	ТВА
	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)

<sup>\*</sup> NATA accreditation does not cover the performance of this service

EPL-AA249 Batch 1

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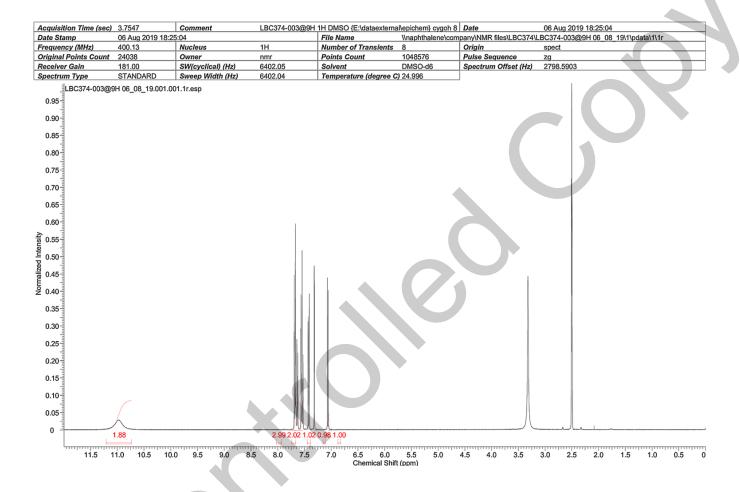
## I. Identity

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

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

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

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



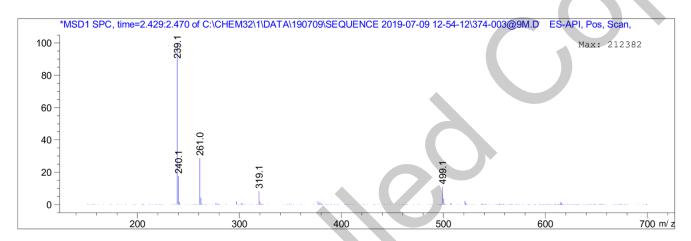
## **Ib.** Mass Spectrum

The mass spectrum of this material was analysed by Liquid Chromatography Mass Spectroscopy (LCMS) using inhouse 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		Mol. Weight
Time (MS)	MS Area	or Ion
2.447	2310048	499.10 I
		261.00 I
		240.10 I
		239.10 I



Theoretical value: 239.1 [M+H]+

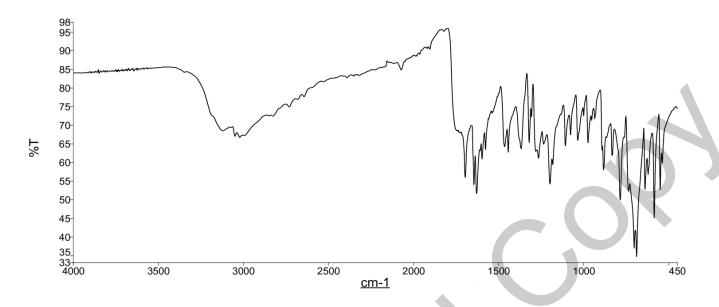
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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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.



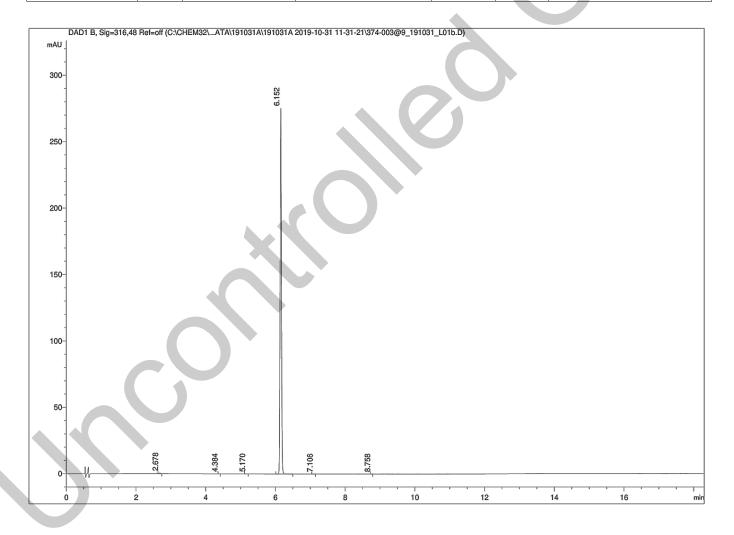
The interpretation of the signals of the Fourier Transform Infra-red Spectrum is consistent with the structural formula.

## 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					DAD Auto	
120 EC C-18 4.6x50 mm	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)	316nm	1.0 µL 0.3mg/mL in 90% acetonitrile
4.00.30 IIIII	0.00	90	10	1.0		10% dimethylsufoxide
2.7 micron	6.00	66	34	1.0		(NO MODIFIERS)
	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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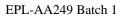
## Area Percent Report - Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.68	1.32	0.19
2	5.17	0.18	0.03
3	6.16	710.34	99.77
4	7.11	0.09	0.01
5	8.77	0.05	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 99.7% (average of 10 duplicate analyses)



## **III. Water Content**

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

**Results:** 

Average 0.3%

#### **IV. Ash Content**

Method: BP 2019 Ash Appendix XIJ Method II

**Result:** 

Contains <0.1% ash.

#### V. Residual Solvents

Method: <sup>1</sup>HNMR

**Result:** 

<0.1 residual solvent by <sup>1</sup>H NMR analysis.

## VI. Final Result

·	
Chromatographic purity (HPLC)	99.7%
Water content	0.3%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	99.4%

This purity is assessed to be 99.4%

Product Reviewed By:

Product Released By:

John Moursounidis, PhD Head Reference Standards Boon Tan Quality Manager

Release Date: 14 December 2019

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

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

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