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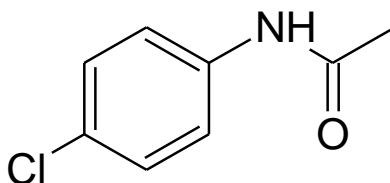
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## Reference Material Product Information Sheet

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



<b>Name</b>	<i>N</i> -(4-chlorophenyl)acetamide
<b>BP Name</b>	Paracetamol Impurity J
<b>Synonym(s)</b>	4-chloro-acetanilide; <i>N</i> -(4-chlorophenyl)ethaneamide
<b>Epichem Item #</b>	EPL-AA119 Batch 1
<b>CAS #</b>	539-03-7
<b>Molecular Formula</b>	C <sub>8</sub> H <sub>8</sub> ClNO
<b>Molecular Weight</b>	169.61 g/mol
<b>Appearance</b>	White powder
<b>Melting Point</b>	178.5-180.0°C
<b>Combustion Analysis</b>	Required (%): C:56.7; H:4.8; N:8.3. Found (%): C:56.7; H:4.7; N:8.2.
<b>Purity*</b>	99.4%
<b>Date of Manufacture</b>	23 May 2012
<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-AA119 Batch 1

Revision 2

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Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

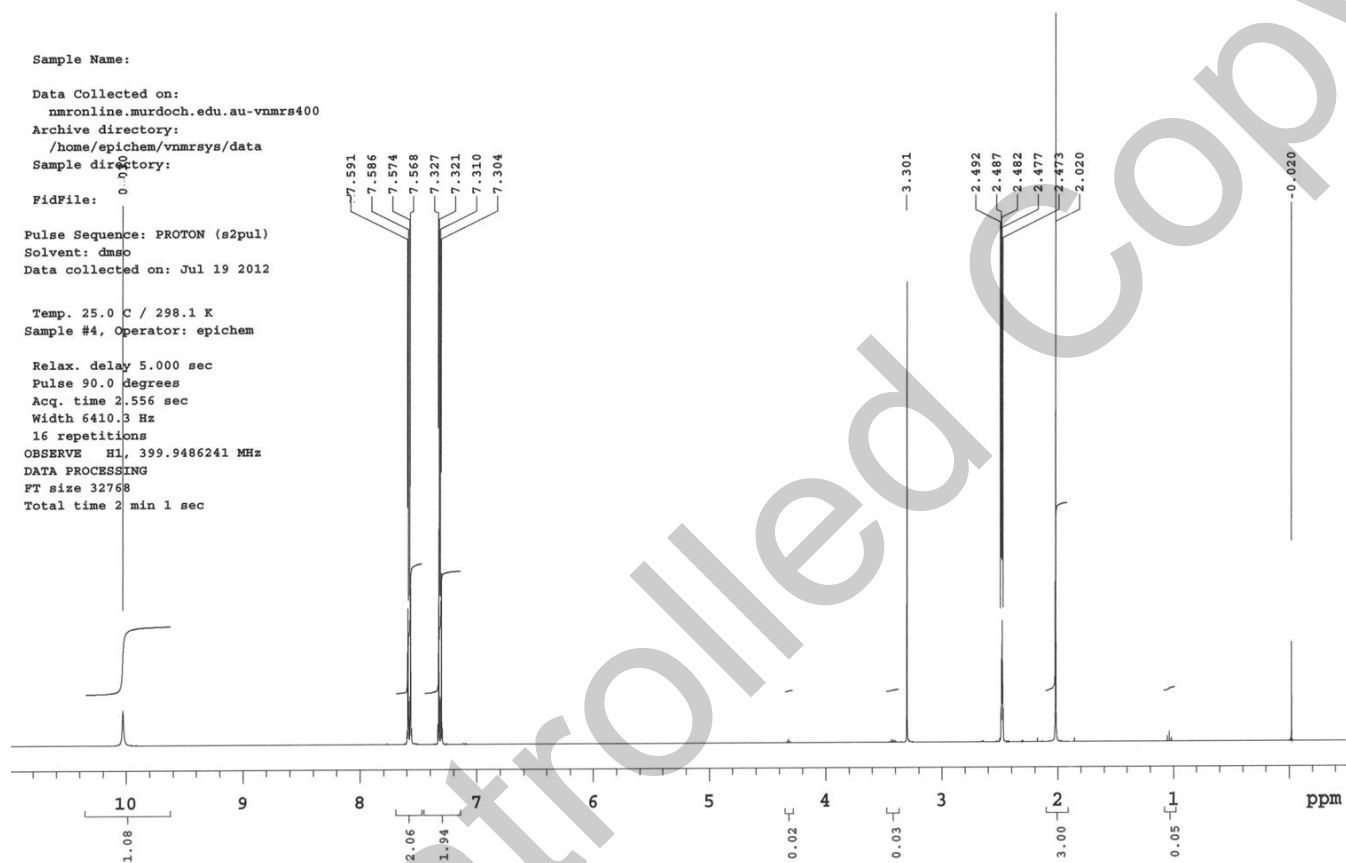
## I. Identity

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

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

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

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



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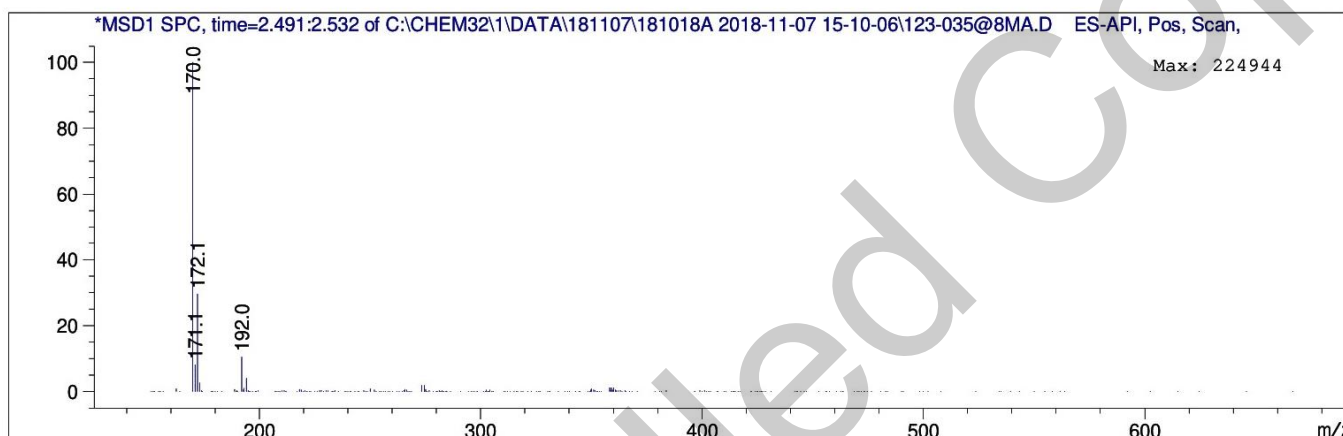
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## Ib. Mass Spectrum

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

Method: ACN/water gradient (+ 0.1% formic acid)  
ZORBAX SB-C8, Monitor C18, 4.6 x 30 mm, 3.5 micron.

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.517	2083234	192.00 I 172.10 I 170.00 I



Theoretical value: 170.0 [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.

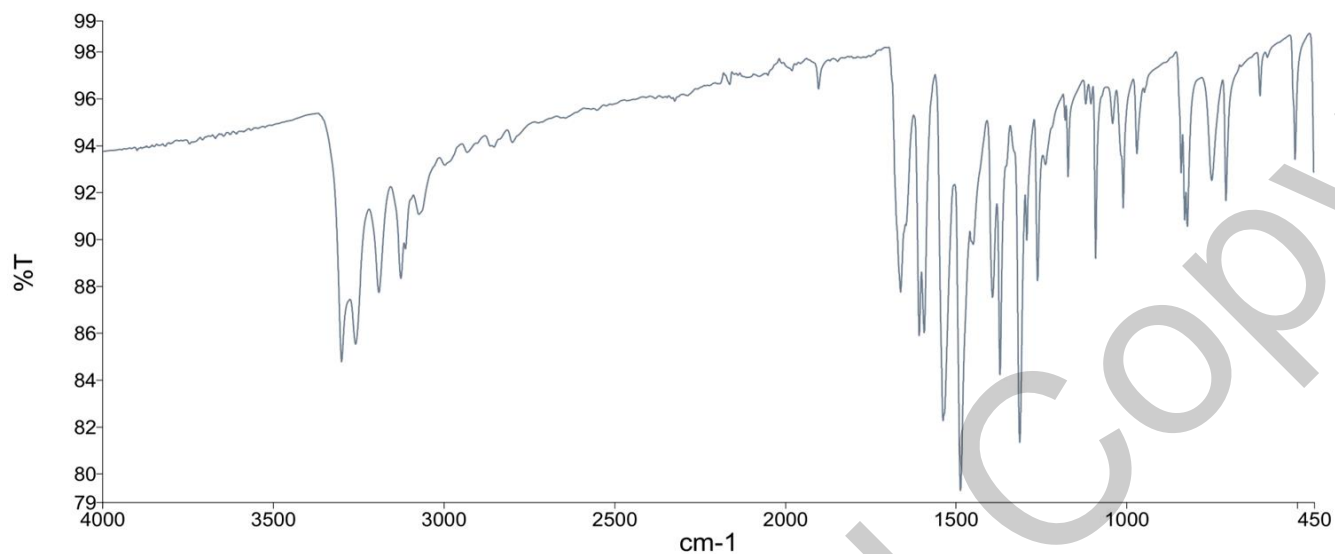
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### Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform 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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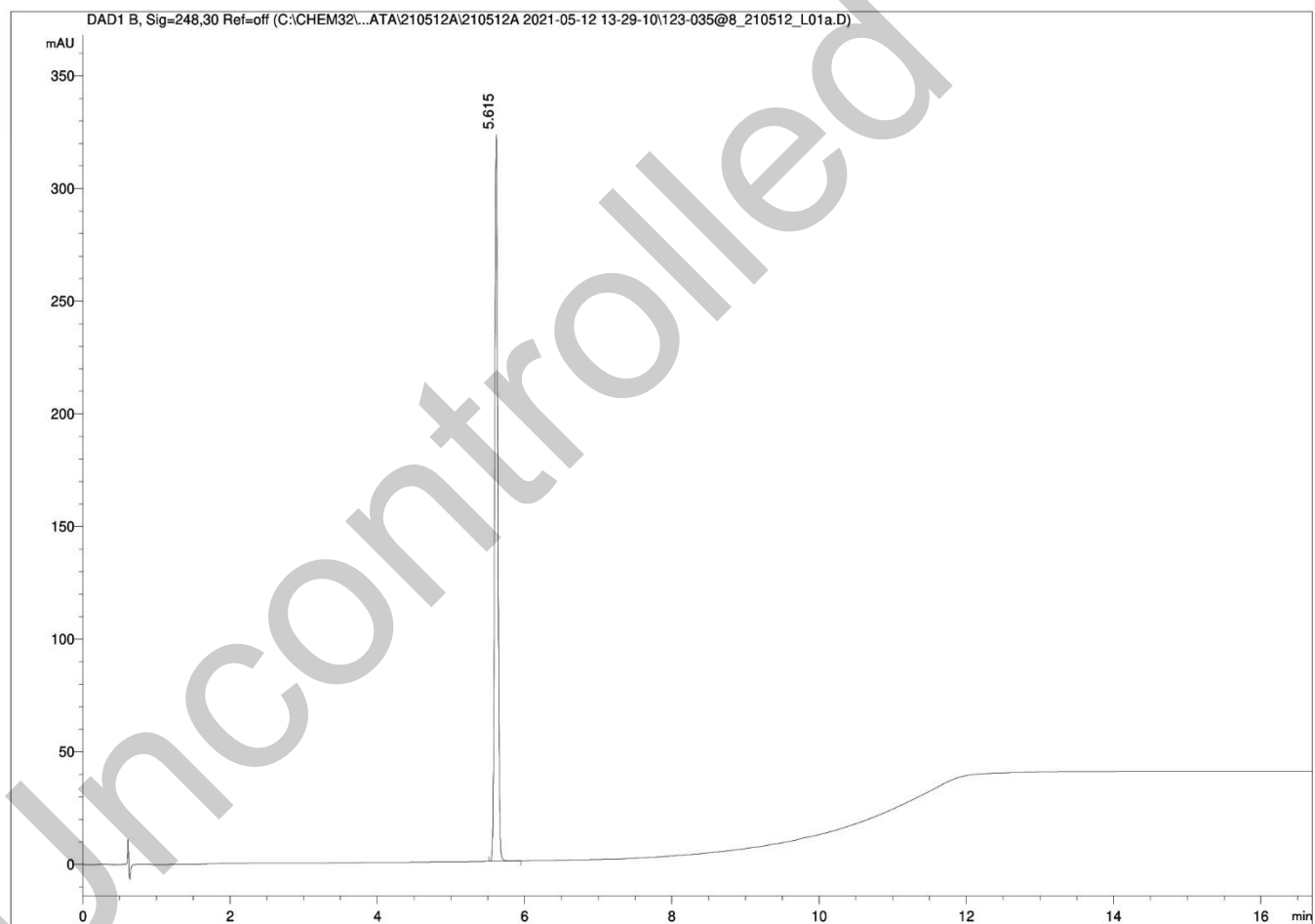
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## II. Purity

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

### HPLC Conditions:

Column	Conditions				Detector	Injector
Agilent Poroshell 120 EC-C18 4.6 x 50mm 2.7 micron	25°C				DAD 248nm	Auto 1.0 µL  0.20 mg/mL in 100% acetonitrile (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	60	40	1.0		
	10.50	5	95	1.0		
	15.50	5	95	1.0		
	16.50	90	10	1.0		
	19.50	90	10	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	5.62	968.26	100.00
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 100.0% (average of 10 duplicate runs)

### III. Water Content

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

#### Results:

Average 0.2%

### IV. Ash Content

Method: BP2012 Ash

#### Result:

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>HNMR

#### Result:

Contains 0.4% Ethanol by <sup>1</sup>HNMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	100.0%
Water content	0.2%
Ash content	<0.1%
Residual solvents	0.4%
Purity*	99.4%

This purity is assessed to be 99.4%.

Product Reviewed By:

Product Released By:

James Rixson, PhD  
Head of Production

Carol Worth, PhD  
Quality Manager

Release Date: 24 June 2022

\*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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