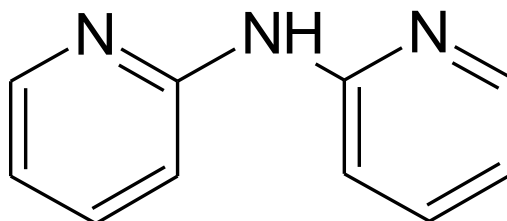


## Reference Material Product Information Sheet

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



<b>Name</b>	2,2'-dipyridylamine
<b>BP/EP Name</b>	Chlorphenamine Impurity B
<b>USP Name</b>	Chlorpheniramine Related Compound B
<b>Synonym(s)</b>	Di(pyridin-2-yl)amine; <i>N</i> -2-pyridinyl-2-pyridinamine; <i>N</i> -(pyridin-2-yl)pyridin-2-amine
<b>Epichem Item #</b>	EPL-AA18 Batch 2
<b>CAS #</b>	1202-34-2
<b>Molecular Formula</b>	C <sub>10</sub> H <sub>9</sub> N <sub>3</sub>
<b>Molecular Weight</b>	171.20 g/mol
<b>Appearance</b>	Off-white crystalline solid
<b>Melting Point</b>	94.6-96.0°C
<b>Combustion Analysis</b>	Required (%): C:70.2; H:5.3; N:24.5. Found (%): C:70.2; H:5.4; N:24.4.
<b>Purity*</b>	99.9%
<b>Date of Manufacture</b>	11 February 2008
<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-AA18 Batch 2

Revision 2

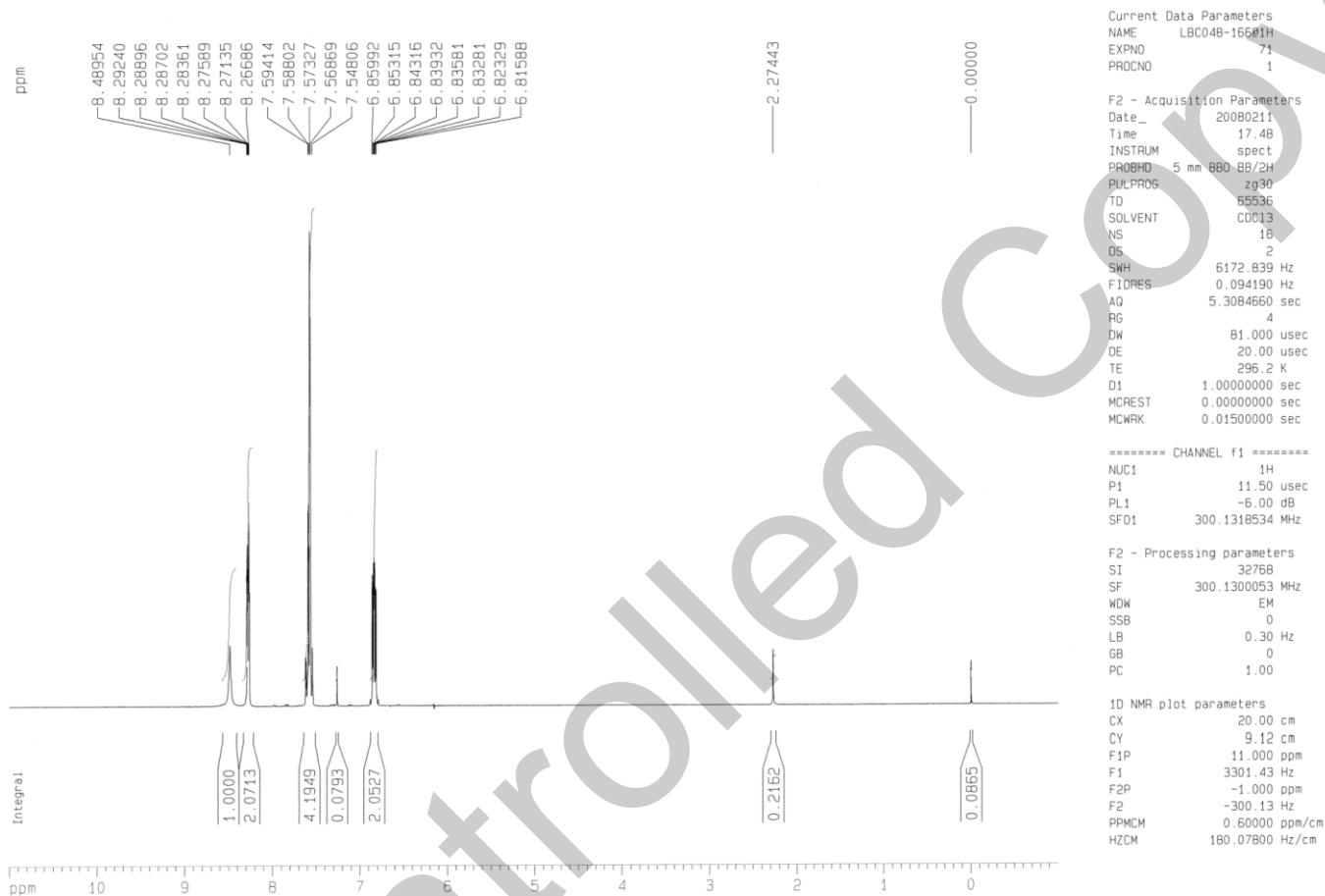
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia  
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

## I. Identity

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

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

Conditions: 300 MHz, CDCl<sub>3</sub>  
<sup>1</sup>HNMR spectrum consistent with chemical structure.



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Revision 2

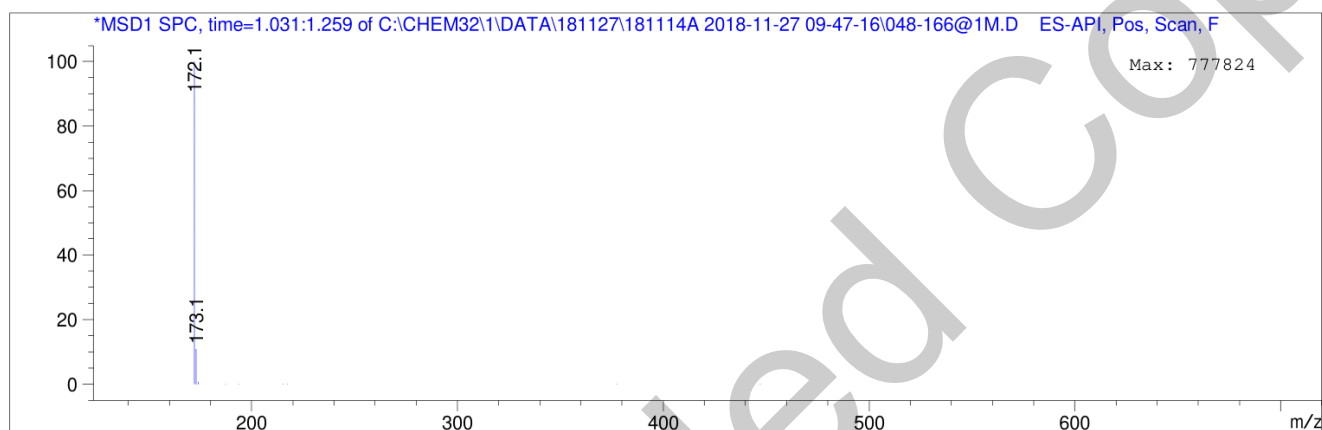
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## Ib. Mass Spectrum

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, 4.6 x 30 mm, 3.5 micron.

Retention Time (MS)	MS Area	Mol. Weight or Ion
1.090	18420756	173.10 I 172.10 I



Theoretical value: 172.1 [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.

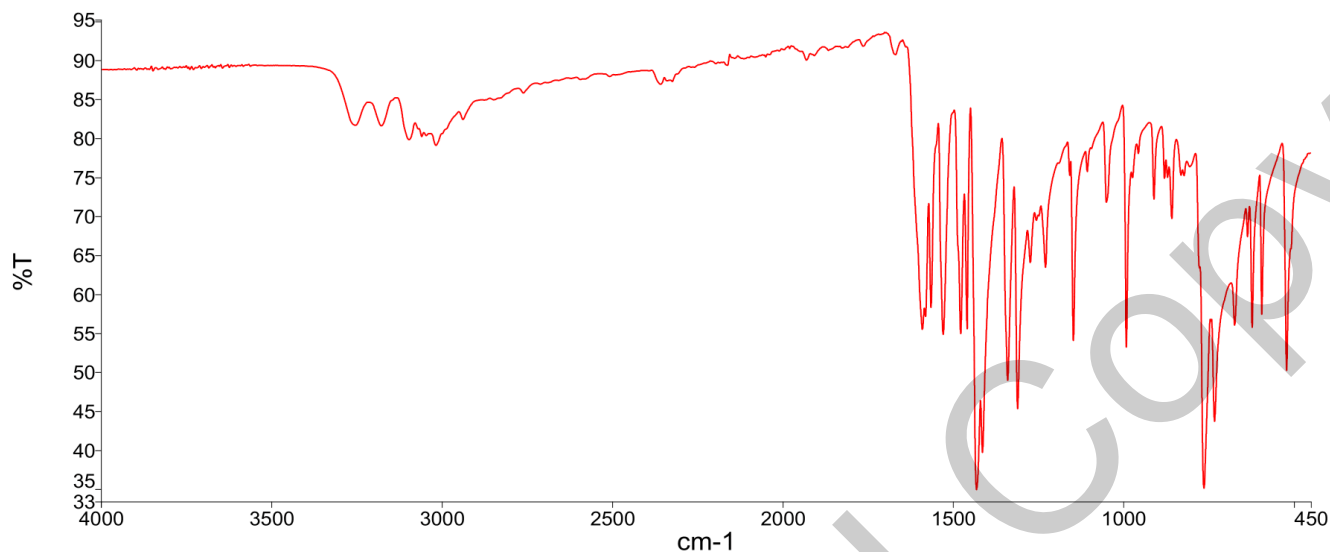
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### Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform 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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Revision 2

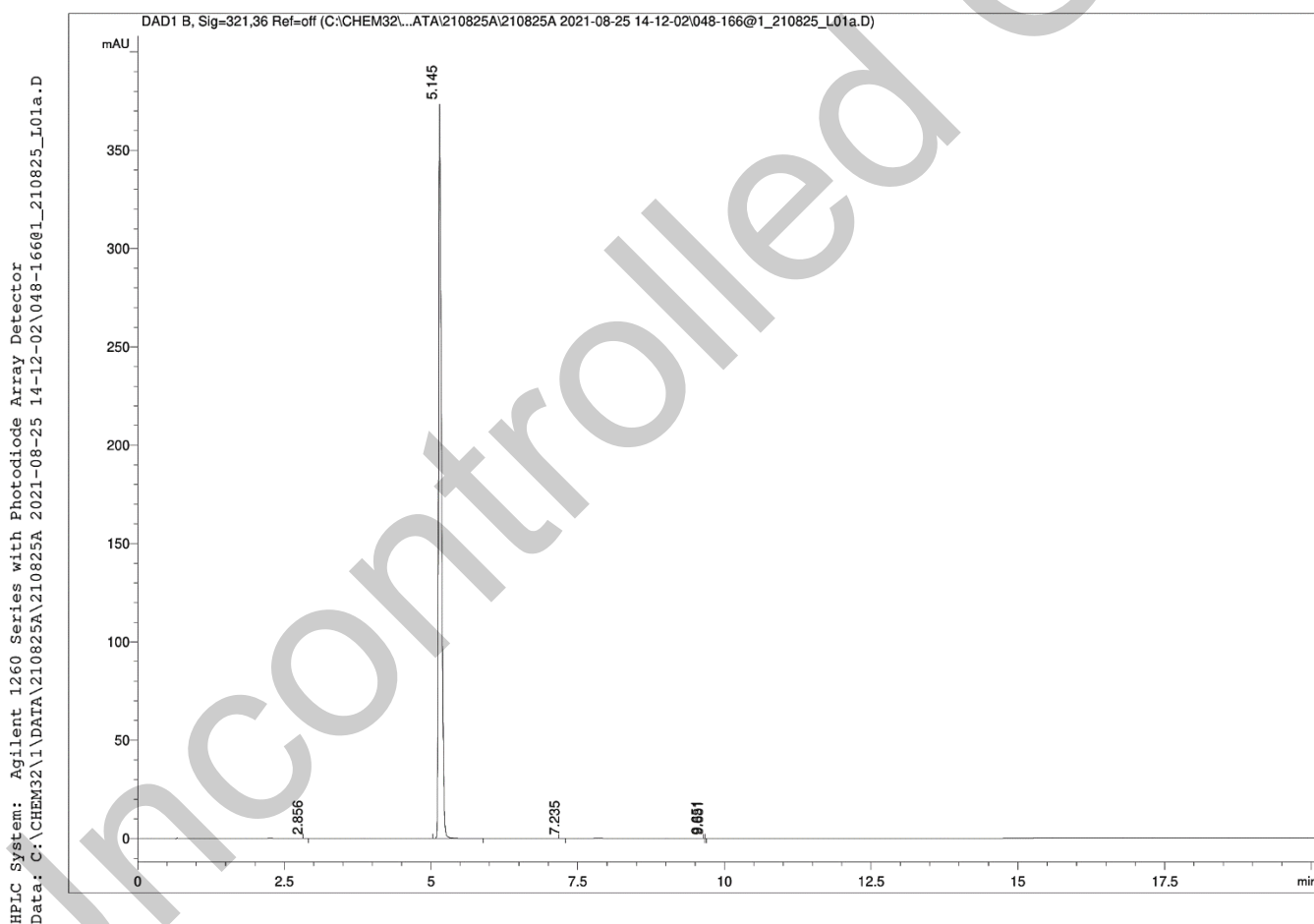
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## II. Purity

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	Auto
4.6 x 50mm	0.00	96	4	1.0	321nm	1.0 µL
2.7 micron	6.00	84	16	1.0		0.30 mg/mL in 100% water (+0.1% TFA)
	13.90	5	95	1.0		
	18.90	5	95	1.0		
	19.90	96	4	1.0		
	24.90	96	4	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.86	0.06	0.00
2	5.15	1318.52	99.99
3	7.24	0.06	0.00
4	9.65	0.04	0.00
5	9.68	0.02	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 100.0% (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: Combustion adjuvant added.

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

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

**Result:**

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

### VI. Final Result

Chromatographic purity (HPLC)	100.0%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	99.9%

This purity is assessed to be 99.9%.

Product Reviewed By:

James Rixson, PhD  
Head of Production

Product Released By:

Carol Worth, PhD  
Quality Manager  
Release Date: 2 February 2022

*\*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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