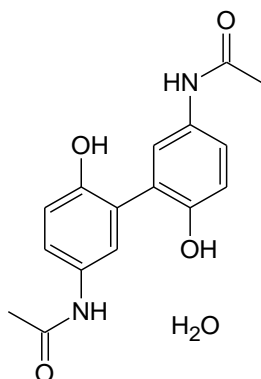


Reference Material Product Information Sheet

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



Name	<i>N,N'</i> -(6,6'-dihydroxy[1,1'-biphenyl]-3,3'-diyl)bis-acetamide monohydrate
USP Name	Acetaminophen dimer
Synonym(s)	<i>N,N'</i> -(6,6'-Dihydroxy-[1,1'-biphenyl]-3,3'-diyl)diacetamide monohydrate
Epichem Item #	EPL-AA260 Batch 2
CAS #	219698-13-2
Molecular Formula	C ₁₆ H ₁₆ N ₂ O ₄ .H ₂ O
Molecular Weight	318.33 g/mol
Appearance	Light brown powder
Melting Point	168.2-179.5°C (decomposition)
Combustion Analysis	Required (%): C:60.4; H:5.7; N:8.8. Found (%): C:60.4; H:5.8; N:8.8.
Purity*	95.9%
Date of Manufacture	27 January 2021
Storage Requirements	Protect from heat, light and moisture.
Special Precautions	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.
Intended Use	This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
Date of Shipment	TBA 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)

* NATA accreditation does not cover the performance of this service

EPL-AA260 Batch 2

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
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I. Identity

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

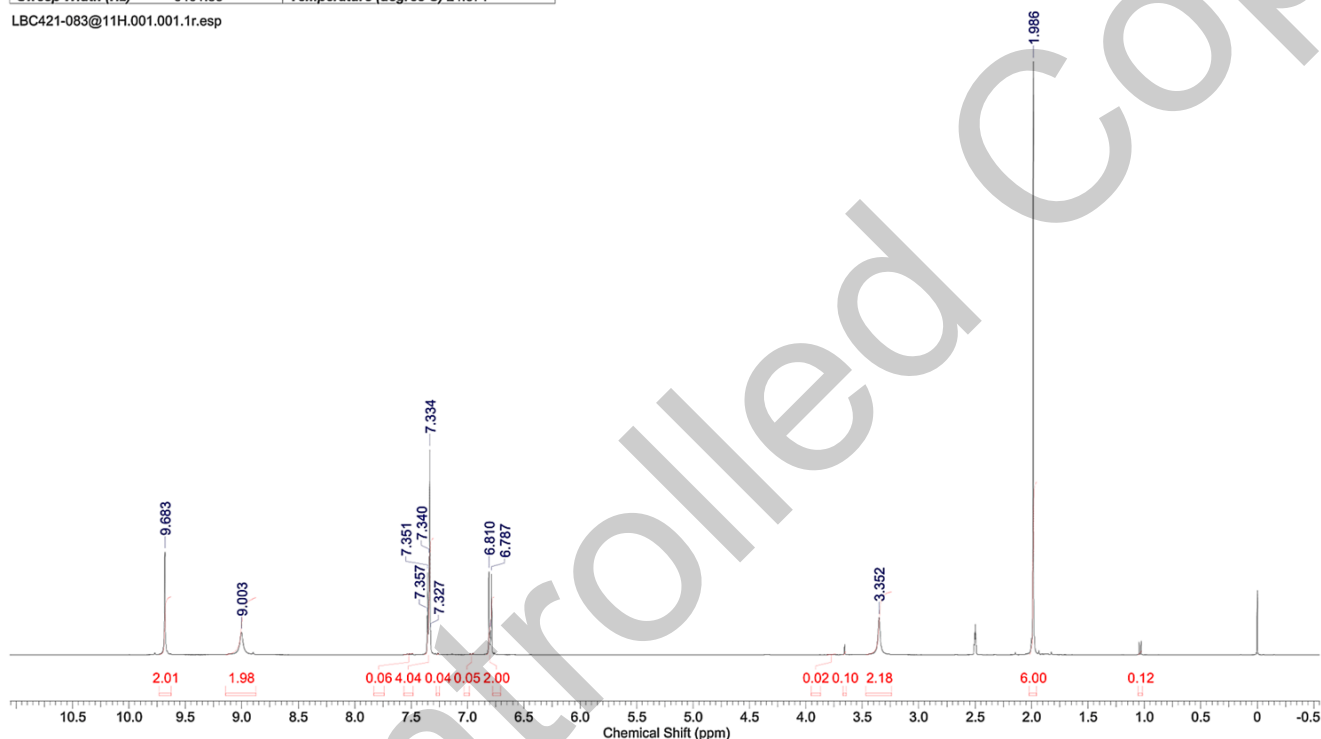
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, DMSO-d₆

0.4% Isopropyl alcohol by ¹H NMR analysis.

Acquisition Time (sec)	3.7547	Comment	LBC421-083@11H 1H DMSO (E:\data\external\epichem) cygoh 5		
Date	25 Jan 2021 17:23:12	Date Stamp	25 Jan 2021 17:23:12		
File Name	\naphthalene\company\NMR files\LBC421\LBC421-083@11H\1\data\11r		Frequency (MHz)	400.13	
Nucleus	1H	Number of Transients	8	Origin	spect
Owner	nmr	Points Count	32768	Original Points Count	24038
Pulse Sequence	zg		Receiver Gain	101.00	
SW(cyclical) (Hz)	6402.05	Solvent	DMSO-d6	Spectrum Offset (Hz)	2797.6726
Sweep Width (Hz)	6401.85	Temperature (degree C)	24.671	Spectrum Type	STANDARD

LBC421-083@11H.001.001.1r.esp



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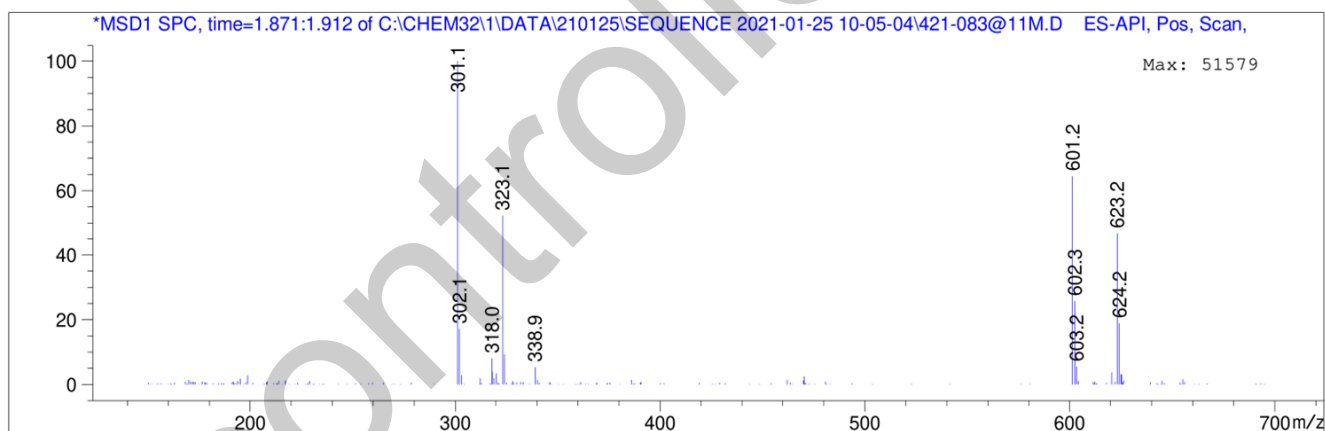
ABN 80 106 769 902

Ib. Mass Spectrum

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

Method: 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
1.894	919916	624.20
		623.15
		602.30
		601.20
		323.10
		302.10
		301.10
		301.10
2.101	183864	653.25
		652.30
		651.20
		629.25
		338.00
		337.00
		332.10
		315.90
		315.15
		315.15
		315.15



Theoretical value: 301.1 [M-H₂O+H]⁺.

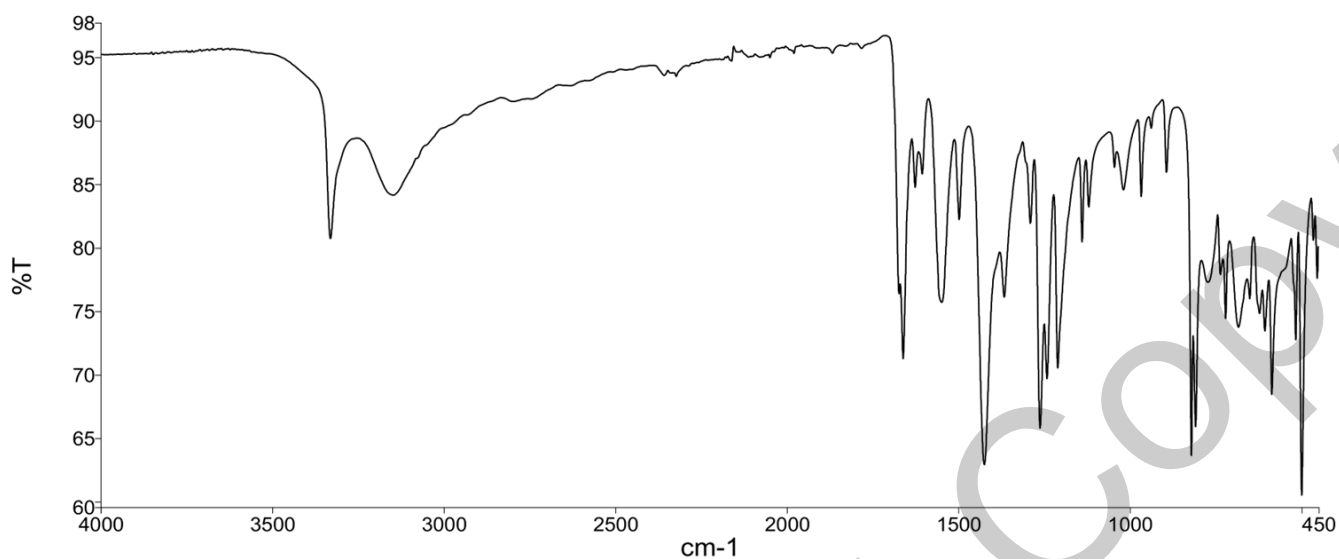
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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Ic. IR Spectrum

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

EPL-AA260 Batch 2

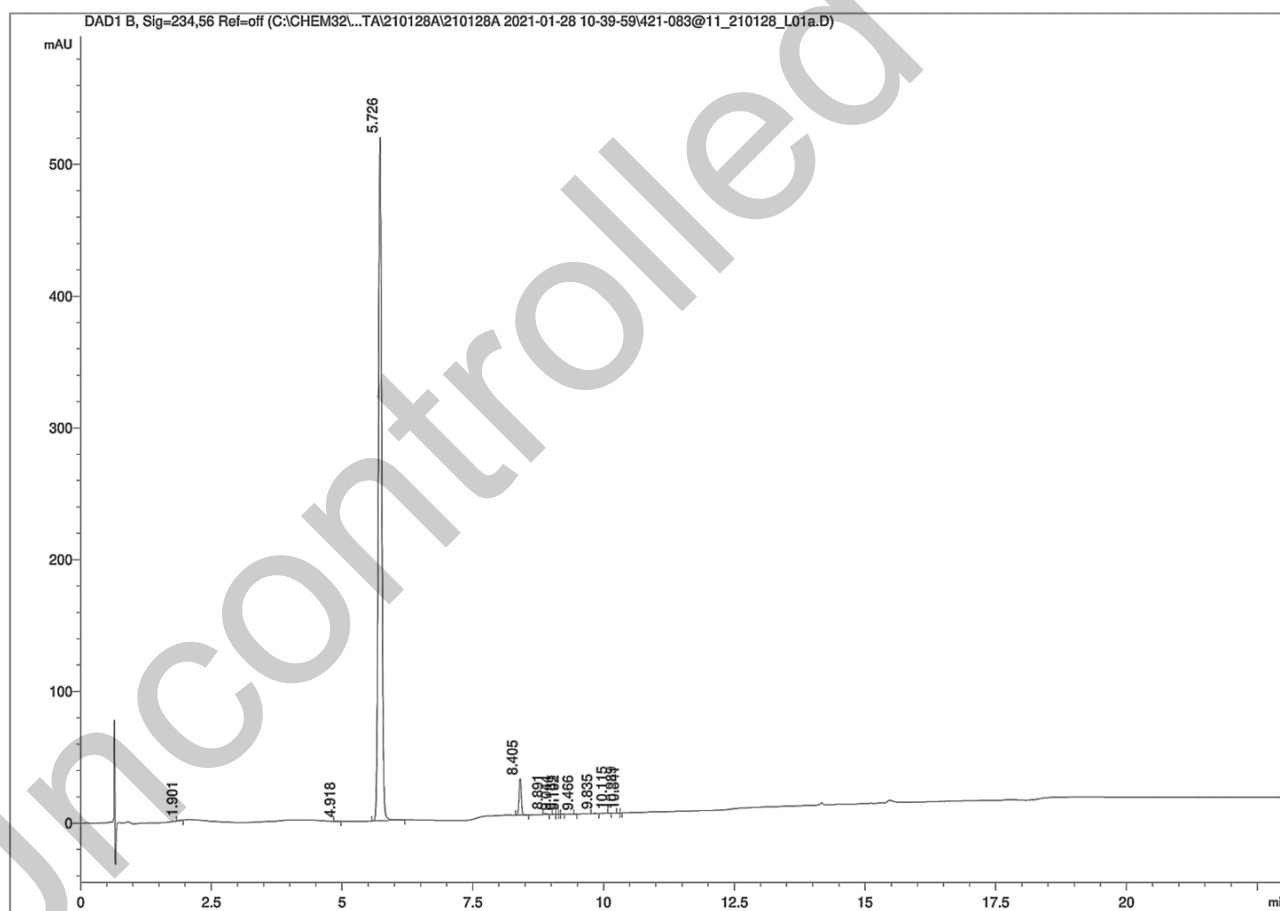
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II. Purity

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

HPLC Conditions:

Column	Conditions				Detector	Injector
Agilent Poroshell 120 EC-C18 4.6 x 50mm 2.7 micron	25°C				DAD 234nm	Auto 1.0 µL 0.60 mg/mL in 50% acetonitrile 50% water (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	95	5	1.0		
	6.00	89	11	1.0		
	11.00	64	36	1.0		
	16.90	5	95	1.0		
	21.90	5	95	1.0		
	22.90	95	5	1.0		
	25.90	95	5	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	1.90	1.52	0.06
2	4.92	0.28	0.01
3	5.73	2310.96	96.38
4	8.40	79.94	3.33
5	8.89	2.44	0.10
6	9.04	0.16	0.01
7	9.13	0.32	0.01
8	9.16	0.32	0.01
9	9.19	0.31	0.01
10	9.47	0.08	0.00
11	9.84	1.06	0.04
12	10.12	0.23	0.01
13	10.29	0.11	0.00
14	10.34	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 96.4% (average of 10 duplicate analyses)

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III. Water Content

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

Results:

Average 5.6%

IV. Ash Content

Method: BP2020 Ash Appendix XI J Method II

Result:

Contains 0.1% ash.

V. Residual Solvents

Method: ¹HNMR

Result:

0.4% Isopropyl alcohol by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	96.4%
Water content	5.6% (consistent with monohydrate 5.7%)
Ash content	0.1%
Residual solvents	0.4%
Purity*	95.9%

This purity is assessed to be 95.9%.

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Boon Tan
Quality Manager

Release Date: 11 February 2021

*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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