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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.

N-(4-(5-(acetylamino)-2-hydroxyphenoxy)phenyl)acetamide
EPL-AA140 Batch 2
2575516-61-7
$C_{16}H_{16}N_2O_4$
300.32 g/mol
Off-white powder
190.9-198.9°C (decomposition)
Required (%): C:64.0; H:5.4; N:9.3. Found (%): C:63.8; H:5.4; N:9.5.
99.0%
11 May 2022
Protect from heat, light and moisture.
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.
This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
TBA
This certificate is valid for one year from the date of shipment provided the substance is unopened and stored under the recommended conditions.
TBA (Proper Storage and Handling Required)

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

EPL-AA140 Batch 2

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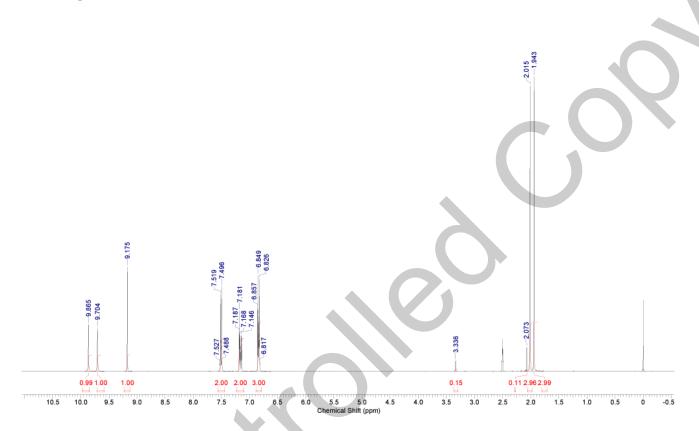
## I. Identity

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.



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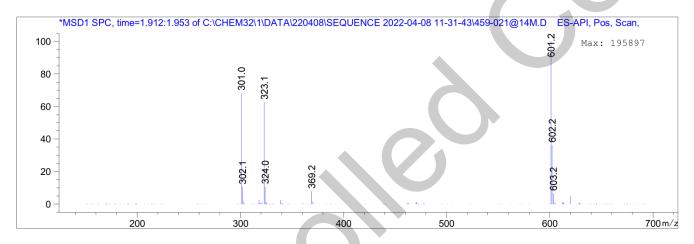
### **Ib.** Mass Spectrum

The mass spectrum of this material was analysed by Liquid Chromatography Mass Spectroscopy (LCMS) using inhouse 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
1.928	3288197	602.20 I 601.20 I 324.05 I
		323.10 I 302.10 I
		301.05 I



Theoretical value: 301.1 [M+H]<sup>+</sup>.

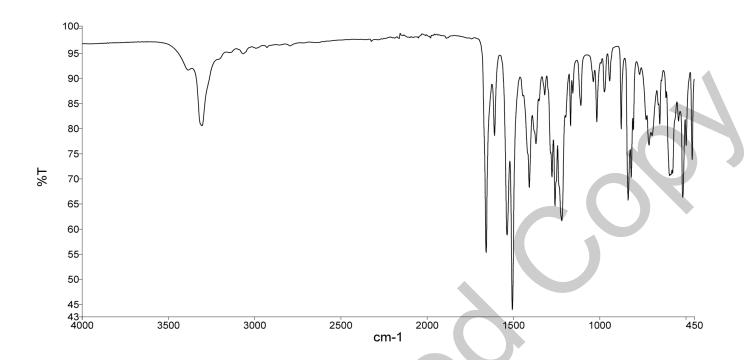
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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## Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform Infrared Spectroscopy (FTIR) using inhouse EM005.WI09.



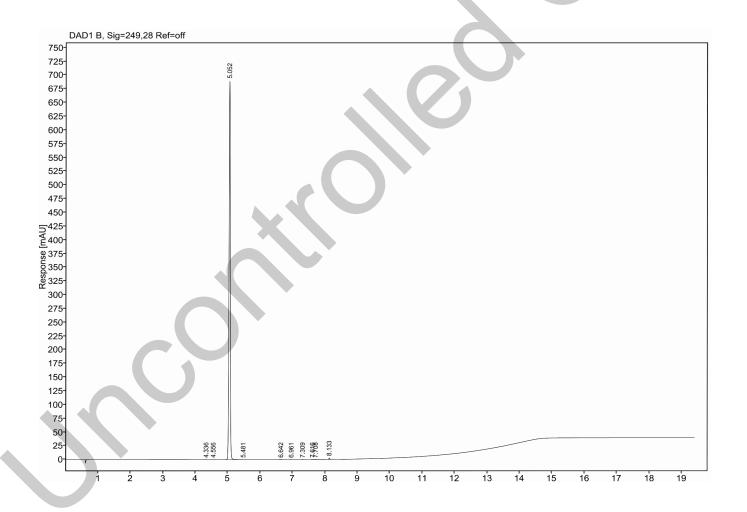
The interpretation of the signals of the Fourier-Transform Infrared Spectrum is consistent with the structural formula.

## 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	35°C				DAD	Auto
120 EC-C18	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)	249nm	1.0 μL 0.4 mg/mL in
4.6 x 50mm	0.00	95	5	1.0		100% acetonitrile (NO MODIFIERS)
2.7 micron	6.00	77	23	1.0		
	13.20	5	95	1.0		
	18.20	5	95	1.0		
	19.20	95	5	1.0		
	22.20	95	5	1.0		



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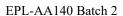
## Area Percent Report - Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.34	0.11	0.01
2	4.56	0.15	0.01
3	5.05	1850.50	99.65
4	5.48	0.17	0.01
5	6.64	0.63	0.03
6	6.96	0.19	0.01
7	7.31	0.44	0.02
8	7.62	0.11	0.01
9	7.71	0.29	0.02
10	8.13	4.48	0.24
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 2013 Ash (Appendix XI J) as per WS001/18594.

**Result:** 

Contains <0.1% ash.

#### V. Residual Solvents

Method: <sup>1</sup>HNMR

**Result:** 

0.5% wt acetonitrile 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	0.5%
Purity*	99.0%

- TD1	• .	•	1		1	$\alpha$	ΔΔ /
Thie	miirit	7 1C	assessed	tΩ	he	uu	110/2
11113	punt	<i>y</i> 13	assesseu	w	$\omega$	"	U / U.

Product Reviewed By: Product Released By:

James Rixson, PhD
Head of Production
Carol Worth, PhD
Quality Manager

Release Date: 12 May 2021

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

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