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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.

1-(6-methoxynaphthalen-2-yl)ethanone
Naproxen Impurity L
1-(6-methoxy-2-naphthalenyl)ethanone; 2-acetyl-6-methoxynaphthalene; 6-acetyl-2-methoxynaphthalene; 6-methoxy-2-acetylnaphthalene; 6-methoxy-2-naphthyl methyl ketone; 6'-methoxy-2'-acetonaphthone; Acetylnerolin.
EPL-AA181 Batch 1
3900-45-6
$C_{13}H_{12}O_2$
200.23 g/mol
White powder
108.5-110.1°C
Required (%): C:78.0; H:6.0; N:0.0. Found (%): C:77.8; H:6.1; N:0.0.
99.9%
2 September 2015
Protect from heat, light and moisture.
This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
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.
TBA
This certificate is valid for one year from the date of shipment provided the substance is stored under the recommended conditions.
TBA (Proper Storage and Handling Required)

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

EPL-AA181 Batch 1 Revision 1

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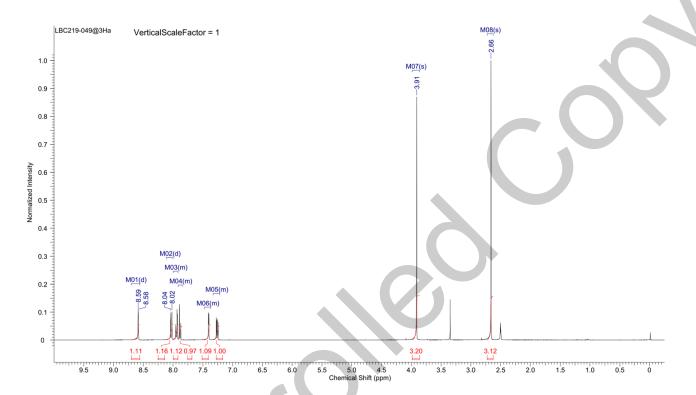
# I. Identity

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.



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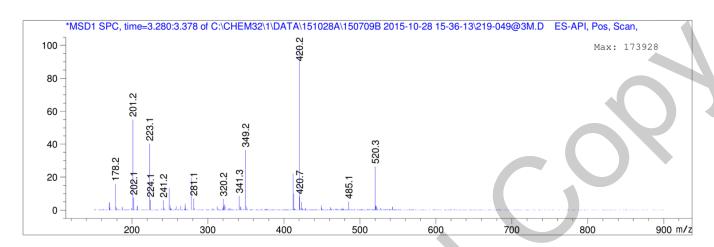
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## **Ib.** Mass Spectrum

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

Method: 5% to 100% ACN in water gradient (+0.1% formic acid)

Poroshell 120 EC-C18, 4.6 x 50mm, 3.5 micron



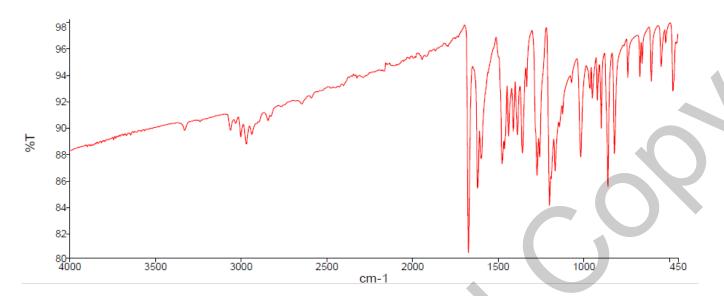
Theoretical value: 201.2 [M+H]+.

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 Infrared Spectroscopy (FTIR) using inhouse EM005.WI09.



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

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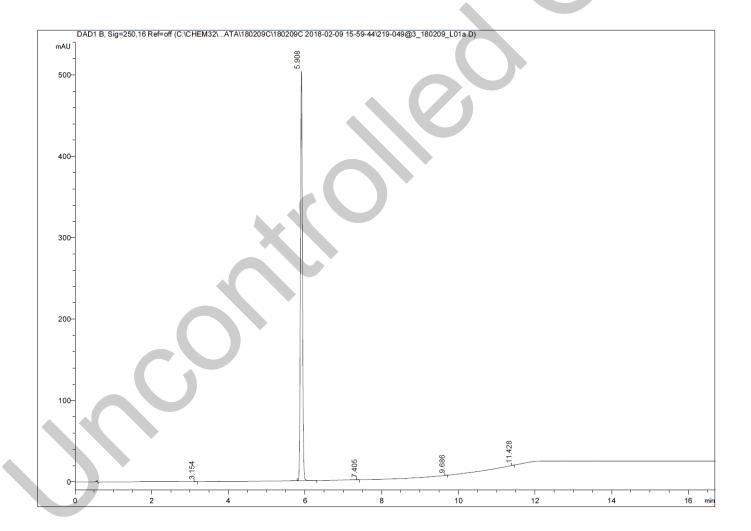
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# II. Purity

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

## **HPLC Conditions:**

Column	Conditi	Conditions				Injector
Agilent Poroshell					DAD	Auto
120 EC-C18 4.6 x 50mm	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)	250nm	1.0 µL 0.15 mg/mL in 100% acetonitrile.
	0.00	75	25	1.0		accionanc.
2.7 micron	7.00 40	60	1.0			
	10.50	5	95	1.0		
	15.50	5	95	1.0		
	16.50	75	25	1.0		
	19.50	75	25	1.0		



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# Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	3.15	0.10	0.01
2	5.91	1801.00	99.97
3	7.40	0.09	0.01
4	9.69	0.14	0.01
5	11.43	0.12	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 100.0% (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% water

### IV. Ash Content

Method: BP2015 Ash (Appendix XI-J) WS001/26397

**Result:** 

Contains < 0.1% ash

### V. Residual Solvents

Method: <sup>1</sup>HNMR

**Result:** 

No significant impurities

## VI. Final Result

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

TT1 .	• .	•	1		1	00 00/
Thic	nurity	7 1 C	assessed	tΛ	he	99 9%
11113	pullty	/ 13	assessea	$\iota \circ$	$\omega$	JJ.J/U.

Product Reviewed By: Product Released By:

John Moursounidis, PhD Boon Tan

Head Reference Standards Quality Manager

Release Date: 29 January 2019

The calculation of the purity follows the formula:

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

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