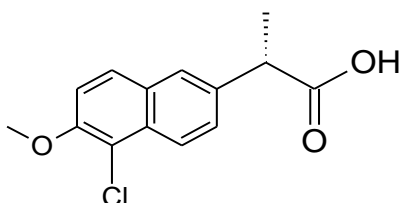


Reference Material Product Information Sheet

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



Name	(2S)-2-(5-chloro-6-methoxynaphthalen-2-yl)propanoic acid
BP Name	Naproxen Impurity B
Synonym(s)	5-Chloronaproxen
Epichem Item #	EPL-AA183 Batch 1
CAS #	89617-86-7
Molecular Formula	C ₁₄ H ₁₃ ClO ₃
Molecular Weight	264.71 g/mol
Appearance	White powder
Melting Point	158.2-163.0°C
Combustion Analysis	Required (%): C:63.5; H:5.0; N:0.0. Found (%): C:63.5; H:4.9; N:0.0.
Purity	99.6 %
Optical Purity	99.4% by HPLC; [α] _D ^{25.9} +52 (c1.00, CHCl ₃)
Date of Manufacture	23 October 2015
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	8 February 2019 This certificate is valid for one year from the date of shipment provided the substance is stored under the recommended conditions.
Retest Date	8 February 2020 (Proper Storage and Handling Required)

EPL-AA183 Batch 1

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

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ABN 80 106 769 902

I. Identity

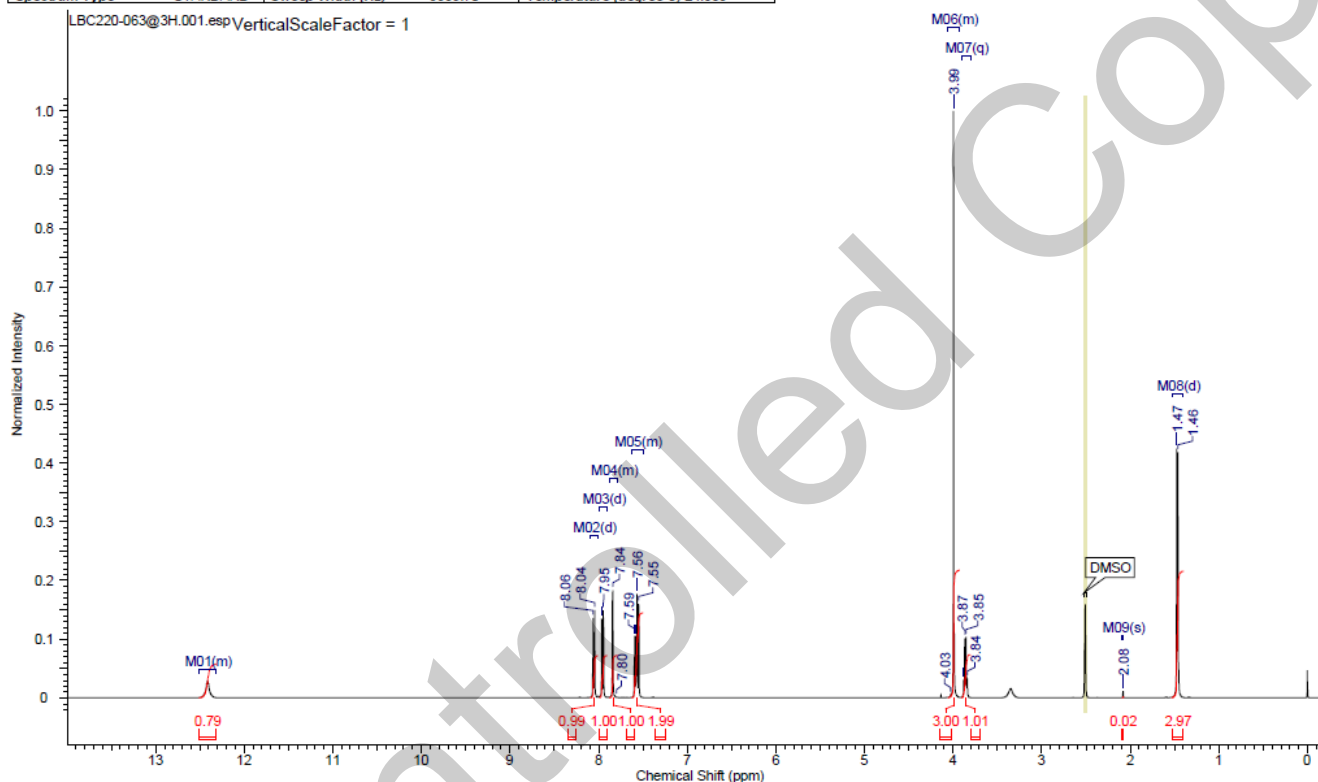
The identity of this product was established using the following analyses:

Ia. ¹HNMR Spectrum

Conditions: 400 MHz, DMSO-d₆

¹HNMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.2768	Date	23 Oct 2015 14:45:20	Date Stamp	23 Oct 2015 14:45:20				
File Name	\NAPHTHALENE\Company\UWA NMR\LBC220-063@3H1.tif			Frequency (MHz)	500.10	Nucleus	1H		
Number of Transients	16	Origin	spect	Original Points Count	32768	Owner	Epichem	Points Count	32768
Pulse Sequence	zg30	Receiver Gain	98.09	SW(cyclical) (Hz)	10000.00	Solvent	DMSO-d6	Spectrum Offset (Hz)	3068.5220
Spectrum Type	STANDARD	Sweep Width (Hz)	9999.70	Temperature (degree C)	24.939				



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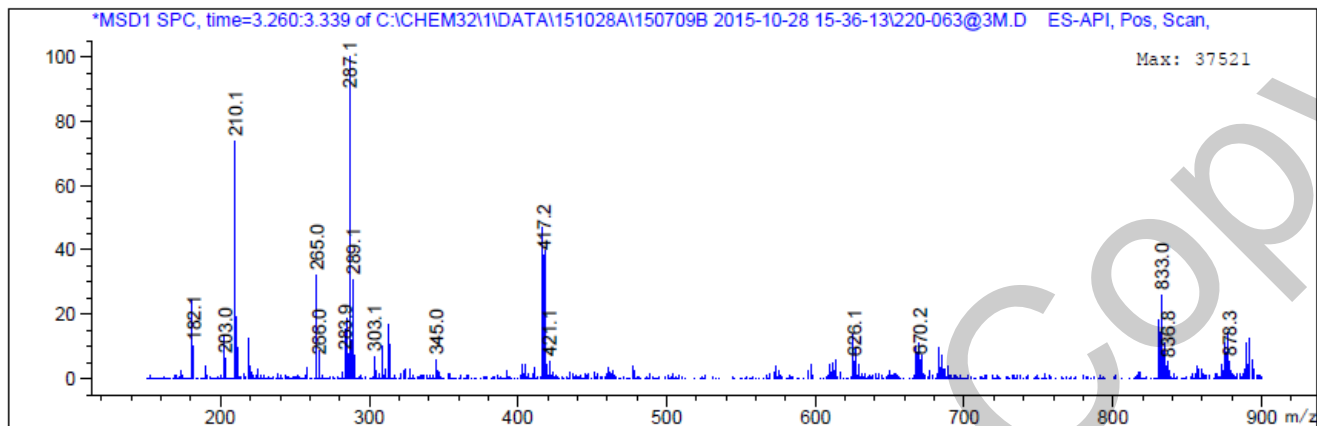
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Ib. Mass Spectrum

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

Method: 5% to 100% ACN in water gradient (+0.1% formic acid)
Poroshell 120 EC-C18, 4.6 x 50mm, 2.7 micron



Theoretical value: 265.1 [M+H]⁺, 287.1 [M+Na]⁺.

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

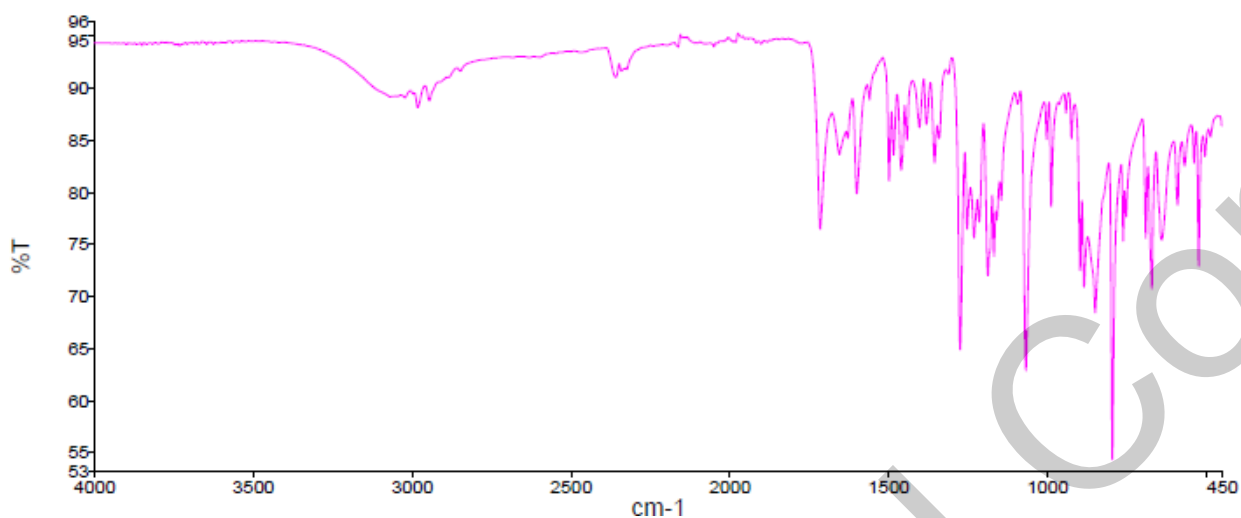
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Ic. IR Spectrum

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

Method: Fourier Transform Infrared (FTIR) Spectroscopy



The signals of the IR spectrum and their interpretation are consistent with the structural formula.

EPL-AA183 Batch 1

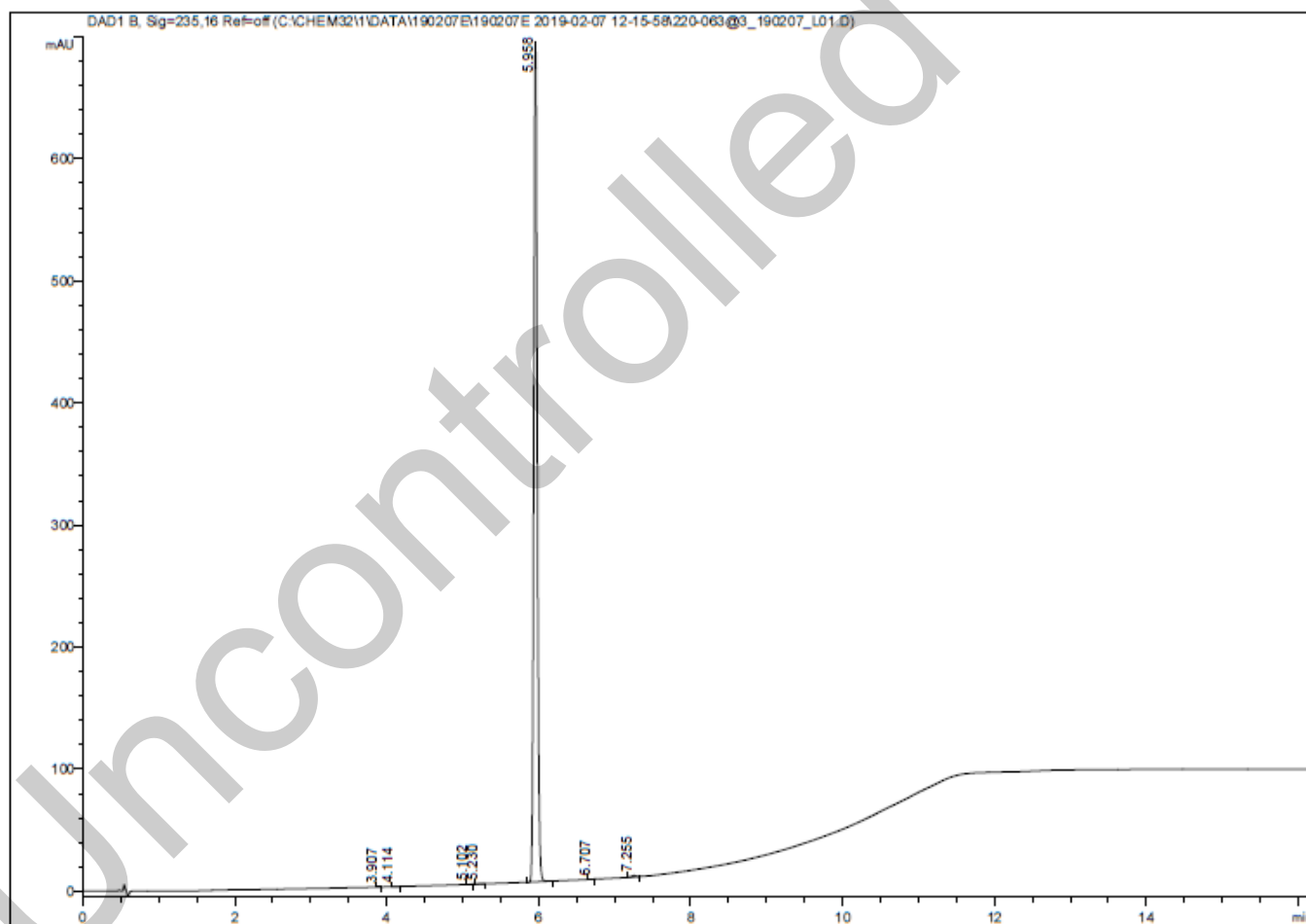
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II. Purity

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 235nm	Auto 1.0 µL 0.20 mg/mL in 100% acetonitrile
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
	0.00	75	25	1.0		
	6.00	45	55	1.0		
	10.00	5	95	1.0		
	15.00	5	95	1.0		
	16.00	75	25	1.0		
	19.00	75	25	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	3.91	0.04	0.00
2	4.11	0.32	0.01
3	5.10	0.25	0.01
4	5.23	0.61	0.03
5	5.96	2153.66	99.73
6	6.71	0.36	0.02
7	7.26	4.18	0.19
Totals		2159.42	100.0

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 99.7% (average of 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: BP2015 Ash (Appendix XI-J) WS001/26829

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹HNMR

Result:

Contains: <0.1%

VI. Final Result

Chromatographic purity (HPLC)	99.7 %
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity	99.6%

This purity is assessed to be 99.6%.

Product Reviewed By:

Product Released By:

John Moursounidis, PhD
Head Reference Standards

Boon Tan
Quality Manager

Release Date: 8 February 2019

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

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