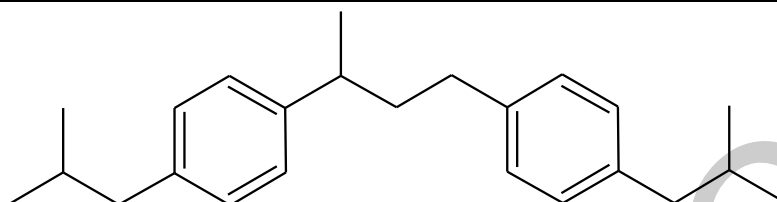


Reference Material Product Information Sheet

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



Name	1-(2-methylpropyl)-4-((3RS)-3-(4-(2-methylpropyl)phenyl)butyl)benzene
BP/EP Name	Ibuprofen Impurity I
USP Name	Not listed
Epichem Item #	EPL-AA197 Batch 1
CAS #	2143535-26-4
Molecular Formula	C ₂₄ H ₃₄
Molecular Weight	322.54g/mol
Appearance	Pale yellow liquid
Combustion Analysis	Required (%): C:89.4; H:10.6. Found (%): C:89.5; H:10.7.
Purity*	97.8%
Date of Manufacture	17 May 2016
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 stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

EPL-AA197 Batch 1

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ABN 80 106 769 902

I. Identity

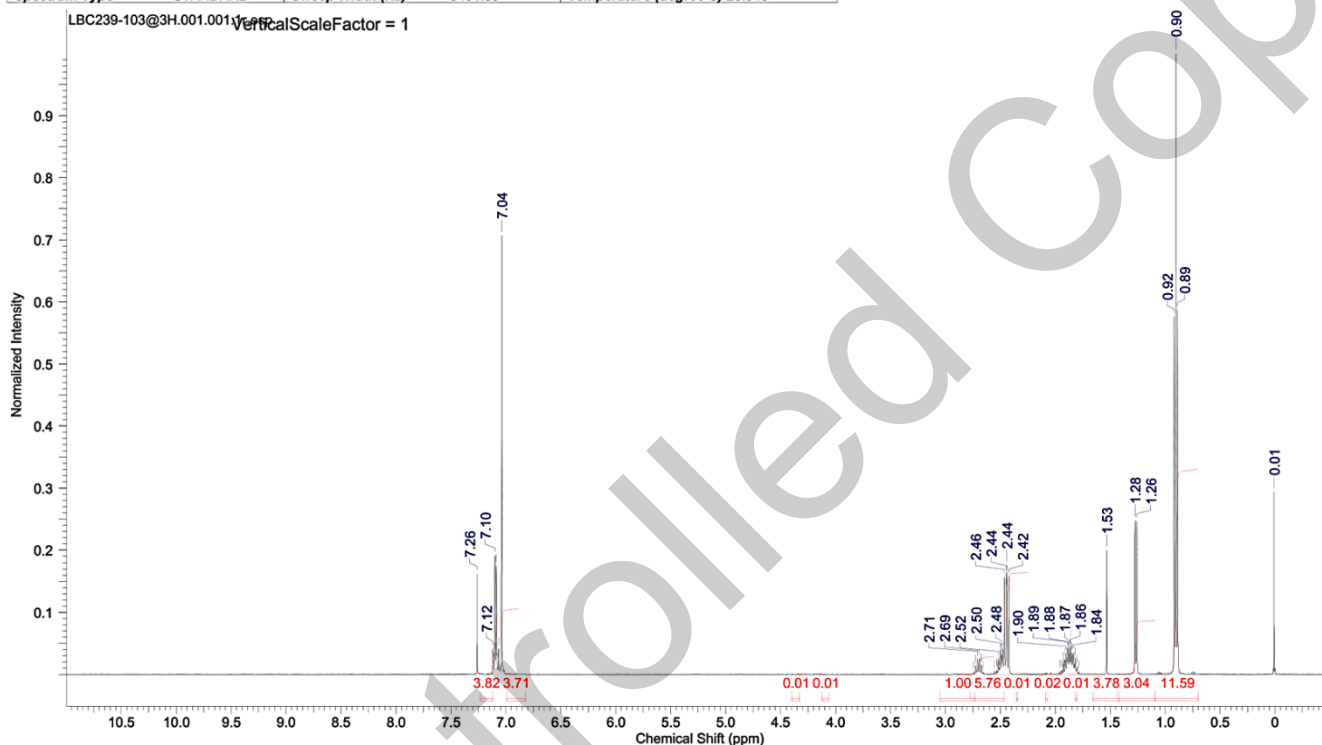
The identity of this product was established using the following analyses:

Ia. ¹H NMR Spectrum

Conditions: 400 MHz, CDCl₃

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC239-103@3H 1H CDCl3 (E:\dataexternal\epichem) cygoh 13		
Date	02 May 2016 17:57:20	Date Stamp	02 May 2016 17:57:20		
File Name	\NAPHTHALENE\Company\NMR files\LBC239-103@3H\1\data\111r		Frequency (MHz)	400.13	
Nucleus	1H	Number of Transients	8	Origin	spect
Owner	nmr	Points Count	32768	Pulse Sequence	zg
SW(cyclical) (Hz)	6402.05	Solvent	CHLOROFORM-d	Receiver Gain	90.50
Spectrum Type	STANDARD	Sweep Width (Hz)	6401.85	Temperature (degree C)	26.945
				Spectrum Offset (Hz)	2791.1379



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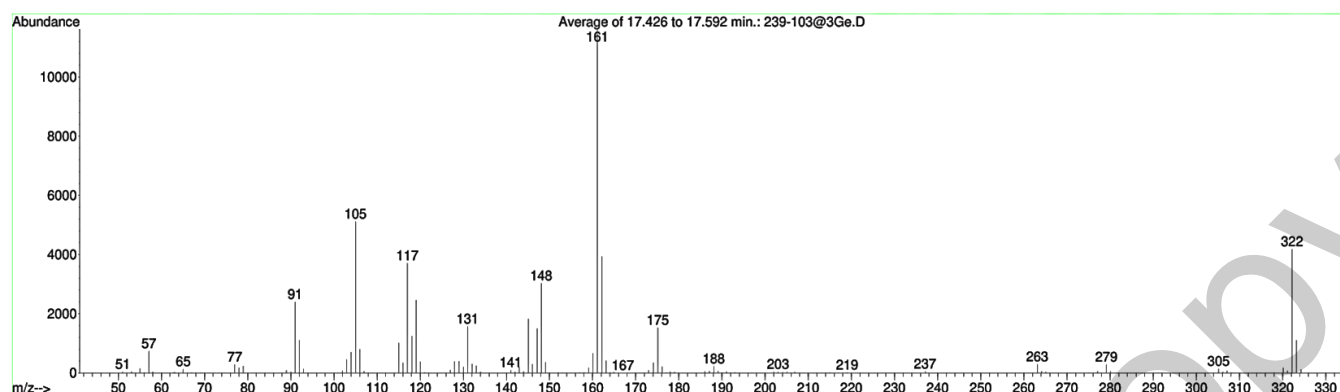
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Ib. Mass Spectrum

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



Theoretical values: 322 [M+.]

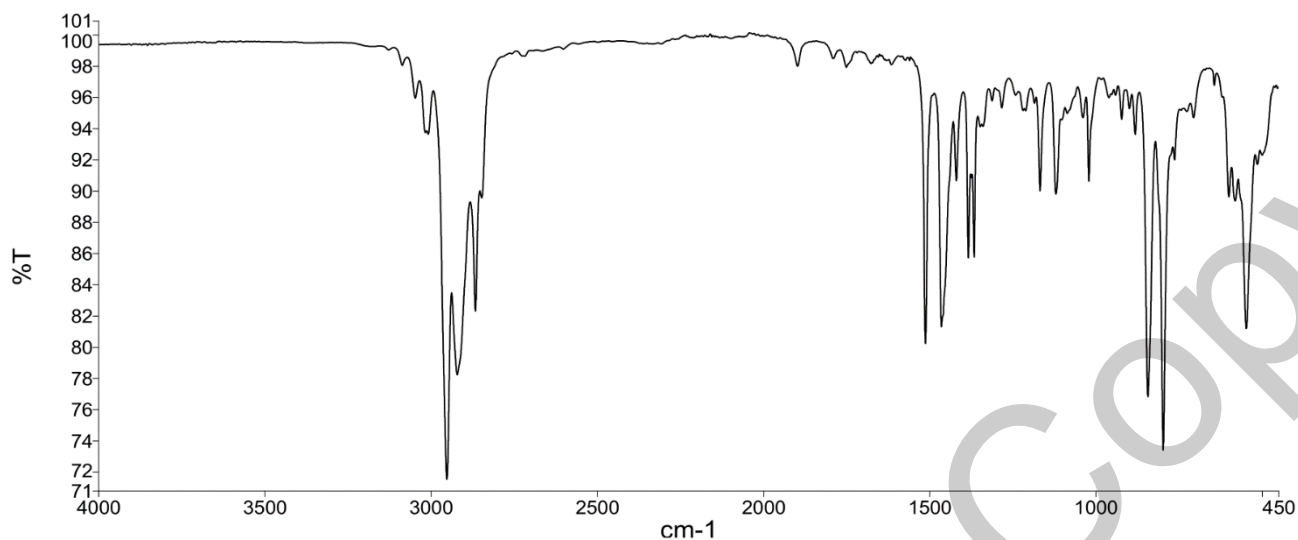
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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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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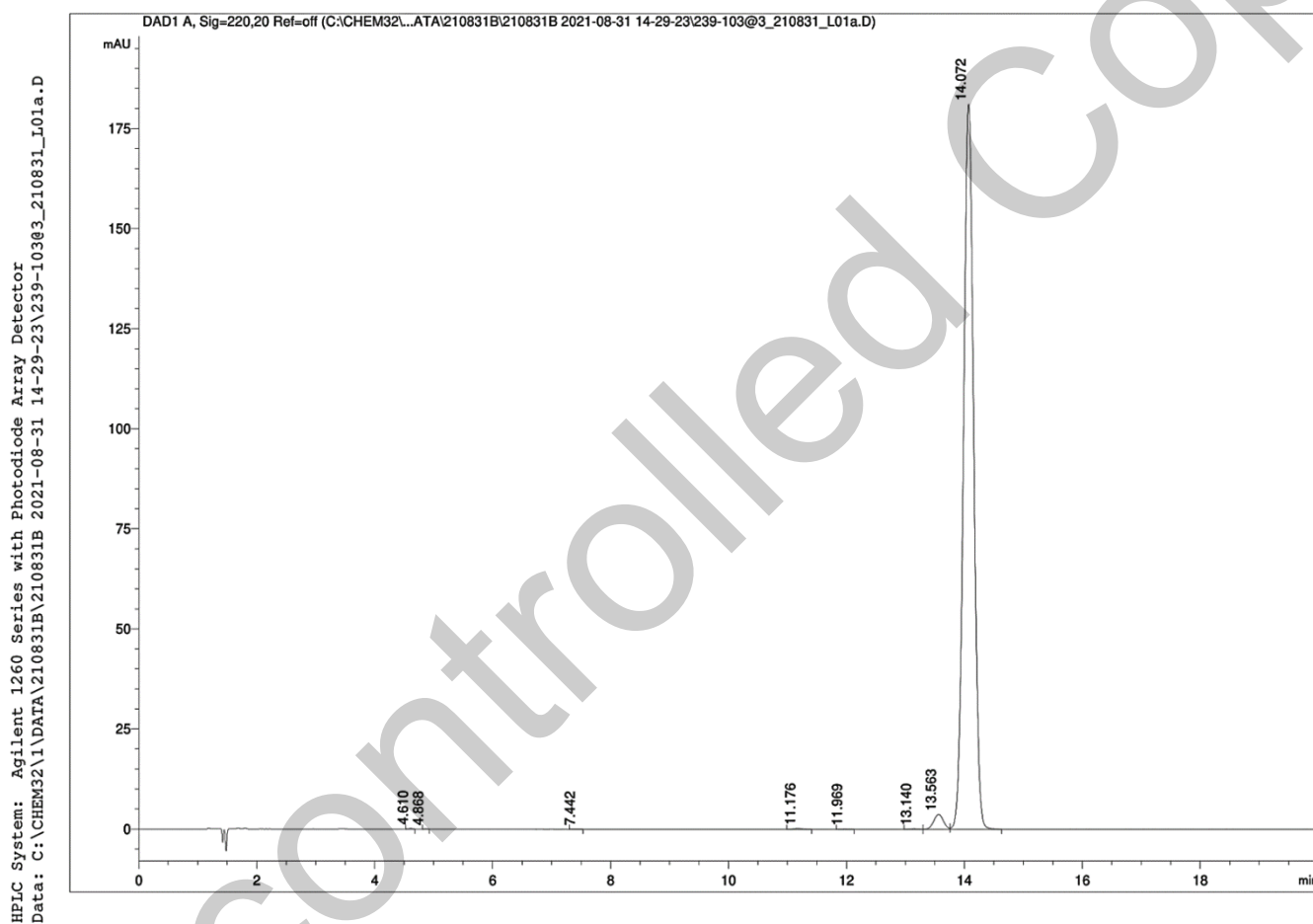
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II. Purity

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 150mm 2.7 micron	25°C			DAD 220nm	Auto 1.0 µL 0.8 mg/mL in 100% acetonitrile (NO MODIFIERS)
	Time (min)	% Line A [Pre-mixed (v/v) 95% acetonitrile / 5% water (+ 0.1% (v/v) TFA)]	Flow rate (mL/min)		
	0.00	100	1.0		
	20.00	100	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.61	0.74	0.03
2	4.87	0.16	0.01
3	7.44	0.26	0.01
4	11.18	2.41	0.11
5	11.97	0.34	0.02
6	13.14	1.01	0.05
7	13.56	42.68	1.94
8	14.07	2157.41	97.84
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 97.8% (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: BP 2016 Ash (Appendix XI J) as per WS001/28508

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹H NMR

Result:

No significant impurities detected by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	97.8%
Water content	<0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity	97.8%

This purity is assessed to be 97.8%.

Product Reviewed By:

James Rixson, PhD
Head of Production

Product Released By:

Carol Worth, PhD
Quality Manager
Release Date: 9 September 2021

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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