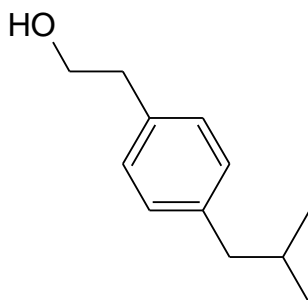


Reference Material Product Information Sheet

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



Name	2-(4-(2-methylpropyl)phenyl)ethanol
BP/EP Name	Ibuprofen Impurity Q
USP Name	Not Listed.
Synonym(s)	(para-isobutylphenyl)ethanol; 2-(4-isobutylphenyl)ethyl alcohol; (4-isobutylphenyl)ethanol.
Epichem Item #	EPL-AA163 Batch 1
CAS #	36039-35-7
Molecular Formula	C ₁₂ H ₁₈ O
Molecular Weight	178.28g/mol
Appearance	Colourless oil
Melting Point	Not applicable.
Combustion Analysis	Required (%): C:80.8; H:10.2; N:0.0. Found (%): C:80.9; H:10.3; N: 0.0.
Purity*	98.5%
Date of Manufacture	18 December 2014
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)

* NATA accreditation does not cover the performance of this service

EPL-AA163 Batch 1

Revision 1

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. ¹HNMR Spectrum

Conditions: 400 MHz, CDCl₃

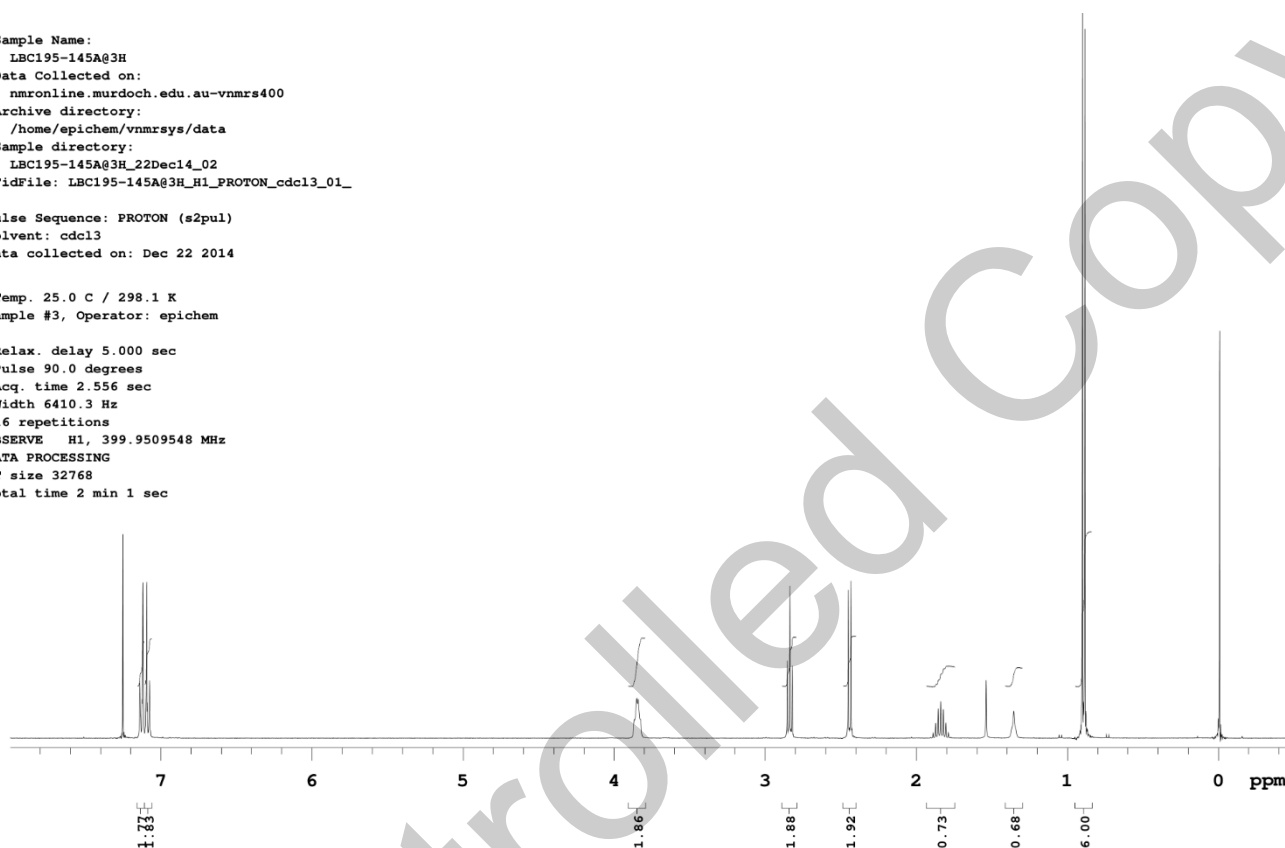
¹HNMR spectrum consistent with chemical structure.

Sample Name: LBC195-145A@3H
Data Collected on: nmronline.murdoch.edu.au-vmrns400
Archive directory: /home/epichem/vmrnsys/data
Sample directory: LBC195-145A@3H_22Dec14_02
FidFile: LBC195-145A@3H_H1_PROTON_cdc13_01_

Pulse Sequence: PROTON (s2pul)
Solvent: cdcl3
Data collected on: Dec 22 2014

Temp. 25.0 C / 298.1 K
Sample #3, Operator: epichem

Relax. delay 5.000 sec
Pulse 90.0 degrees
Acq. time 2.556 sec
Width 6410.3 Hz
16 repetitions
OBSERVE H1, 399.9509548 MHz
DATA PROCESSING
FT size 32768
Total time 2 min 1 sec



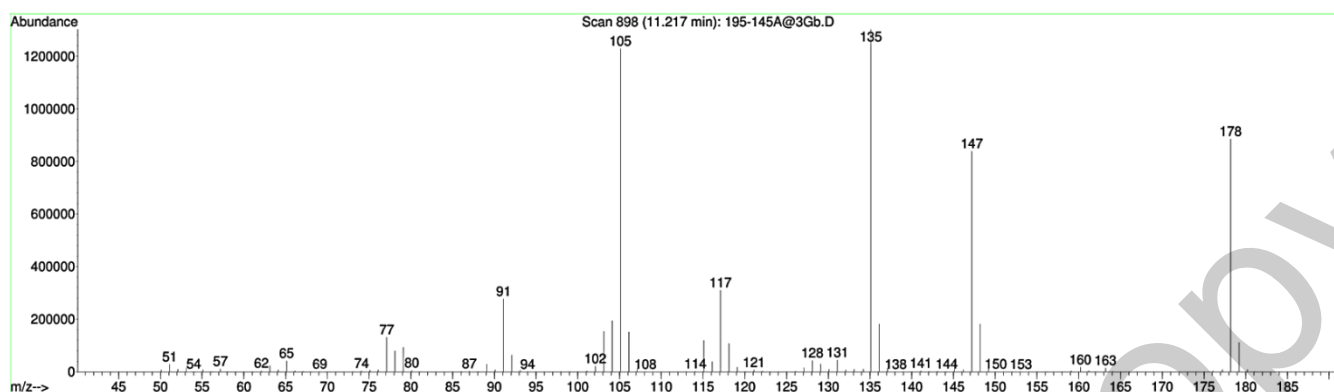
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Ib. Mass Spectrum

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

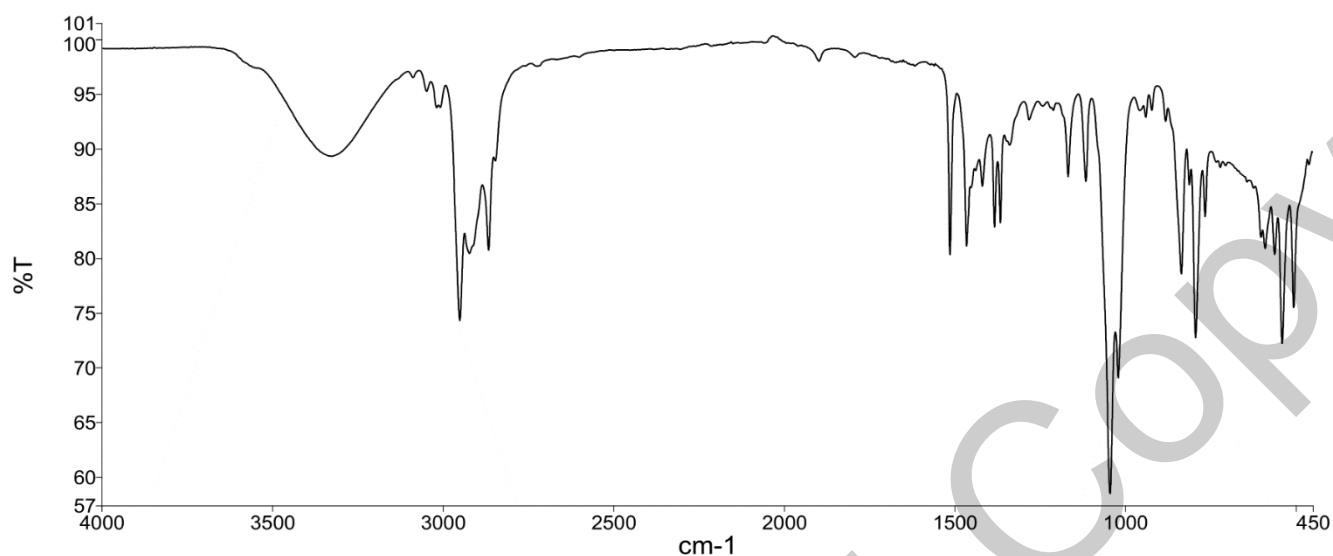


Theoretical values: 178 [M]⁺.

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

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-AA163 Batch 1

Revision 1

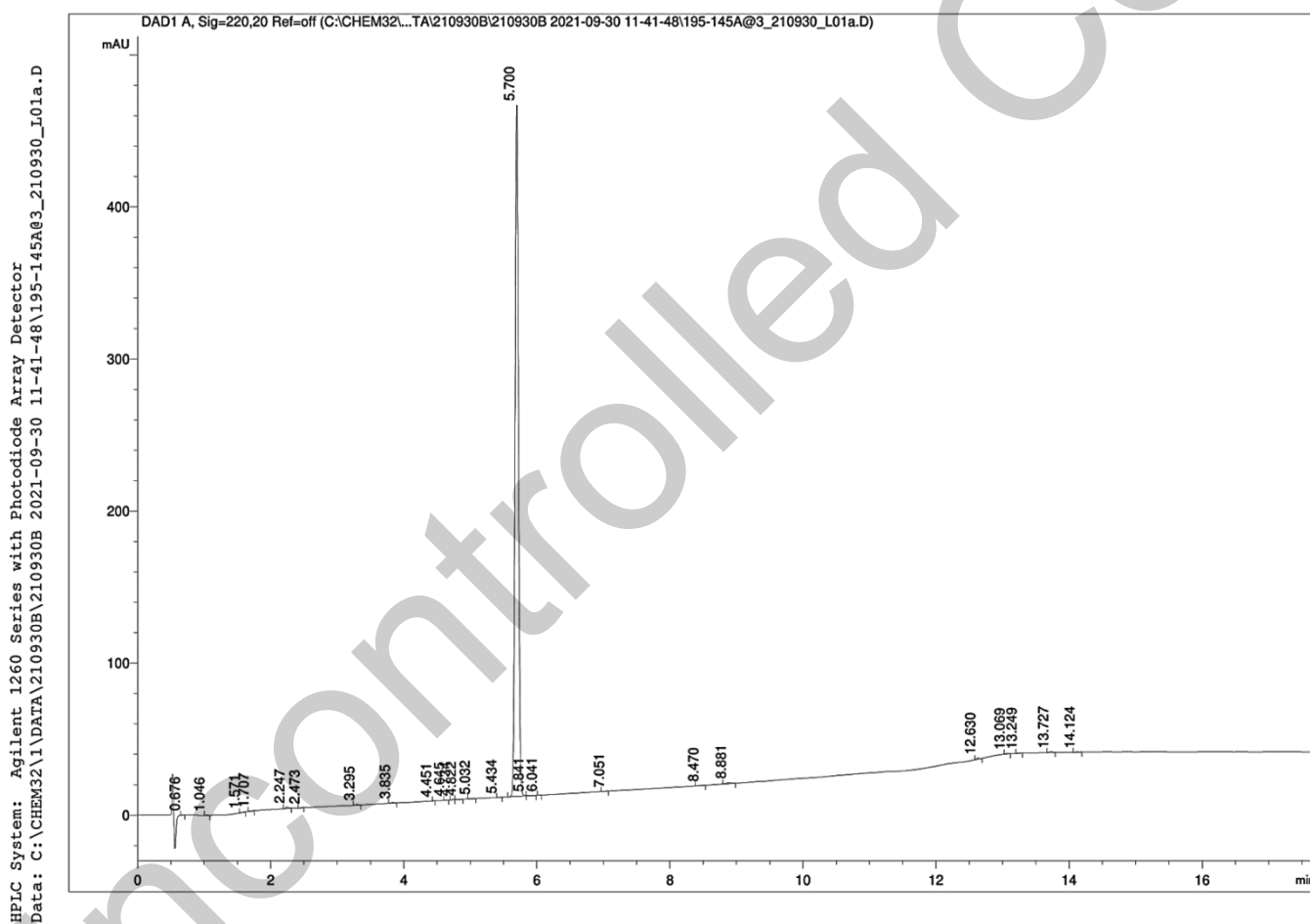
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II. Purity

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 220nm	Auto 1.0 µL 0.8 mg/mL in 100% acetonitrile (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	70	30	1.0		
	10.00	20	80	1.0		
	11.50	5	95	1.0		
	16.50	5	95	1.0		
	17.50	70	30	1.0		
	20.50	70	30	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	0.68	0.46	0.03
2	1.05	0.53	0.03
3	1.57	0.40	0.03
4	1.71	0.39	0.02
5	2.25	2.64	0.17
6	2.47	0.19	0.01
7	3.30	1.67	0.11
8	3.83	1.08	0.07
9	4.45	0.04	0.00
10	4.64	0.14	0.01
11	4.73	0.08	0.01
12	4.82	0.26	0.02
13	5.03	0.64	0.04
14	5.43	0.14	0.01
15	5.70	1568.69	98.78
16	5.84	0.96	0.06
17	6.04	0.06	0.00
18	7.05	0.29	0.02
19	8.47	0.65	0.04
20	8.88	3.26	0.21
21	12.63	1.77	0.11
22	13.07	0.98	0.06
23	13.25	0.59	0.04
24	13.73	1.42	0.09
25	14.12	0.80	0.05
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 98.7% (average of 10 duplicate runs)

III. Water Content

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

Results:

Average 0.2%

IV. Ash Content

Method: BP 2015 Ash (Appendix XI J) as per WS001/23962

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)	98.7%
Water content	0.2%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	98.5%

This purity is assessed to be 98.5%.

Product Reviewed By:

James Rixson, PhD
Head of Production

Product Released By:

Carol Worth, PhD
Quality Manager
Release Date: 12 October 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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