



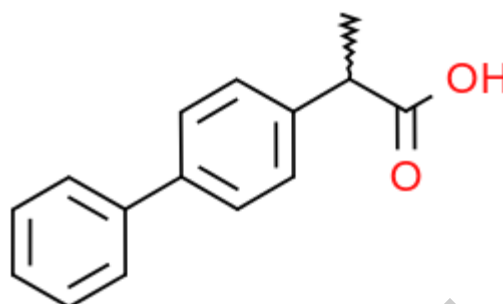
Accredited for compliance with ISO 17034.
 Accreditation Number 20126
 NATA is a signatory to the ILAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of testing, medical testing, calibration, inspection, proficiency testing scheme providers and reference materials producers reports and certificates.
This document shall not be reproduced except in full.



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.



Name	(RS)-2-(biphenyl-4-yl)propanoic acid
BP/EP Name	Flurbiprofen Impurity A
USP Name	Flurbiprofen Related Compound A
Synonym(s)	α -methyl-[1,1'-Biphenyl]-4-acetic acid; Biprofen
Epichem Item #	EPL-AA99 Batch 3
CAS #	6341-72-6
Molecular Formula	C ₁₅ H ₁₄ O ₂
Molecular Weight	226.28 g/mol
Appearance	White powder
Melting Point	145.3-147.5°C
Combustion Analysis	Required (%): C:79.6; H:6.2; N:0.0. Found (%): C:79.8; H:6.5; N:<0.3.
Purity*	99.0%
Date of Manufacture	4 May 2023
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-AA99 Batch 3

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
 Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

I. Identity

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

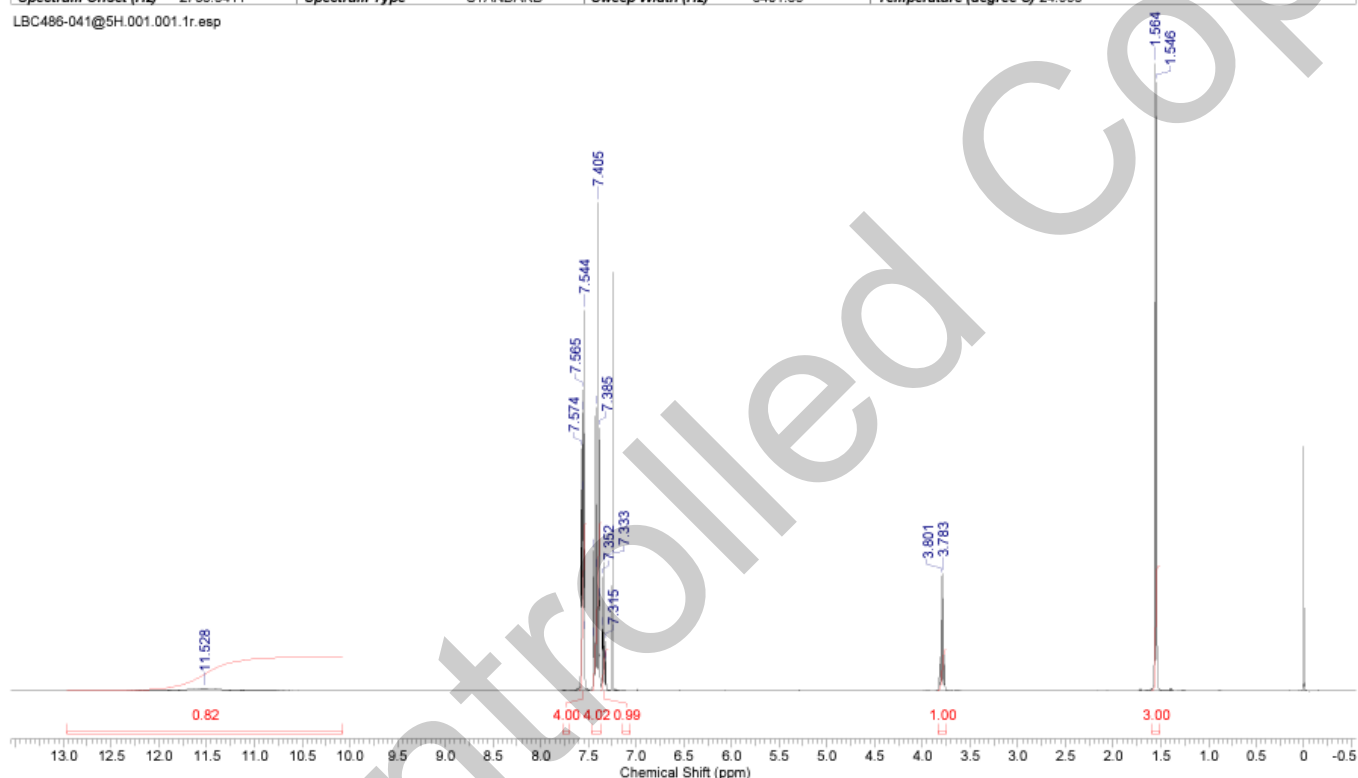
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, CDCl₃

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC486-041@5H 1H CDCl3 (E:\dataexternal\epichem) cygoh 17	Date	04 May 2023 16:57:36
Date Stamp	04 May 2023 16:57:36	File Name	W\NAPHTHALENE\Company\015 NMR files\LBC486\LBC486-041@5H\1\data\111r	Origin	spect
Frequency (MHz)	400.13	Nucleus	1H	Number of Transients	8
Original Points Count	24038	Owner	nmr	Points Count	32768
Receiver Gain	144.00	SW(cyclical) (Hz)	6402.05	Solvent	CHLOROFORM-d
Spectrum Offset (Hz)	2786.3411	Spectrum Type	STANDARD	Sweep Width (Hz)	6401.85
				Temperature (degree C)	24.996

LBC486-041@5H.001.001.1r.esp



EPL-AA99 Batch 3

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

Tel + 61 (0)8 6167 5200

Fax + 61 (0)8 6167 5201

www.epichem.com.au

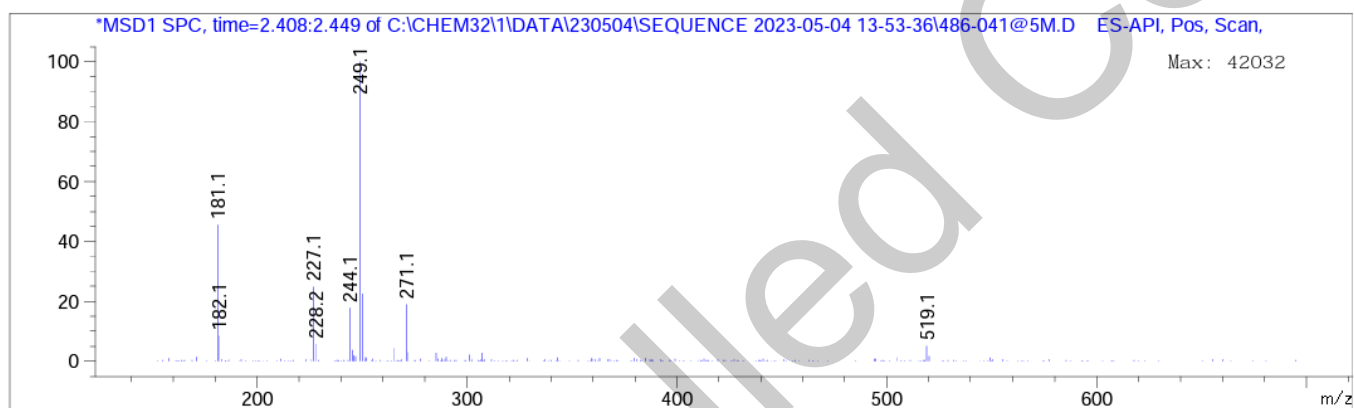
ABN 80 106 769 902

Ib. Mass Spectrum

The mass spectrum of this material was analysed by Liquid Chromatography Mass Spectroscopy (LCMS) using in-house 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
2.426	632401	271.10 I
		250.10 I
		249.10 I
		244.15 I
		227.10 I
		181.10 I



Theoretical values: 227.1 [M+H]⁺.

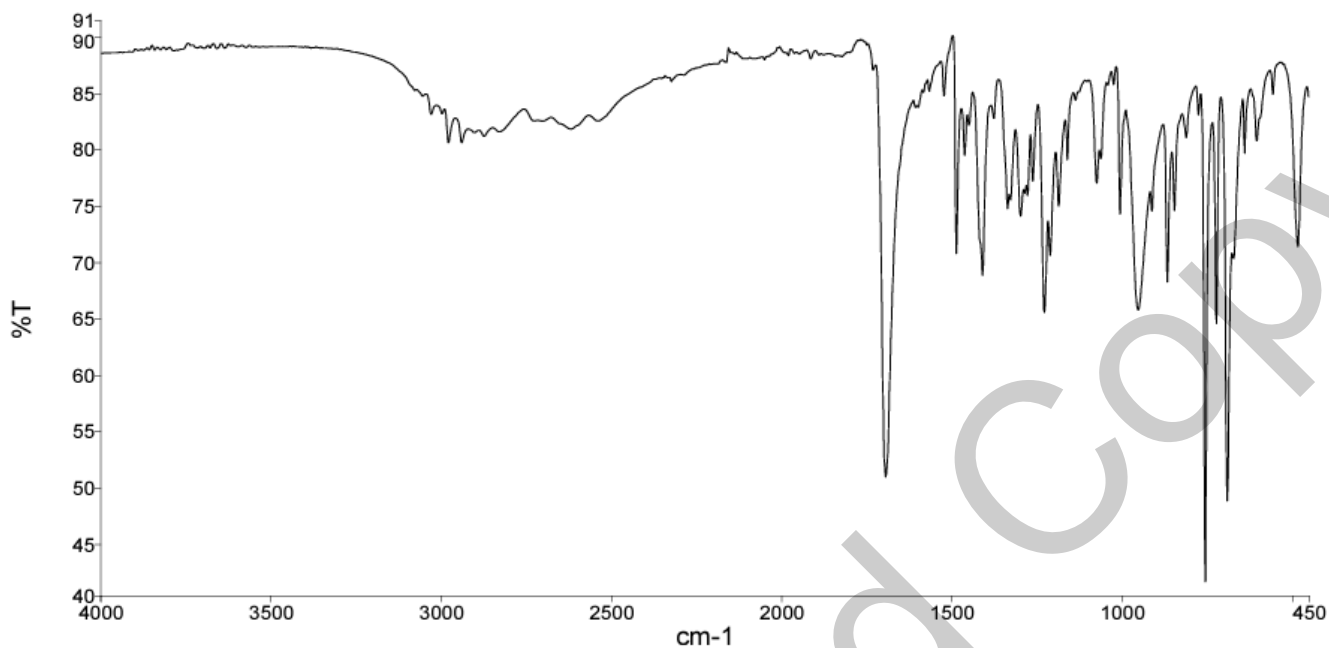
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

EPL-AA99 Batch 3

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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-AA99 Batch 3

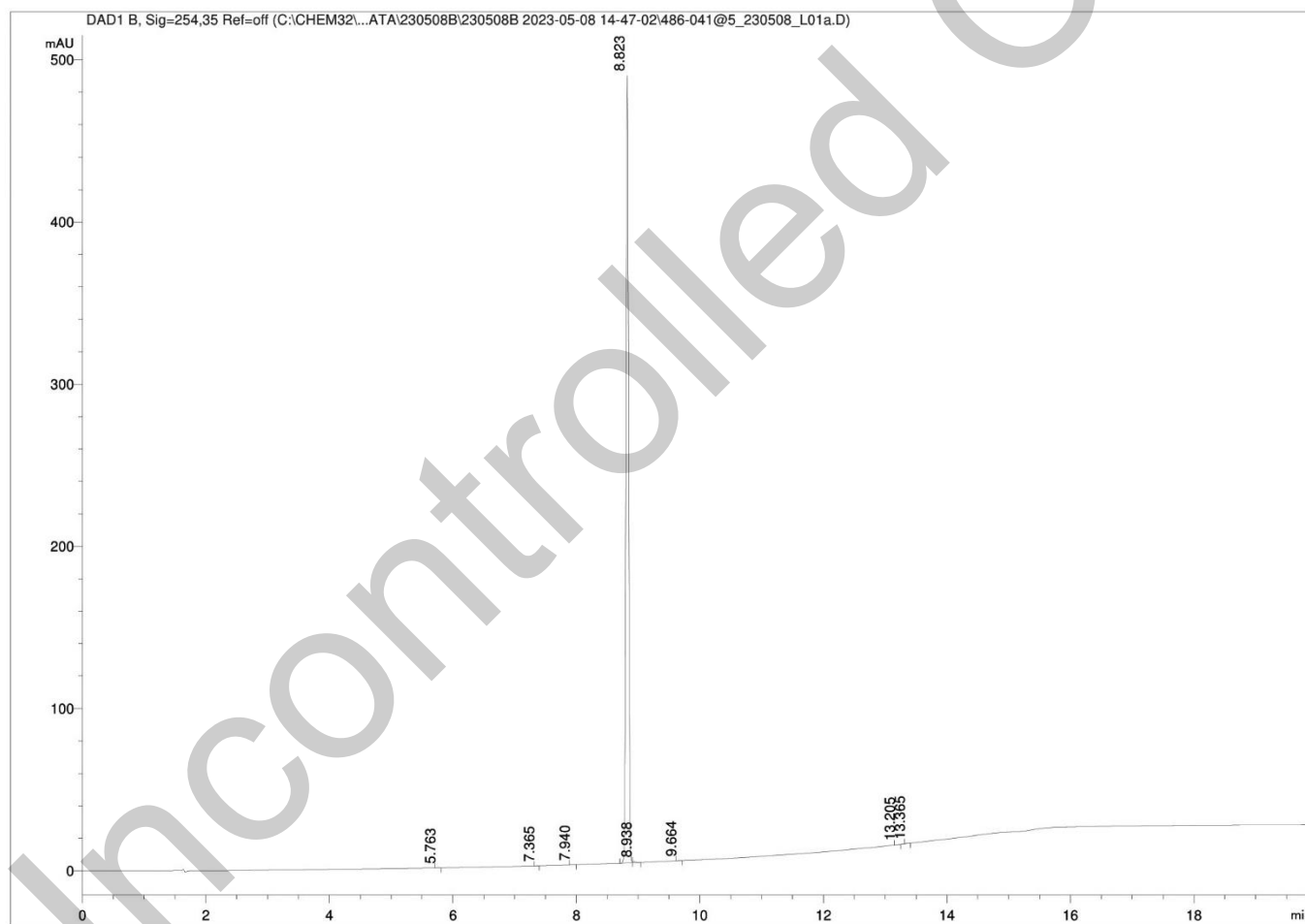
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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	18°C				DAD 254nm	Auto 1.0 µL 0.3 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		
	13.00	5	95	1.0		
	18.00	5	95	1.0		
	19.00	70	30	1.0		
28.00	70	30	1.0			



EPL-AA99 Batch 3

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	5.76	0.28	0.02
2	7.36	0.14	0.01
3	7.94	0.37	0.03
4	8.82	1380.37	99.71
5	8.94	2.26	0.16
6	9.66	0.44	0.03
7	13.21	0.27	0.02
8	13.37	0.28	0.02
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 99.7% (average of 10 duplicate runs)

EPL-AA99 Batch 3

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

III. Water Content

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

Results:

Average 0.1%

IV. Ash Content

Method: Current BP (Appendix XI J, Method II); Current Ph Eur (2.4.16)

Result:

Contains 0.6% ash.

V. Residual Solvents

Method: ¹H NMR

Result:

No significant impurities detected by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.7%
Water content	0.1%
Ash content	0.6%
Residual solvents	<0.1%
Purity*	99.0%

This purity is assessed to be 99.0%.

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Carol Worth, PhD
Quality Manager

Release Date: 14 June 2023

**NATA accreditation does not cover the performance of this service.*

The calculation of the purity follows the formula:

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

EPL-AA99 Batch 3

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902