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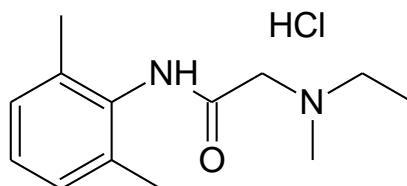
The results of the tests, calibrations and/or measurements included in this document are traceable to Australia/national standards.
NATA is a signatory to the APLAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of reference materials certificates.



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.



Name	<i>N</i> -(2,6-dimethylphenyl)-2-(ethylmethylamino)acetamide hydrochloride (1:1)
BP Name	Lidocaine Impurity K hydrochloride
Epichem Item #	EPL-AA247 Batch 1
CAS #	50295-20-0
Molecular Formula	C ₁₃ H ₂₁ ClN ₂ O
Molecular Weight	256.77 g/mol
Appearance	White powder
Melting Point	169.2-174.8°C
Combustion Analysis	Required (%): C:60.8, H:8.2, N:10.9. Found (%): C:60.9, H:8.4, N:11.0.
Purity*	99.5%
Date of Manufacture	16 August 2019
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 unopened and stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

* NATA accreditation does not cover the performance of this service

EPL-AA247 Batch 1

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

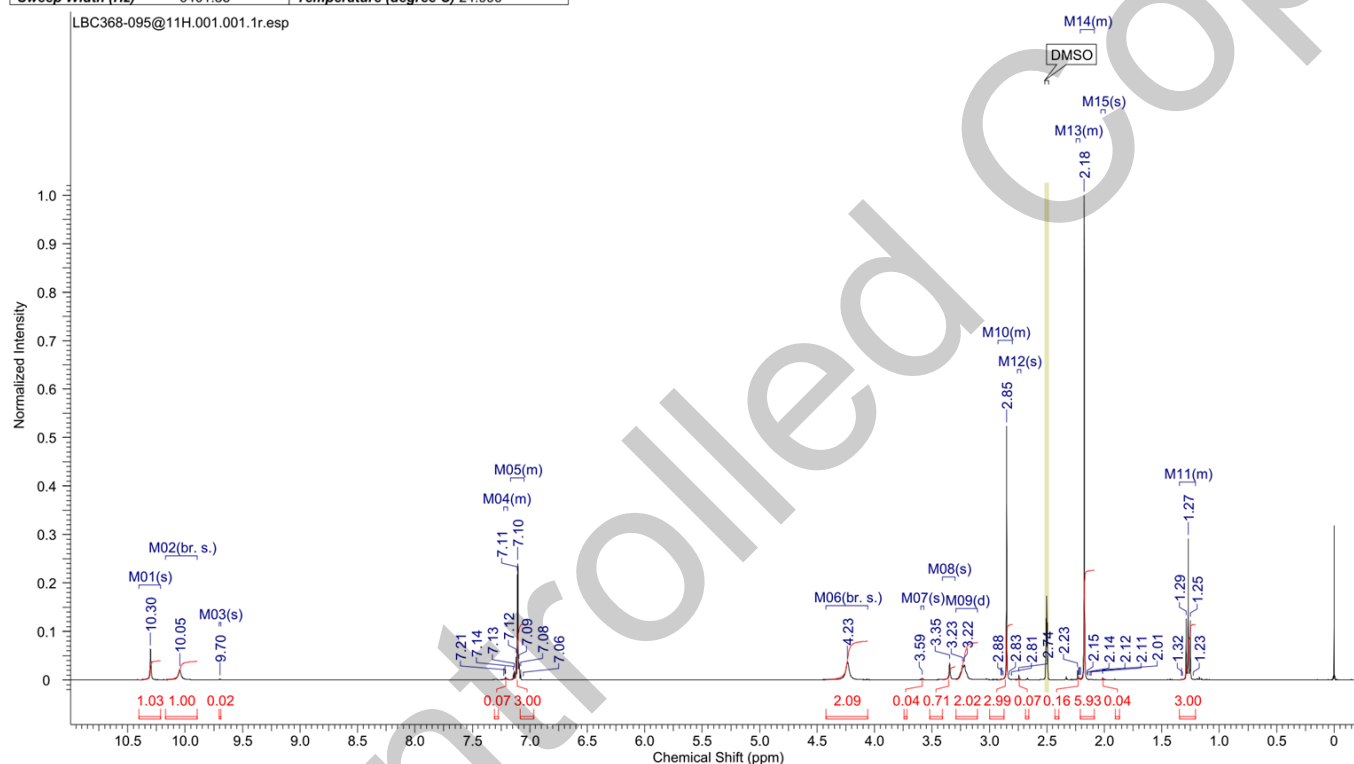
The identity of this product was established using the following analyses:

Ia. ¹H NMR Spectrum

Conditions: 400 MHz, DMSO-d₆

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC368-095@11H 1H DMSO (E:\data\external\epichem) cygoh 8				
Date	19 Aug 2019 17:53:04	Date Stamp	19 Aug 2019 17:53:04				
File Name	\naphthalene\company\NMR files\LBC368-095@11H\1\pdata\11r		Frequency (MHz)	400.13			
Nucleus	1H	Number of Transients	16	Original Points Count	24038		
Owner	nmr	Points Count	32768	Pulse Sequence	zg	Receiver Gain	128.00
SW(cyclical) (Hz)	6402.05	Solvent	DMSO-d ₆	Spectrum Offset (Hz)	2799.3372	Spectrum Type	STANDARD
Sweep Width (Hz)	6401.85	Temperature (degree C)	24.996				



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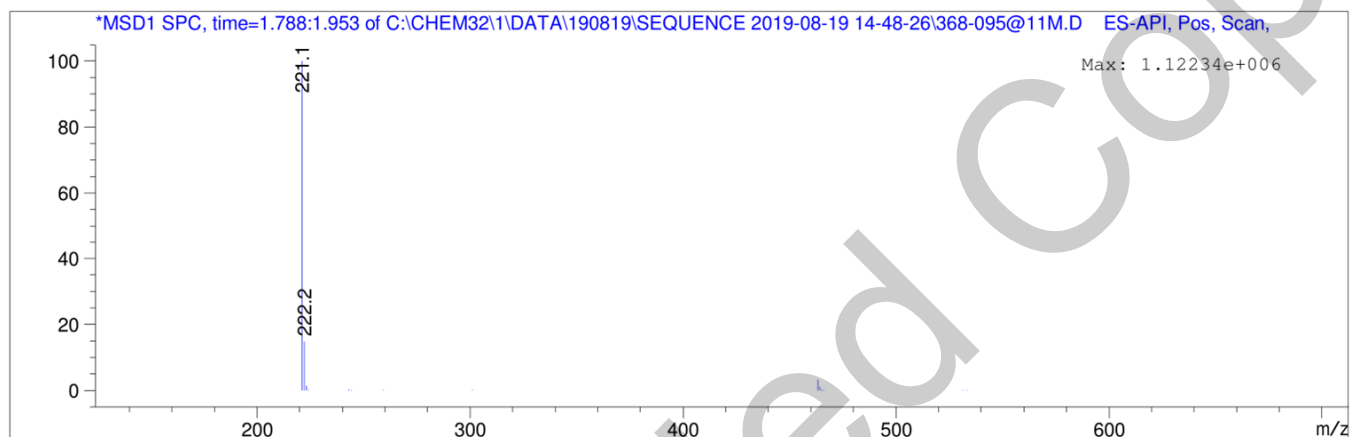
ABN 80 106 769 902

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
1.838	18079728	222.20 I 221.15 I



Theoretical value: 221.1 [M-Cl]⁺.

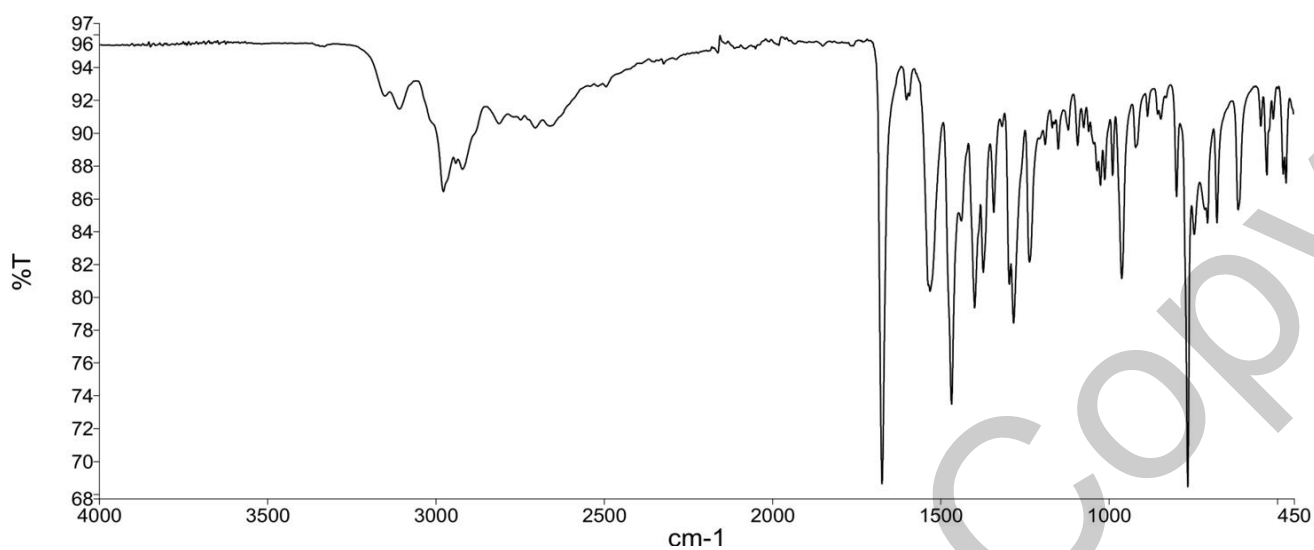
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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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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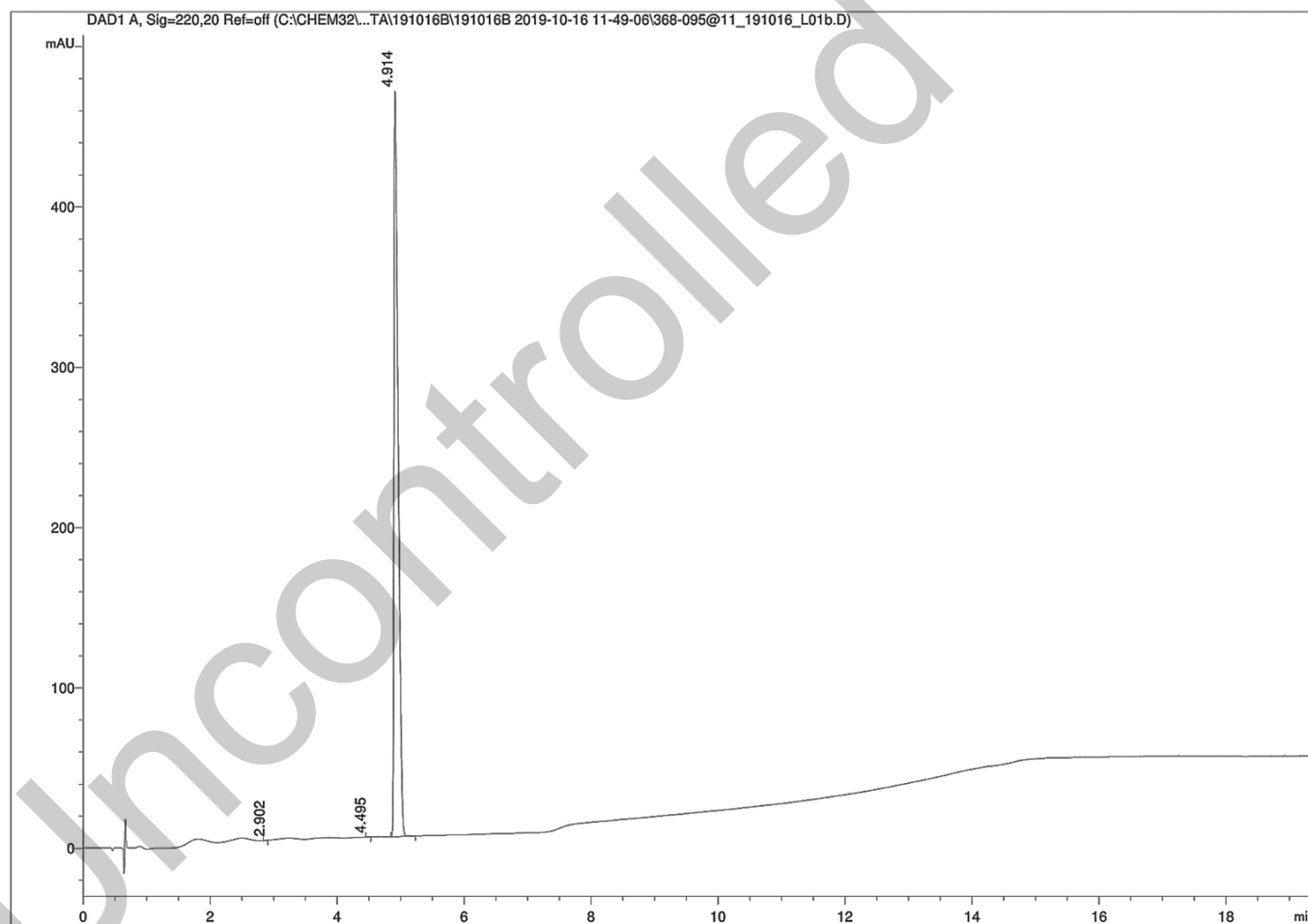
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II. Purity

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 C-18 4.6x50 mm 2.7 micron	45°C				DAD 220nm	Auto 1.0 µL 1.2mg/mL in water (+0.1% TFA)
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
	0.00	95	5	1.0		
	6.00	77	23	1.0		
	13.20	5	95	1.0		
	18.20	5	95	1.0		
	19.20	95	5	1.0		
	22.20	95	5	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.74	0.04	0.00
2	4.52	0.32	0.02
3	4.93	2095.60	99.98
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% (average of 10 duplicate analyses)

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III. Water Content

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

Results:

Average 0.2%

IV. Ash Content

Method: BP 2019 Ash Appendix XII Method II

Result:

Contains 0.3% ash.

V. Residual Solvents

Method: ¹H NMR

Result:

<0.1 residual solvent by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	100%
Water content	0.2%
Ash content	0.3%
Residual solvents	<0.1%
Purity*	99.5%

This purity is assessed to be 99.5%

Product Reviewed By:

Product Released By:

John Moursounidis, PhD
Head Reference Standards

Boon Tan
Quality Manager

Release Date: 28 November 2019

*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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