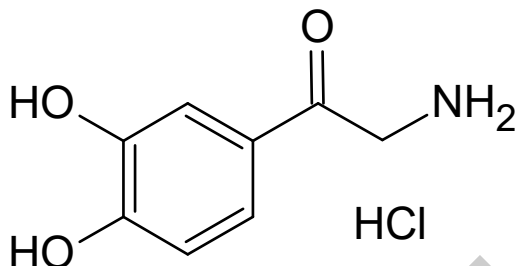


Reference Material Product Information Sheet

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



Name	2-amino-1-(3,4-dihydroxyphenyl)ethanone hydrochloride
BP/EP Name	Noradrenaline Impurity B
USP Name	Not listed.
Synonym(s)	Noradrenalone hydrochloride
Epichem Item #	EPL-AA222 Batch 3
CAS #	5090-29-9
Molecular Formula	C ₈ H ₉ NO ₃ .HCl
Molecular Weight	203.63 g/mol
Appearance	Pale brown powder
Melting Point	254.0-255.9°C (decomposition)
Combustion Analysis	Required (%): C:47.2; H:5.0; N:6.9. Found (%): C:45.4; H:5.2; N:6.3
Purity*	96.0%
Date of Manufacture	25 June 2019
Storage Requirements	Hygroscopic. 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

I. Identity

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

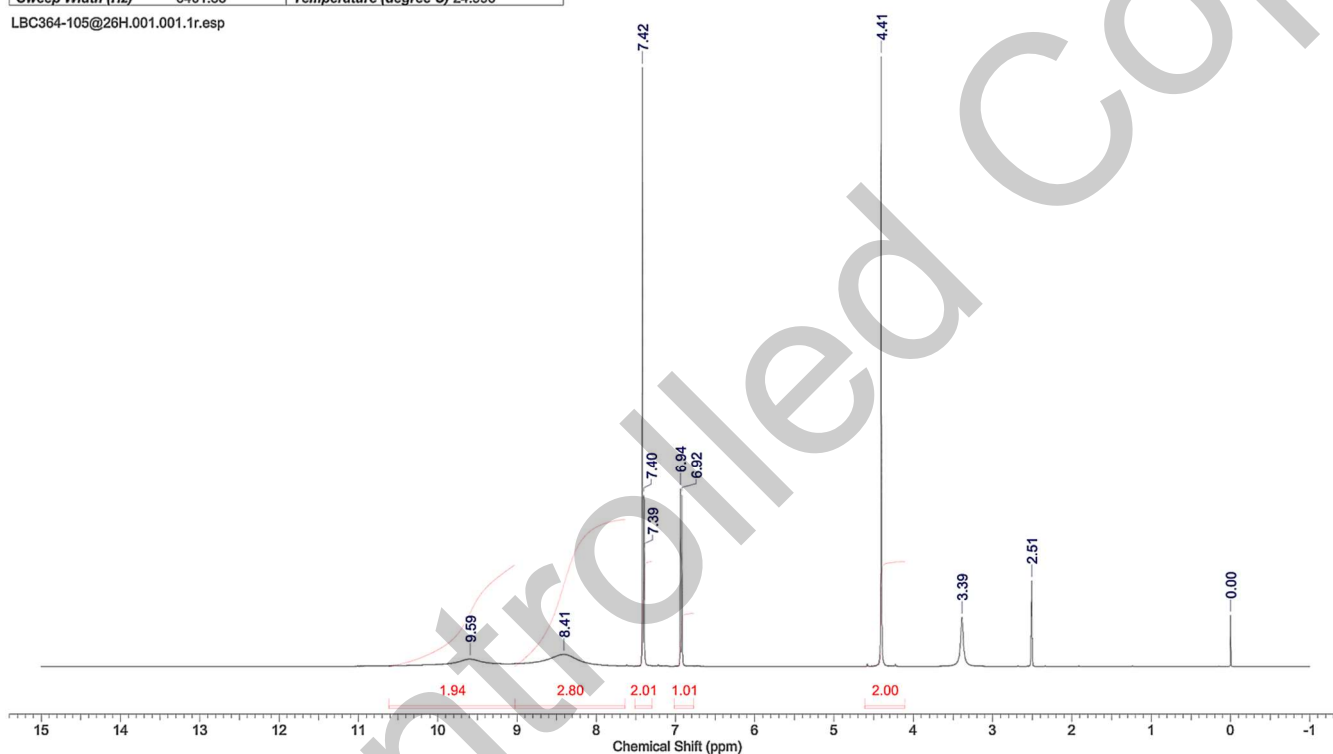
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, DMSO-d₆

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC364-105@26H 1H DMSO (E:\dataexternal\epichem) cygoh 20		
Date	16 Jul 2019 17:27:28	Date Stamp	16 Jul 2019 17:27:28		
File Name	\naphthalene\company\NMR files\LBC364\LBC364-105@26H\1\data\1\1r		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	DMSO-d6	Receiver Gain	90.50
Sweep Width (Hz)	6401.85	Temperature (degree C)	24.996	Spectrum Offset (Hz)	2801.9419
				Spectrum Type	STANDARD

LBC364-105@26H.001.001.1r.esp



EPL-AA222 Batch 3

Revision 2

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

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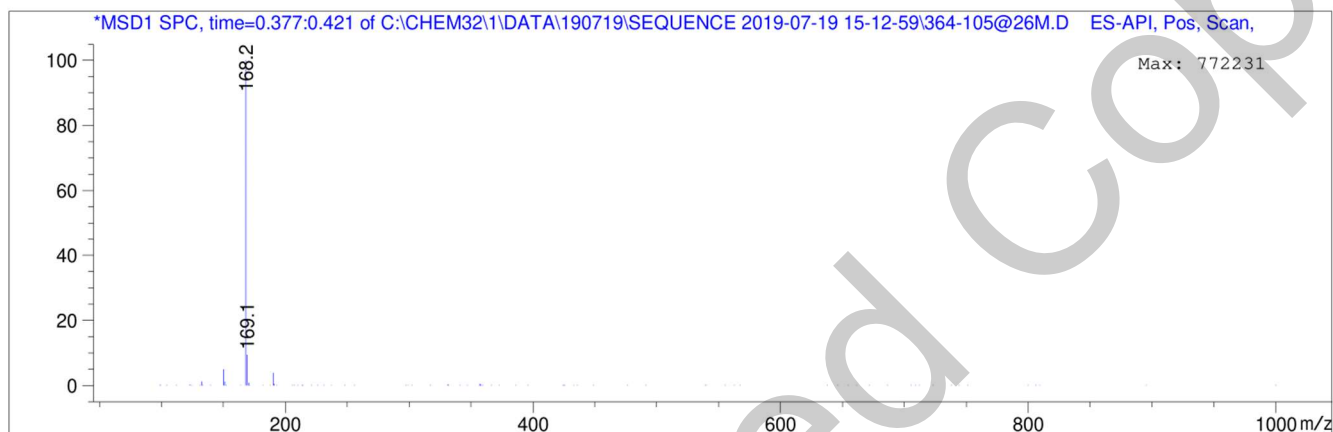
ABN 80 106 769 902

Ib. Mass Spectrum

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

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

Retention Time (MS)	MS Area	Mol. Weight or Ion
0.401	5293407	168.20 I

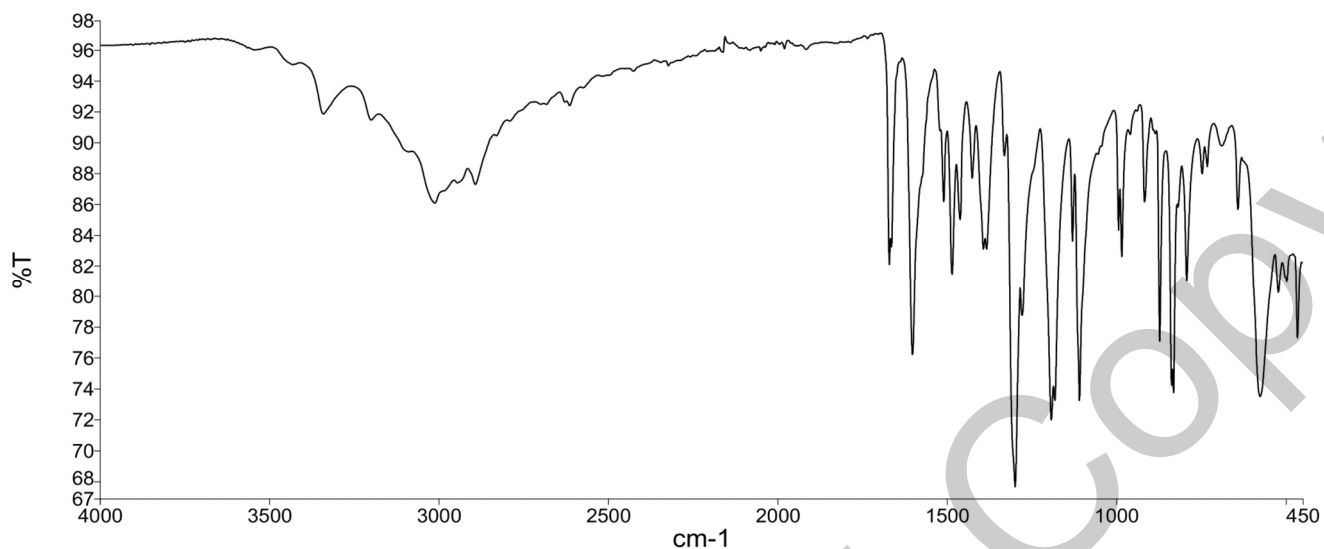


Theoretical values: 168.2 [M+H]⁺.

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.



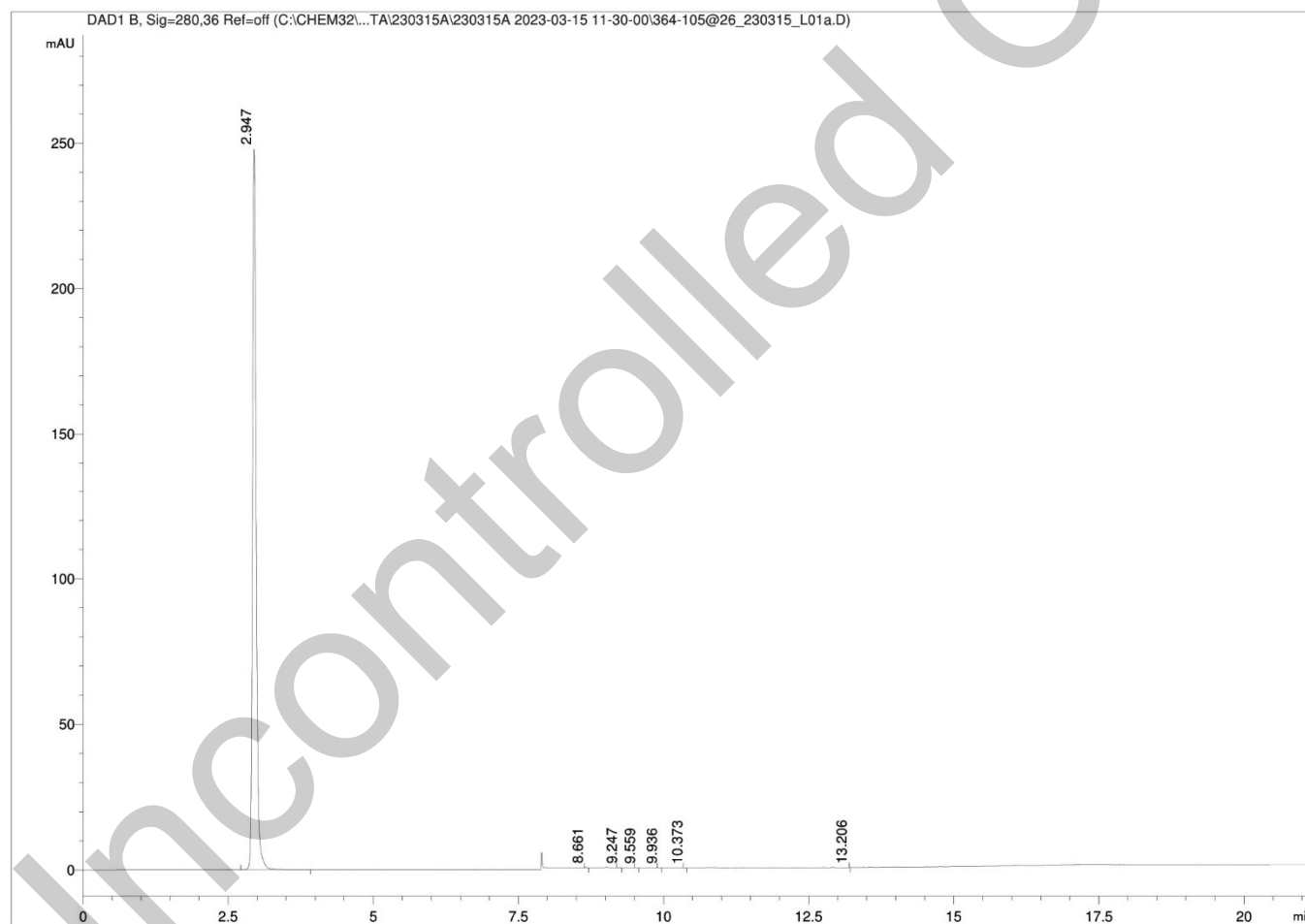
The interpretation of the signals of the Fourier-Transform Infrared Spectrum is consistent with the structural formula.

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
Fortis H2o 4.6 x 100mm 3 micron	15°C				DAD 280nm	Auto 1.0 µL 0.5 mg/mL in water + 0.1% (v/v) 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	100	0	1.0		
	5.00	100	0	1.0		
	14.50	5	95	1.0		
	19.50	5	95	1.0		
	20.50	100	0	1.0		
	26.50	100	0	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	2.95	1086.75	99.93
2	8.66	0.33	0.03
3	9.25	0.29	0.03
4	9.56	0.04	0.00
5	9.94	0.07	0.01
6	10.37	0.04	0.00
7	13.21	0.01	0.00
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 99.9% (average of 10 duplicate runs)

III. Water Content

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

Results:

Average 3.7%

IV. Ash Content

Method: BP2019 Appendix XI J Method II

Result:

Contains 0.2% ash.

V. Residual Solvents

Method: ¹H NMR

Result:

No significant impurities detected by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.9%
Water content	3.7%
Ash content	0.2%
Residual solvents	<0.1%
Purity*	96.0%

This purity is assessed to be 96.0%.

Product Reviewed By:



Jacob Heppell, PhD
Chemist

Product Released By:



Carol Worth, PhD
Quality Manager

Release Date: 20 March 2023

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

The calculation of the purity follows the formula:

$$\text{Purity(\%)} = \frac{((\text{Chromatographic purity [HPLC]}) \times (100 - (\text{water content} + \text{ash content} + \text{volatile contents})))}{100}$$