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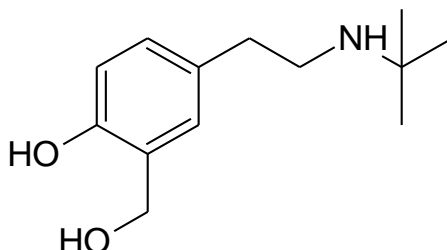
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## Reference Material Product Information Sheet

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



<b>Name</b>	4-(2-(tert-butylamino)ethyl)-2-(hydroxymethyl)phenol
<b>USP Name</b>	Levalbuterol Related Compound A
<b>Synonym(s)</b>	5-(2-((1,1-dimethylethyl)amino)ethyl)-2-hydroxy-benzenemethanol
<b>Epichem Item #</b>	EPL-AA281 Batch 1
<b>CAS #</b>	1823256-56-9
<b>Molecular Formula</b>	C <sub>13</sub> H <sub>21</sub> NO <sub>2</sub>
<b>Molecular Weight</b>	223.32 g/mol
<b>Appearance</b>	Off-white solid
<b>Melting Point</b>	150.6-153.4°C
<b>Combustion Analysis</b>	Required (%): C:69.9; H:9.5; N:6.3. Found (%): C:69.6; H:9.7; N:6.2.
<b>Purity*</b>	98.3%
<b>Date of Manufacture</b>	11 May 2021
<b>Storage Requirements</b>	Protect from heat, light and moisture.
<b>Special Precautions</b>	<b>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.</b>
<b>Intended Use</b>	This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
<b>Date of Shipment</b>	TBA This certificate is valid for one year from the date of shipment provided the substance is stored under the recommended conditions.
<b>Retest Date</b>	TBA (Proper Storage and Handling Required)

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

EPL-AA281 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:

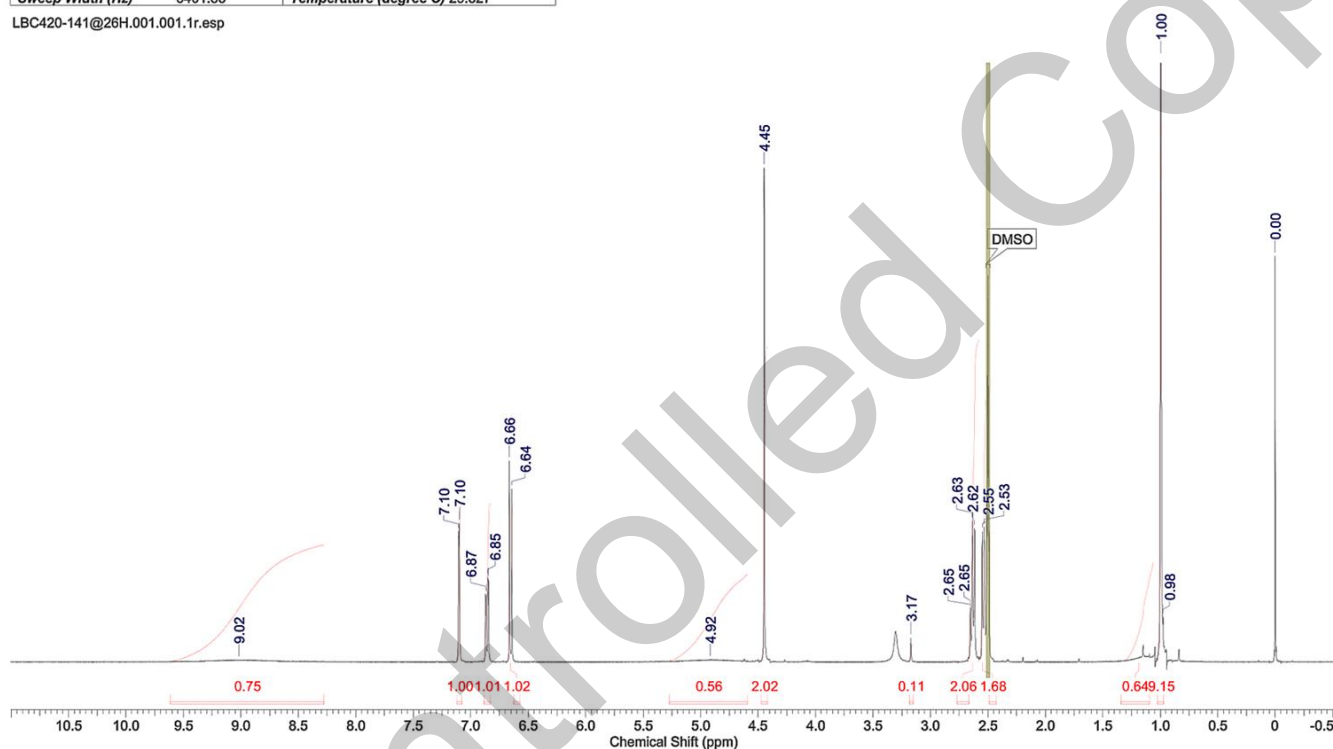
### Ia. <sup>1</sup>H NMR Spectrum

Conditions: 400 MHz, DMSO-d<sub>6</sub>

<sup>1</sup>H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC420-141@26H 1H DMSO (E:\data\external\epichem) cygoh 9				
Date	10 May 2021 17:21:04	File Name	\naphthalene\company\NMR files\LBC420-141@26H\1\data\111r	Date Stamp	10 May 2021 17:21:04		
Nucleus	1H	Number of Transients	8	Origin	spect	Frequency (MHz)	400.13
Owner	nmr	Points Count	32768	Pulse Sequence	zg	Original Points Count	24038
SW(cyclical) (Hz)	6402.05	Solvent	DMSO-d6	Spectrum Offset (Hz)	2797.5325	Receiver Gain	161.00
Sweep Width (Hz)	6401.85	Temperature (degree C)	29.327	Spectrum Type	STANDARD		

LBC420-141@26H.001.001.1r.esp



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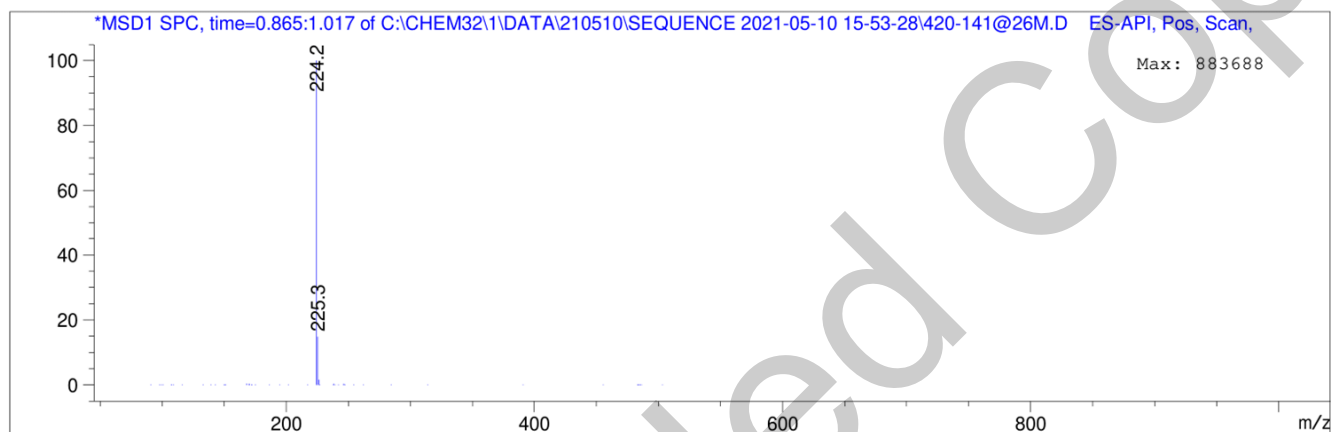
ABN 80 106 769 902

## 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
0.913	13712234	225.25 I
		224.20 I



Theoretical value: 224.2 [M+H]<sup>+</sup>.

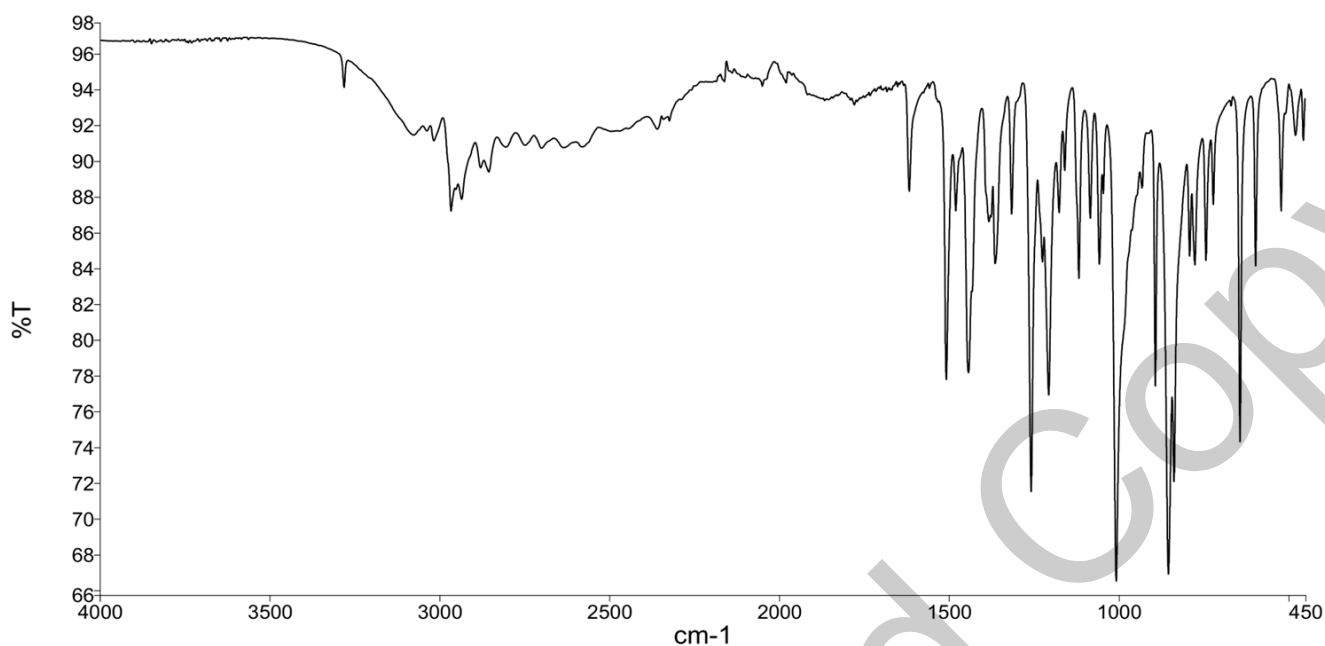
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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### Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform Infra-red Spectroscopy (FTIR) using in-house EM005.WI09.



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

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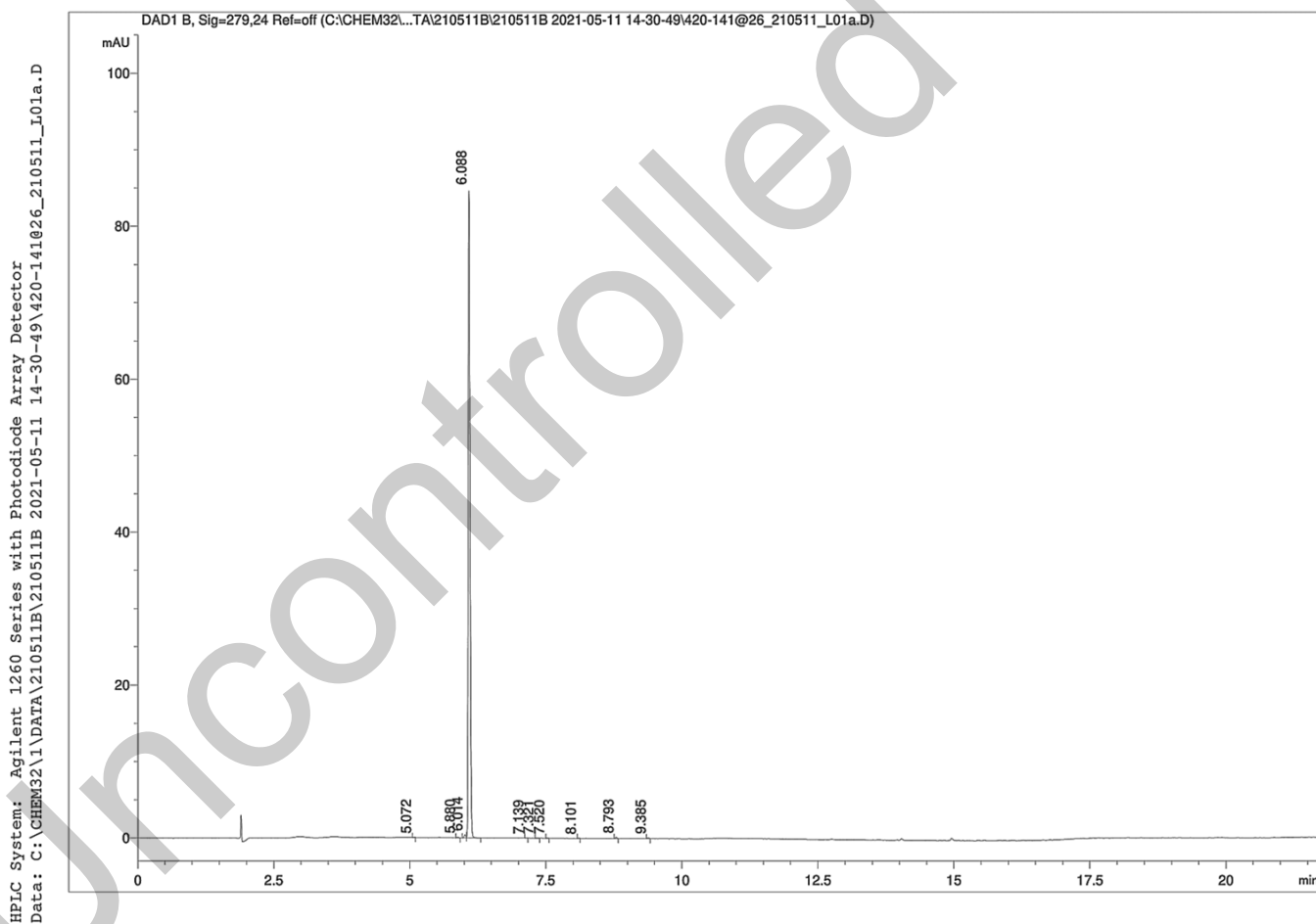
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## II. Purity

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	55°C				DAD 279nm	Auto 2.0 µL 0.30 mg/mL in 50% acetonitrile 50% water (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	97	3	1.0		
	8.00	73	27	1.0		
	14.80	5	95	1.0		
	19.80	5	95	1.0		
	20.80	97	3	1.0		
	30.80	97	3	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	5.07	0.05	0.03
2	5.88	0.20	0.11
3	6.01	0.81	0.43
4	6.09	186.92	98.93
5	7.14	0.07	0.04
6	7.32	0.10	0.05
7	7.52	0.07	0.04
8	8.10	0.09	0.05
9	8.79	0.36	0.19
10	9.38	0.28	0.15
Total			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 98.9% (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 2021 Appendix XI J Method II

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>HNMR

**Result:**

0.5% Methanol by <sup>1</sup>H NMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	98.9%
Water content	0.1%
Ash content	<0.1%
Residual solvents	0.5%
Purity*	98.3%

This purity is assessed to be 98.3%.

Product Reviewed By:

Product Released By:

James Rixson, PhD  
Head of Production

Boon Tan  
Quality Manager

Release Date: 1 June 2021

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

The calculation of the purity follows the formula:

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

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