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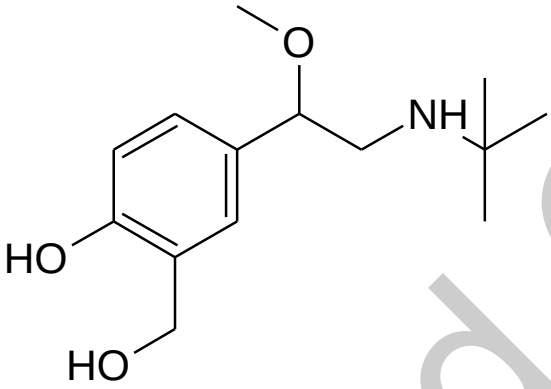
Reference Material Product Information Sheet

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



Name	4-(2-(*tert*-butylamino)-1-methoxyethyl)-2-(hydroxymethyl)phenol
BP Name	Salbutamol Impurity A
Synonym(s)	5-((1*RS*)-2-((1,1-dimethylethyl)amino)-1-methoxyethyl)-2-hydroxyphenylmethanol
Epichem Item #	EPL-AA227 Batch 1
CAS #	870076-72-5
Molecular Formula	$C_{14}H_{23}NO_3$
Molecular Weight	253.34 g/mol
Appearance	Off-white powder
Melting Point	112.4-118.2°C
Combustion Analysis	Required (%): C:66.4; H:9.2; N:5.5. Found (%): C:66.2; H:9.1; N:5.6.
Purity	97.9%
Date of Manufacture	7 December 2017
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.**
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)

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:

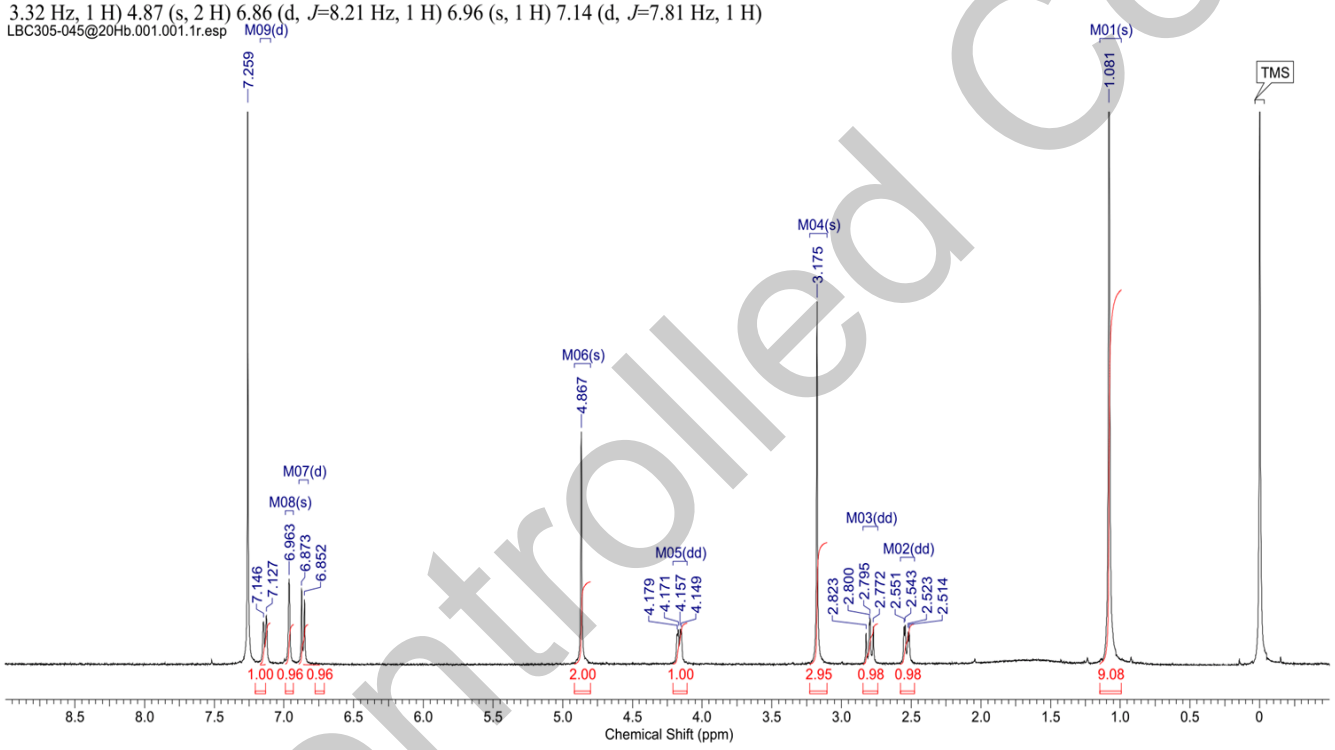
Ia. ^{1}HNMR Spectrum

Conditions: 400 MHz, $CDCl_3$

^{1}HNMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	***Comment***	LBC305-045@20Hb 1H CDCl3 {E:\dataexternal\epichem} cygoh 7				
Date	04 Dec 2017 17:14:40			***Date Stamp***	04 Dec 2017 17:14:40		
File Name	\\naphthalene\company\NMR files\LBC305-045@20Hb\1\pdata\1\1r					***Frequency (MHz)***	400.13
Nucleus	1H	***Number of Transients***	8	***Origin***	spect	***Original Points Count***	24038
Owner	nmr	***Points Count***	32768	***Pulse Sequence***	zg	***Receiver Gain***	203.00
SW(cyclical) (Hz)	6402.05	***Solvent***	CHLOROFORM-d			***Spectrum Offset (Hz)***	2790.7302
Spectrum Type	STANDARD	***Sweep Width (Hz)***	6401.85	***Temperature (degree C)***	26.945		

^{1}H NMR (400 MHz, CHLOROFORM-*d*) δ ppm 1.08 (s, 9 H) 2.53 (dd, *J*=11.43, 3.42 Hz, 1 H) 2.80 (dd, *J*=11.23, 9.48 Hz, 1 H) 3.18 (s, 3 H) 4.16 (dd, *J*=8.99, 3.32 Hz, 1 H) 4.87 (s, 2 H) 6.86 (d, *J*=8.21 Hz, 1 H) 6.96 (s, 1 H) 7.14 (d, *J*=7.81 Hz, 1 H)



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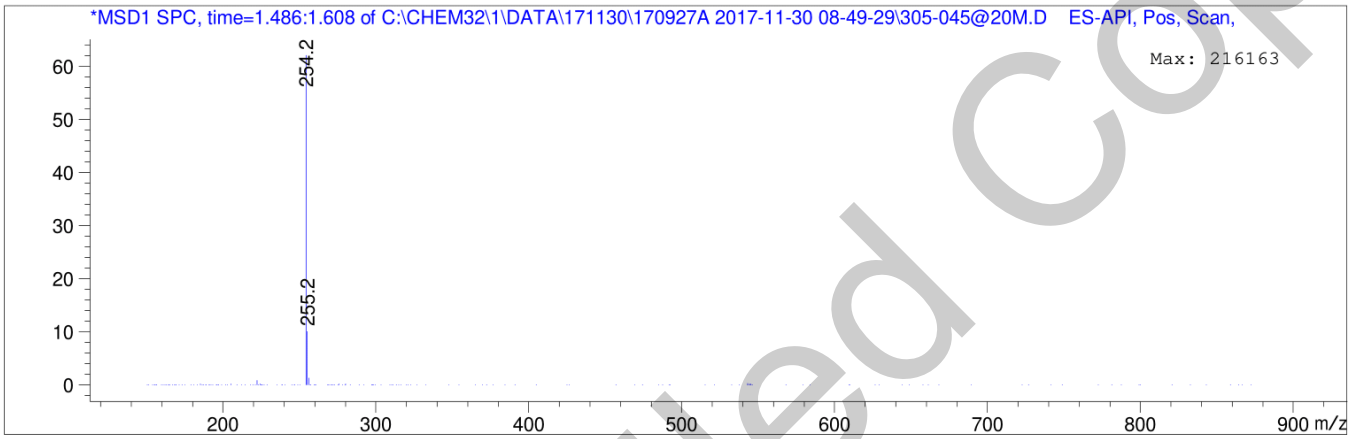
Ib. Mass Spectrum

Method: 5% to 100% ACN in water gradient (+0.1% formic acid)

Zorbax Eclipse XDB-C8, 3.0 x 100 mm, 3.5 micron

Retention Time (MS)	MS Area	Mol. Weight or Ion
1.532	3240750	255.20 I 254.20 I
1.847	2505349	255.15 I 254.20 I



Theoretical value: 254.2 $[M+H]^+$.

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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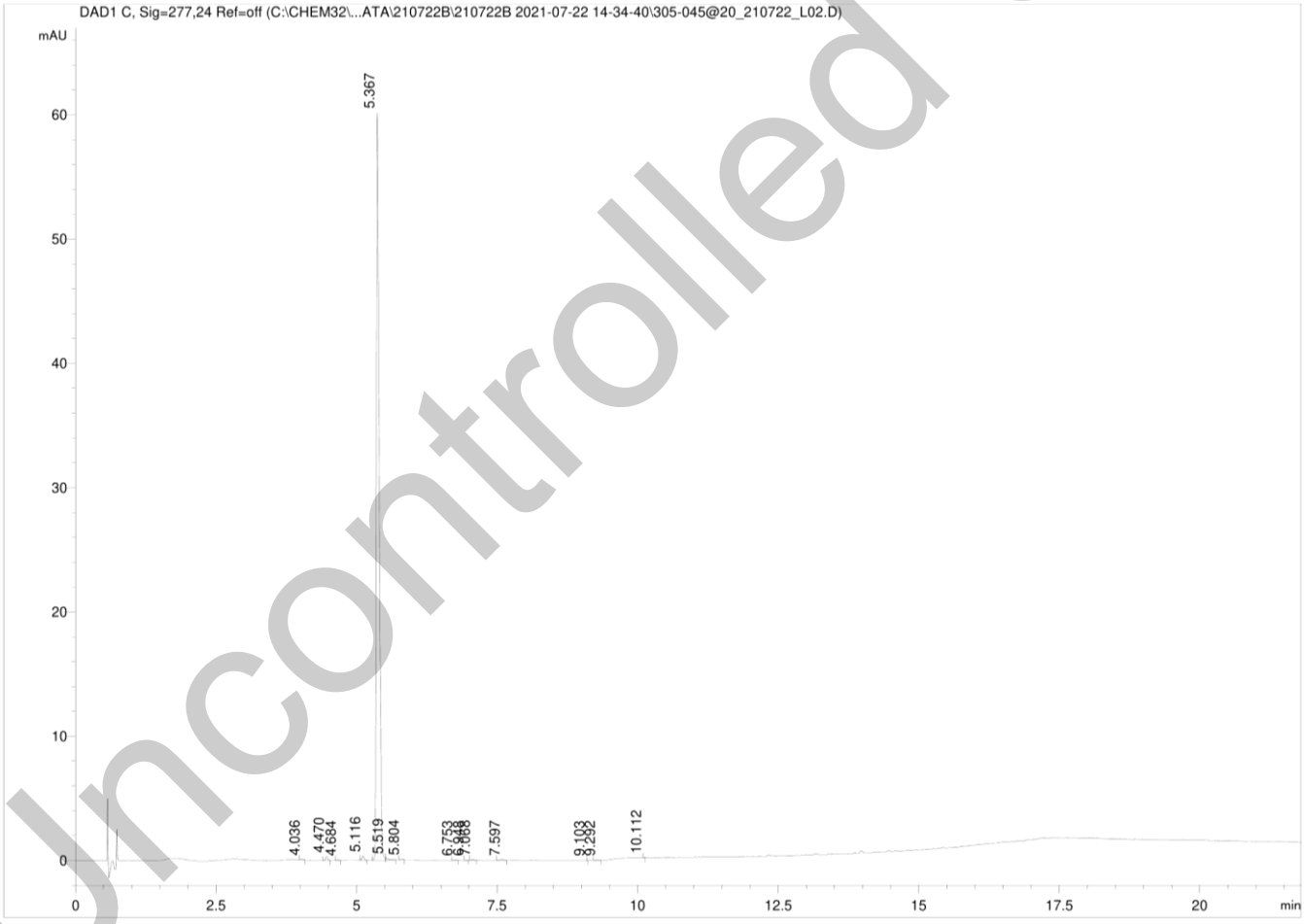
II. Purity

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	15ºC				DAD 277nm	Auto 1.0 µL 0.9 mg/mL in 100% methanol (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	81	19	1.0		
	15.60	5	95	1.0		
	20.60	5	95	1.0		
	21.60	97	3	1.0		
	26.60	97	3	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.02	0.10	0.04
2	4.46	0.88	0.39
3	4.67	0.04	0.02
4	5.11	0.89	0.39
5	5.35	223.07	98.45
6	5.51	0.45	0.20
7	5.79	0.17	0.08
8	6.76	0.12	0.05
9	6.95	0.07	0.02
10	7.07	0.16	0.07
11	7.61	0.32	0.14
12	8.16	0.01	0.01
13	9.28	0.15	0.07
14	10.18	0.02	0.01
15	11.85	0.02	0.01
16	13.84	0.14	0.06
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 98.5% (average of 10 duplicate runs)

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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 2018 Ash (Appendix XI J) Method II

Result:

Contains 0.4% ash.

V. Residual Solvents

Method: ^{1}HNMR

Result:

No significant impurities detected by ^{1}H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	98.5%
Water content	0.2%
Ash content	0.4%
Residual solvents	<0.1%
Purity*	97.9%

This purity is assessed to be 97.9%.

Product Reviewed By:

James Rixson, PhD
Head of Production

Product Released By:

Carol Worth, PhD
Quality Manager

Release Date: 1 July 2022

*The calculation of the purity follows the formula:

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

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