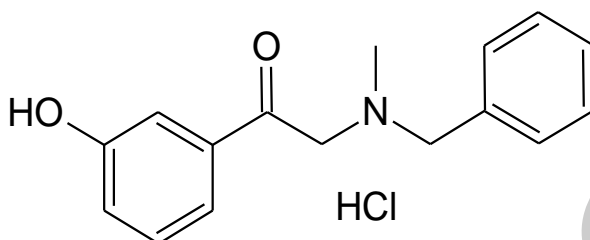


Reference Material Product Information Sheet

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



Name	2-benzyl(methyl)amino-1-(3-hydroxyphenyl)ethanone hydrochloride
BP Name	Phenylephrine Impurity E (hydrochloride)
Synonym(s)	2-[Benzyl(methyl)amino]-1-(3-hydroxyphenyl)ethan-1-one hydrochloride
Epichem Item #	EPL-AA148 Batch 1
CAS #	71786-67-9
Molecular Formula	C ₁₆ H ₁₇ NO ₂ .HCl
Molecular Weight	291.78 g/mol
Appearance	Cream powder
Melting Point	213-218.2°C (decomposition)
Combustion Analysis	Required (%): C: 65.9; H: 6.2; N: 4.8. Found (%): C: 65.7; H: 6.5; N: 4.8
Purity	99.3%
Date of Manufacture	24 July 2014
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-AA148 Batch 1

Revision 1

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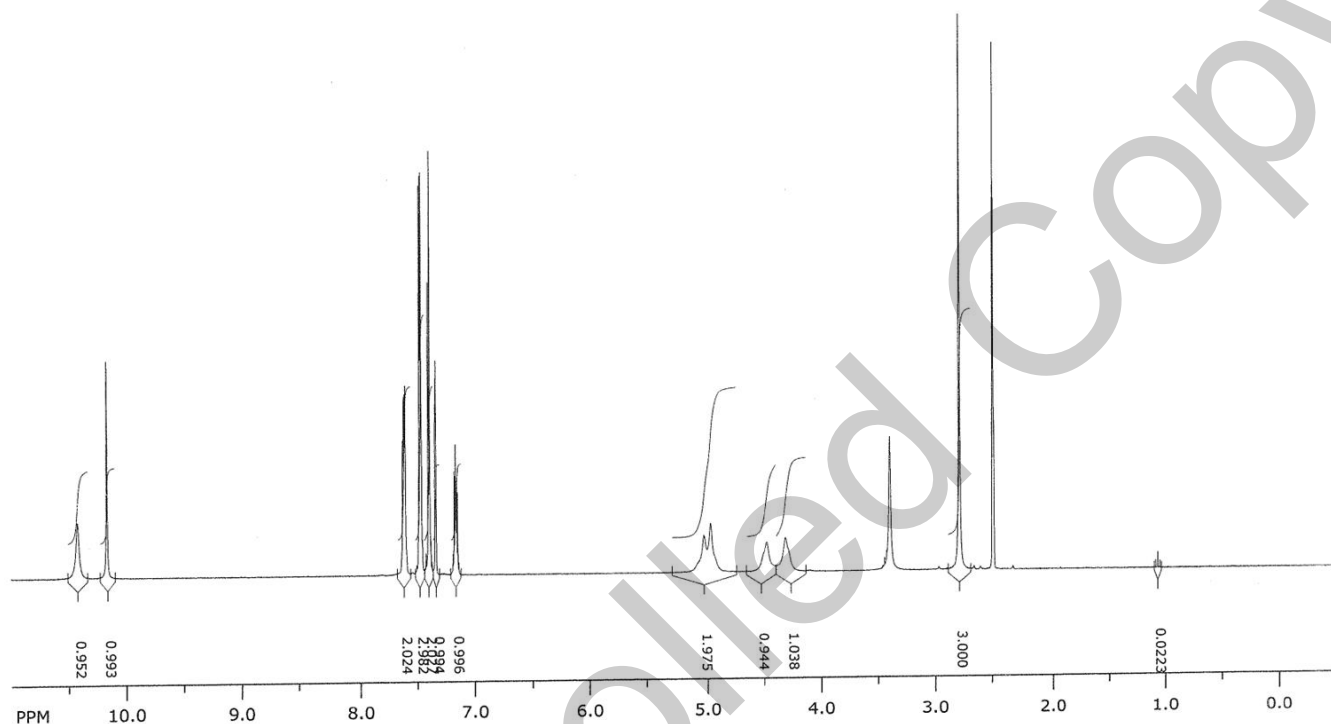
I. Identity

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

Ia. ¹HNMR Spectrum

Conditions: 400 MHz, DMSO-d₆

¹HNMR spectrum consistent with chemical structure.



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Revision 1

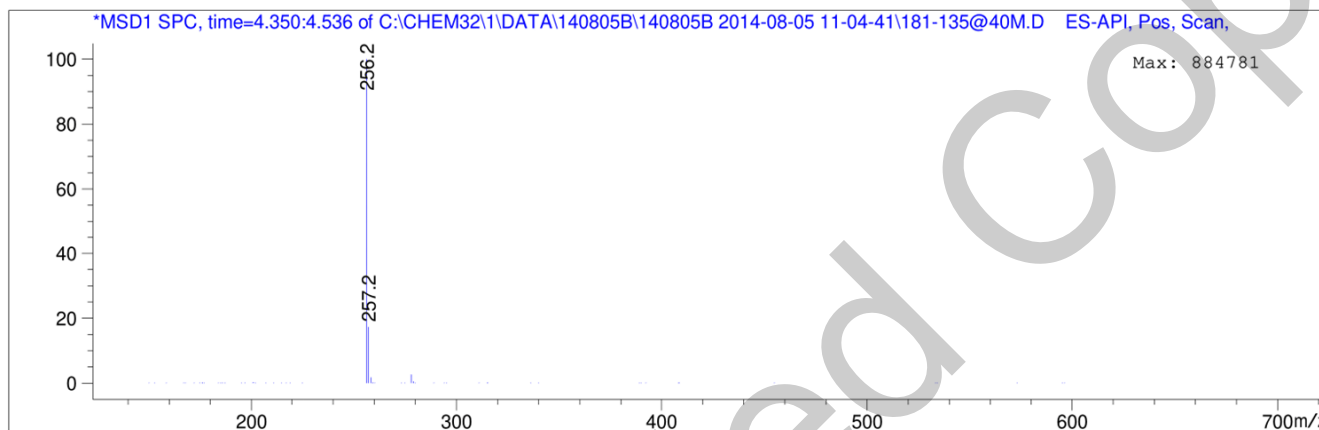
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Ib. Mass Spectrum

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)
Agilent Poroshell 120 SB-C8, 2.1 x 100mm, 2.7 micron

Retention Time (MS)	MS Area	Mol. Weight or Ion
4.414	15212230	257.20 256.20



Theoretical value: 256.2 [M-HCl+H]⁺.

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

EPL-AA148 Batch 1

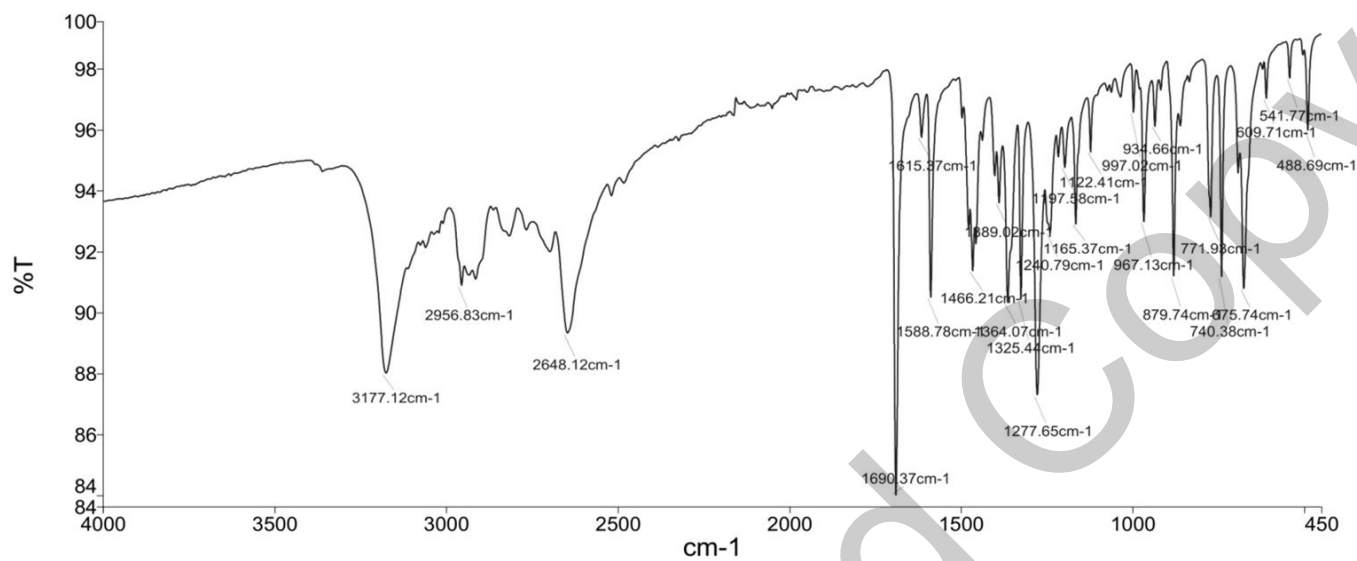
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Ic. IR Spectrum

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

Method: Fourier Transform Infrared (FTIR) Spectroscopy



The interpretation of the signals of the Fourier Transform Infra-red Spectrum 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) in-house EM005.WI07.

HPLC Conditions:

Column	Conditions				Detector	Injector
Agilent Poroshell 120 EC-C18 4.6 x 50mm 2.7 micron	25°C				DAD 258nm	Auto 1.0 µL 0.45 mg/mL in 50% acetonitrile 50% 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	65	35	1.0		
	12.00	5	95	1.0		
	17.00	5	95	1.0		
	18.00	95	5	1.0		
	21.00	95	5	1.0		

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Area Percent Reported By Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	1.92	0.05	0.01
2	2.58	0.03	0.00
3	4.66	0.02	0.00
4	4.97	0.08	0.01
5	5.05	0.04	0.01
6	5.11	0.02	0.00
7	5.22	731.67	99.55
8	5.55	0.68	0.09
9	5.6	0.08	0.01
10	5.9	0.03	0.00
11	6.47	0.24	0.03
12	6.6	0.87	0.12
13	6.69	0.03	0.00
14	6.78	0.08	0.01
15	6.9	0.04	0.01
16	7.36	0.63	0.09
17	7.7	0.18	0.02
18	7.81	0.08	0.01
19	8.53	0.07	0.01
20	8.59	0.07	0.01
Totals			100.0

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 99.5% (average of duplicate runs)

III. Water Content

Method: Karl-Fischer Coulometer

Result:

Contains 0.1% water.

IV. Ash Content

Method: BP2014 Ash (Appendix XI J) as per WS001/22287

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹HNMR

Result:

Contains 0.12% ethanol by ¹HNMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.5%
Water content	0.1%
Ash content	<0.1%
Residual solvents	0.1%
Purity*	99.3%

This purity is assessed to be 99.3%

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Carol Worth, PhD
Quality Manager

Release Date: 27 June 2022

**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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