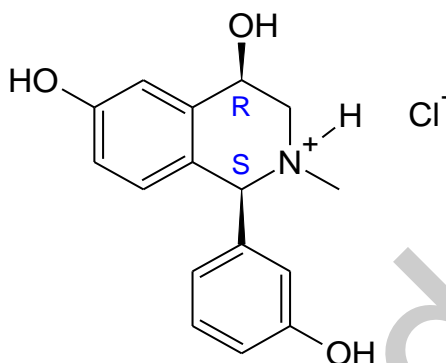


Reference Material Product Information Sheet

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



Name	(1S,4R)-4,6-dihydroxy-1-(3-hydroxyphenyl)-2-methyl-1,2,3,4-tetrahydroisoquinolinium chloride
Synonym(s)	Phenylephrine 3-hydroxybenzaldehyde adduct (1S,4R isomer) hydrochloride salt
Epichem Item #	EPL-AA225 Batch 1
CAS #	Not available
Molecular Formula	C ₁₆ H ₁₈ ClNO ₃
Molecular Weight	307.78 g/mol
Appearance	Off-white powder
Melting Point	216.1-218.5°C (decomposition)
Combustion Analysis	Required (%): C:62.4; H:5.9; N:4.6. Found (%): C:61.7; H:6.0; N:4.8.
Purity	98.1%
Date of Manufacture	15 February 2018
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 unopened and stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

EPL-AA225 Batch 1

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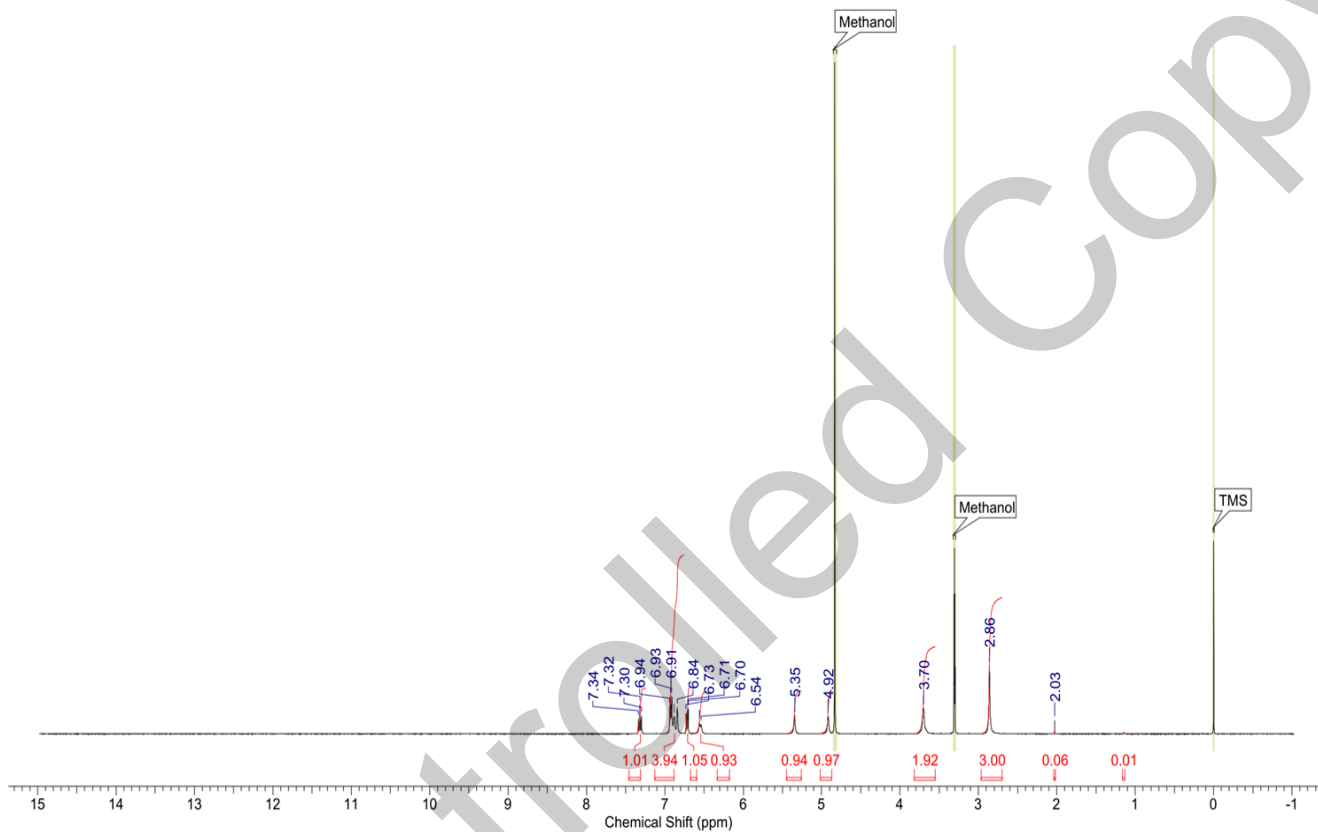
I. Identity

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

Ia. ¹HNMR Spectrum

Conditions: 400 MHz, Methanol-d₄

¹HNMR spectrum consistent with chemical structure.

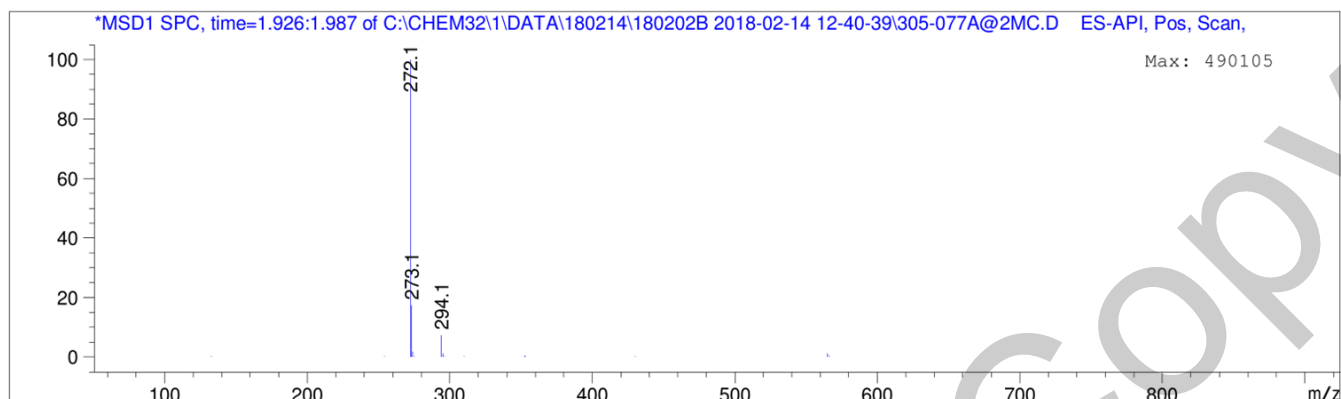


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Ib. Mass Spectrum

Method: 5% to 100% ACN in water gradient (+0.1% formic acid)
Zorbax Eclipse XDB-C8, 3.0 x 100 mm, 3.5 micron



Theoretical value: 272.1 [M-HCl+H]⁺.

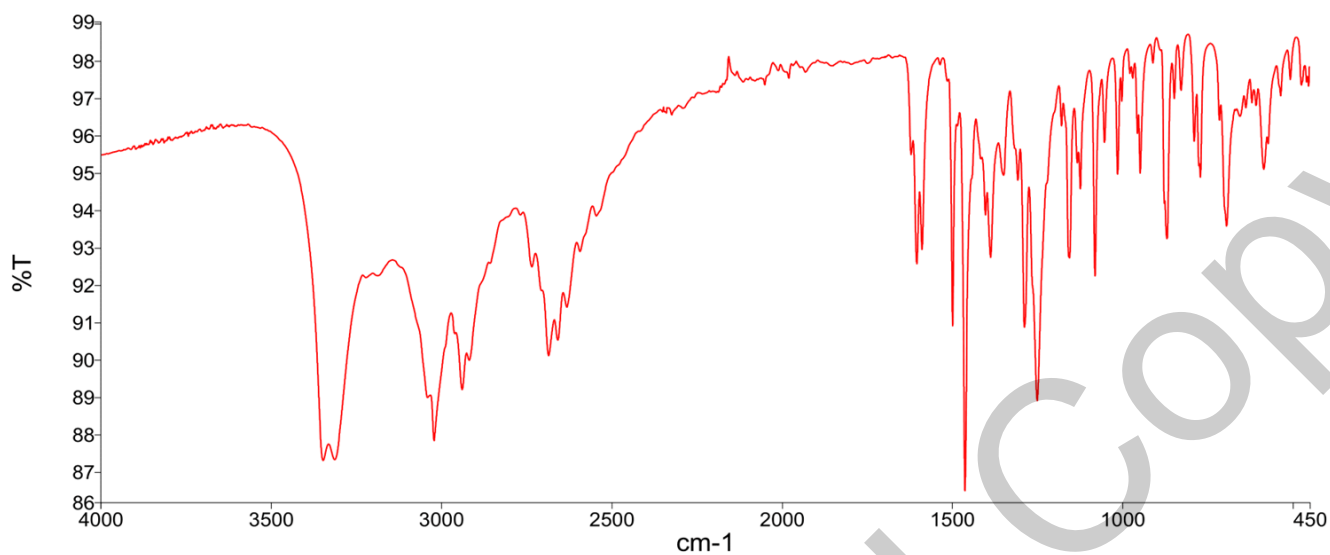
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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Ic. IR Spectrum

Method: Fourier Transform Infrared (FTIR) Spectroscopy



The signals of the IR spectrum and their interpretation are consistent with the structural formula.

EPL-AA225 Batch 1

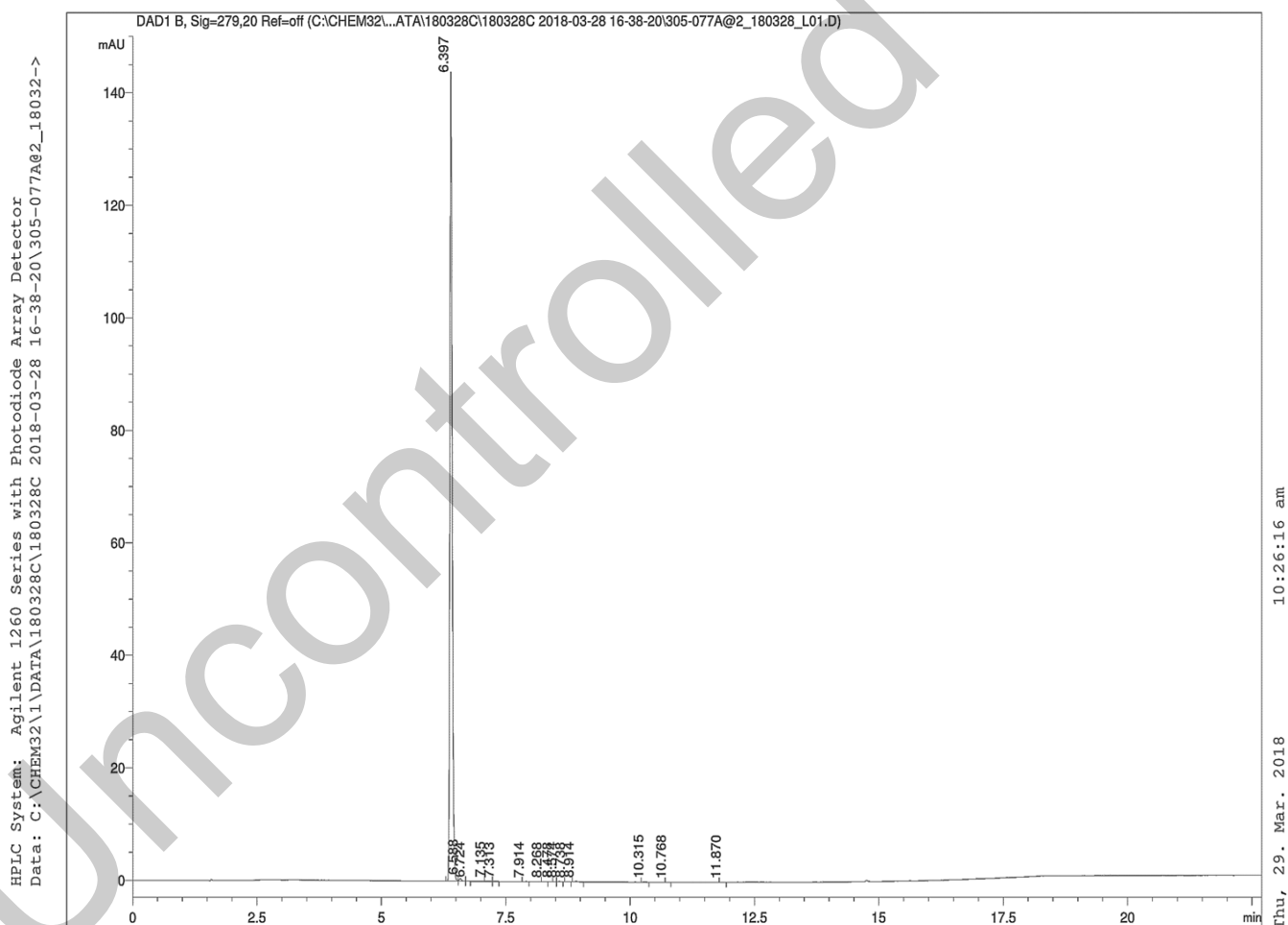
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II. Purity

The purity of this material was analysed by high performance liquid chromatography (HPLC) using in-house EM005.WI07.

HPLC Conditions:

Column	Conditions				Detector	Injector
Fortis H2o 4.6x100 mm 3 micron	25°C				DAD 279nm	Auto 1.0 µL 0.65mg/mL in 100% 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		
	10.00	65	35	1.0		
	16.00	5	95	1.0		
	21.00	5	95	1.0		
	22.00	95	5	1.0		
	28.00	95	5	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	6.40	454.77	99.17
2	6.59	1.63	0.36
3	6.72	0.08	0.02
4	7.14	0.25	0.05
5	7.31	0.07	0.02
6	7.91	0.13	0.03
7	8.27	0.12	0.03
8	8.48	0.11	0.02
9	8.57	0.26	0.06
10	8.74	0.26	0.06
11	8.91	0.55	0.12
12	10.32	0.11	0.02
13	10.77	0.08	0.02
14	11.87	0.16	0.04
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 99.2% (average of 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 2018 Ash (Appendix XI J) Method II

Result:

Contains 0.6% ash.

V. Residual Solvents

Method: ¹HNMR

Result:

Contains 0.3% acetonitrile.

VI. Final Result

Chromatographic purity (HPLC)	99.2%
Water content	0.2%
Ash content	0.6%
Residual solvents	0.3%
Purity*	98.1%

This purity is assessed to be 98.1%.

Product Reviewed By:

Product Released By:

John Moursounidis, PhD
Head Reference Standards

Boon Tan
Quality Manager

Release Date: 6 April 2018

*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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