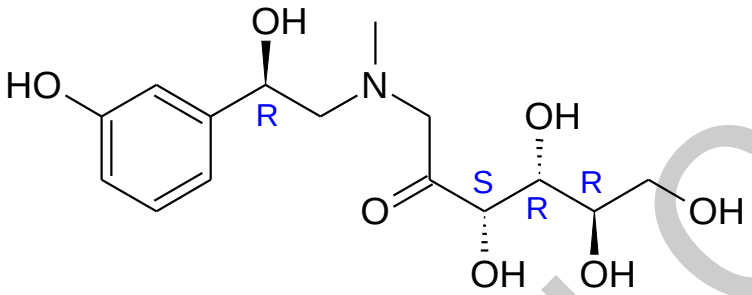
Our Formula. Your Success.

Reference Material Product Information Sheet

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



Name	Phenylephrine D-(+)-glucose adduct
Synonym(s)	Mixture of cyclic hemiacetals of (3*S*,4*R*,5*R*)-3,4,5,6-tetrahydroxy-1-(((2*R*)-2-hydroxy-2-(3-hydroxyphenyl)ethyl)(methyl)amino)hexan-2-one
BP/EP Name	Not listed.
USP Name	Not listed.
Epichem Item #	EPL-AA200 Batch 2
CAS #	2575516-66-2
Molecular Formula	$C_{15}H_{23}NO_7$
Molecular Weight	329.35 g/mol
Appearance	Yellow powder
Melting Point	72.7-87.5°C (decomposition).
Combustion Analysis	Required (%):C 54.7; H 7.0; N 4.2. Found (%): C: 52.8; H: 7.3; N: 4.3
Purity	89.0%
Date of Manufacture	17 October 2017
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)

EPL-AA200 Batch 2

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

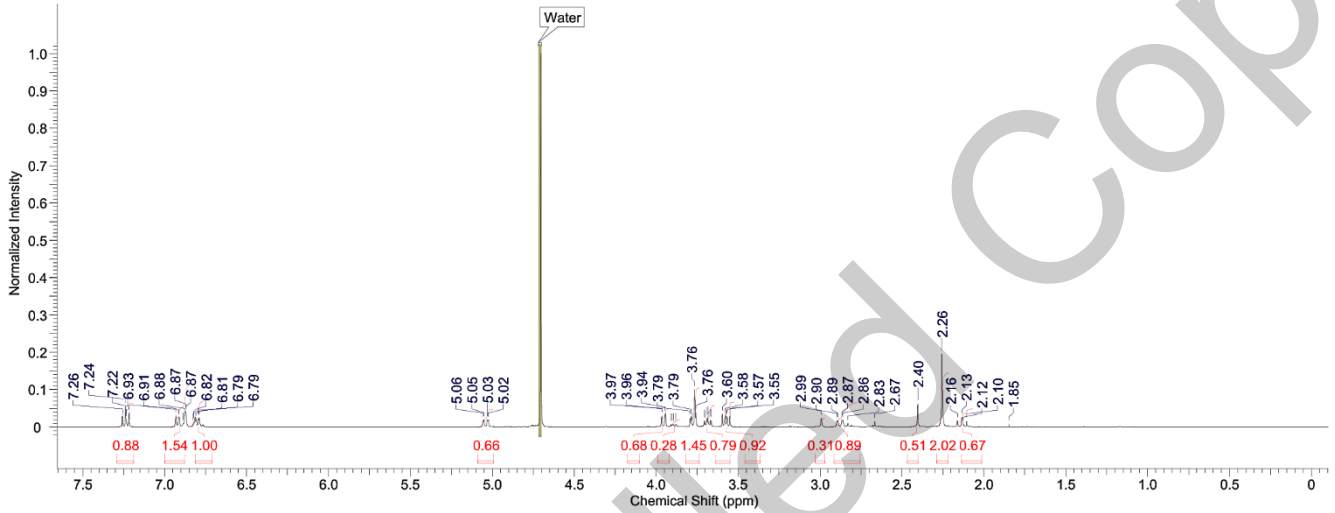
The identity of this product was established using the following analyses:

Ia. ^{1}HNMR Spectrum

Conditions: 400 MHz, D_2O

^{1}HNMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	***Comment***	LBC295-127@6H 1H D2O {E:\dataexternal\epichem} cygoh 14			***Date***	17 Oct 2017 17:36:00
Date Stamp	17 Oct 2017 17:36:00			***File Name***	\\naphthalene\company\NMR files\LBC295-127@6H\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	45.20	***SW(cyclical) (Hz)***	6402.05	***Solvent***	DEUTERIUM OXIDE		
Spectrum Offset (Hz)	2800.9097	***Spectrum Type***	STANDARD	***Sweep Width (Hz)***	6401.85	***Temperature (degree C)***	26.945



EPL-AA200 Batch 2

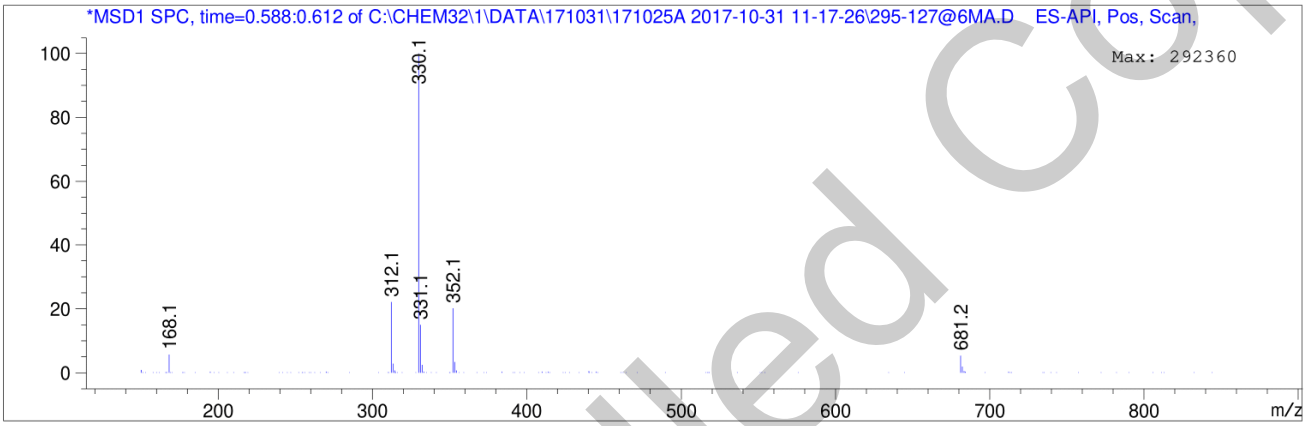
Ib. Mass Spectrum

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)

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

Retention Time (MS)	MS Area	Mol. Weight or Ion
0.596	2361738	352.10 I
		331.10 I
		330.10 I
		312.10 I



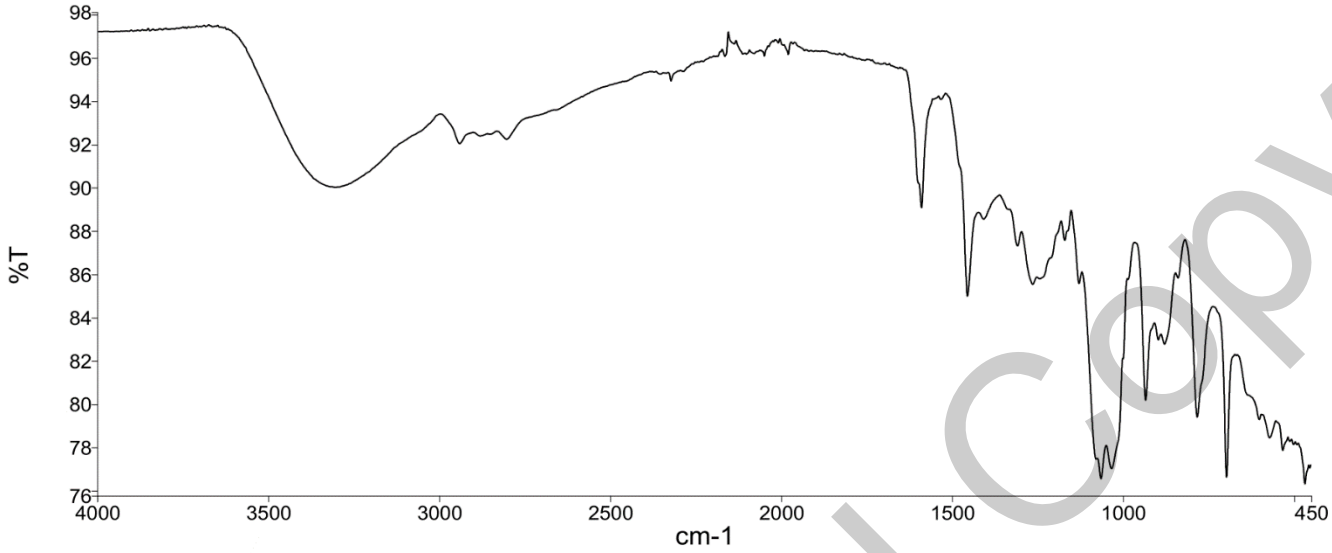
Theoretical value: 330.1 $[M+H]^+$.

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

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

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.

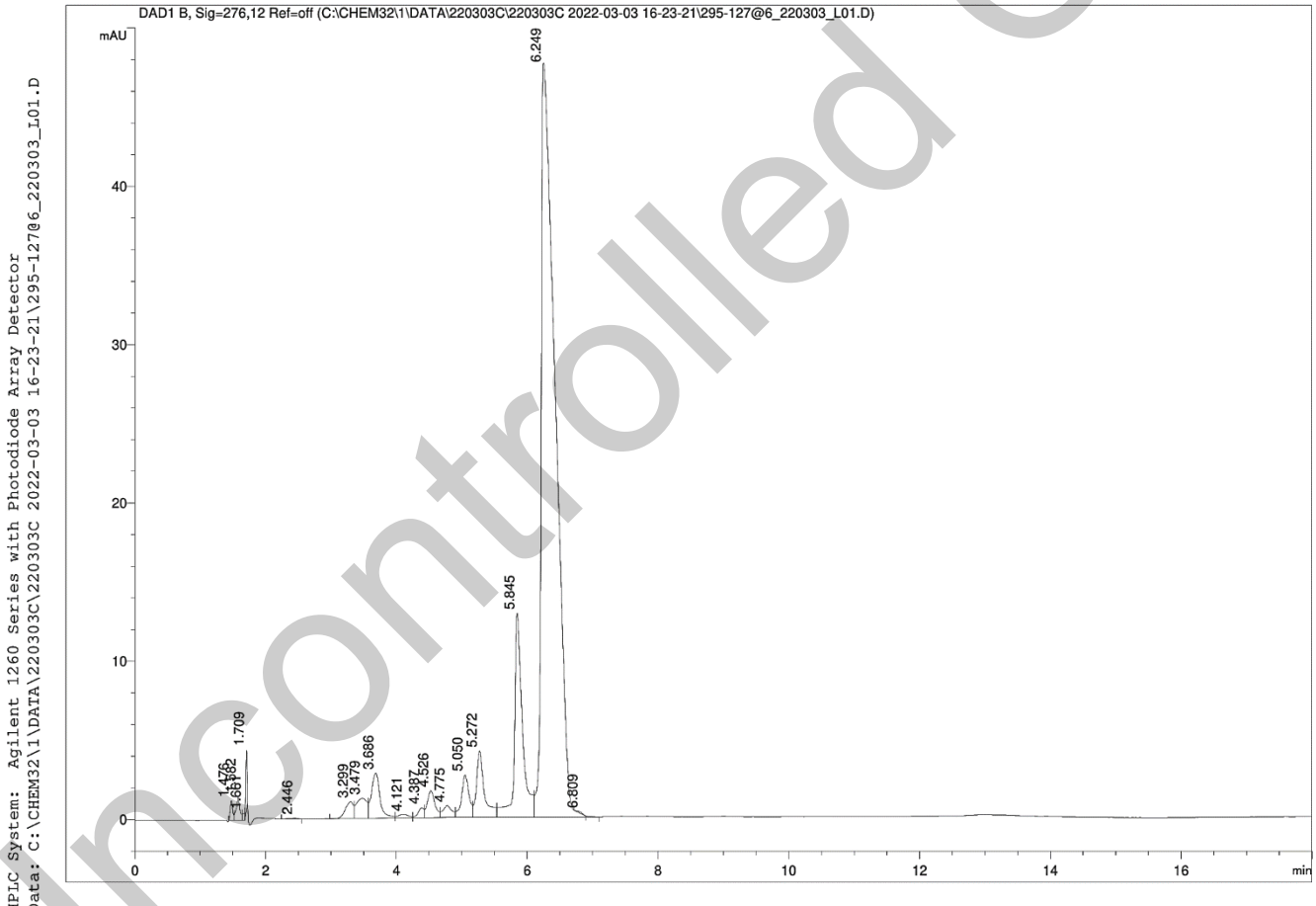
EPL-AA200 Batch 2

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 HILIC 4.6 x 100mm 2.7 micron	25ºC				DAD 276nm	Auto 1.0 µL 2.0 mg/mL in 100% 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	3	97	0.8		
	2.00	3	97	0.8		
	10.00	15	85	0.8		
	13.00	40	60	0.8		
	16.00	40	60	0.8		
	17.00	3	97	0.8		
	28.00	3	97	0.8		



EPL-AA200 Batch 2

Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	1.48	3.04	0.32
2	1.58	5.73	0.59
3	1.66	1.07	0.11
4	1.71	5.00	0.52
5	2.45	0.67	0.07
6	3.30	9.25	0.96
7	3.48	14.38	1.49
8	3.69	25.89	2.68
9	4.12	2.34	0.24
10	4.39	3.90	0.40
11	4.53	13.74	1.42
12	4.77	7.17	0.74
13	5.05	21.37	2.21
14	5.27	34.87	3.61
15	5.85	109.71	11.36
16	6.25	706.80	73.21
17	6.81	0.48	0.05
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 90.4% (average of duplicate runs and sum of presumed tautomers at peaks 13,14,15,16).

EPL-AA200 Batch 2

III. Water Content

Method: Karl-Fischer titration using in-house EM005.WI04.
Results:
Average 1.4%

IV. Ash Content

Method: BP2017 (Appendix XI J) Method II
Result:
Contains 0.2% ash.

V. Residual Solvents

Method: ^{1}HNMR
Result:
No significant impurities detected by ^{1}H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	90.4%
Water content	1.4%
Ash content	0.2%
Residual solvents	<0.1%
Purity	89.0%

This purity is assessed to be 89.0%.

Product Reviewed By:

Jacob Heppell, PhD
Chemist

Product Released By:

Carol Worth, PhD
Quality Manager
Release Date: 9 March 2022

The calculation of the purity follows the formula:

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

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