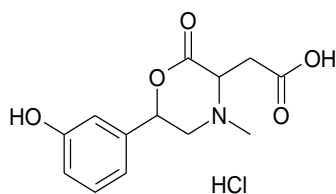


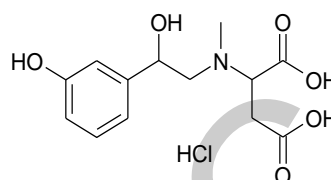
Reference Material Product Information Sheet

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



Lactone Form

In water, the lactone form is in equilibrium with the open form



Open Form

Material is supplied as the lactone form

Name	3-(carboxymethyl)-6-(3-hydroxyphenyl)-4-methyl-2-oxomorpholin-4-ium hydrochloride
Synonym(s)	PEMA (phenylephrine maleic acid adduct)
Epichem Item #	EPL-AA88 Batch 10
CAS #	Not available
Molecular Formula	C ₁₃ H ₁₅ NO ₅ .HCl (lactone form)
Molecular Weight	301.73 g/mol (lactone form)
Appearance	White crystals
Melting Point	193.7-196.8°C
Combustion Analysis	Required (%): C:51.8; H:5.3; N:4.6. Found (%): C:51.8; H:5.3; N:4.6.
Purity*	99.1%
Date of Manufacture	18 May 2016
Storage Requirements	<i>HYGROSCOPIC</i> 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 unopened and stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

* NATA accreditation does not cover the performance of this service

EPL-AA88 Batch 10

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

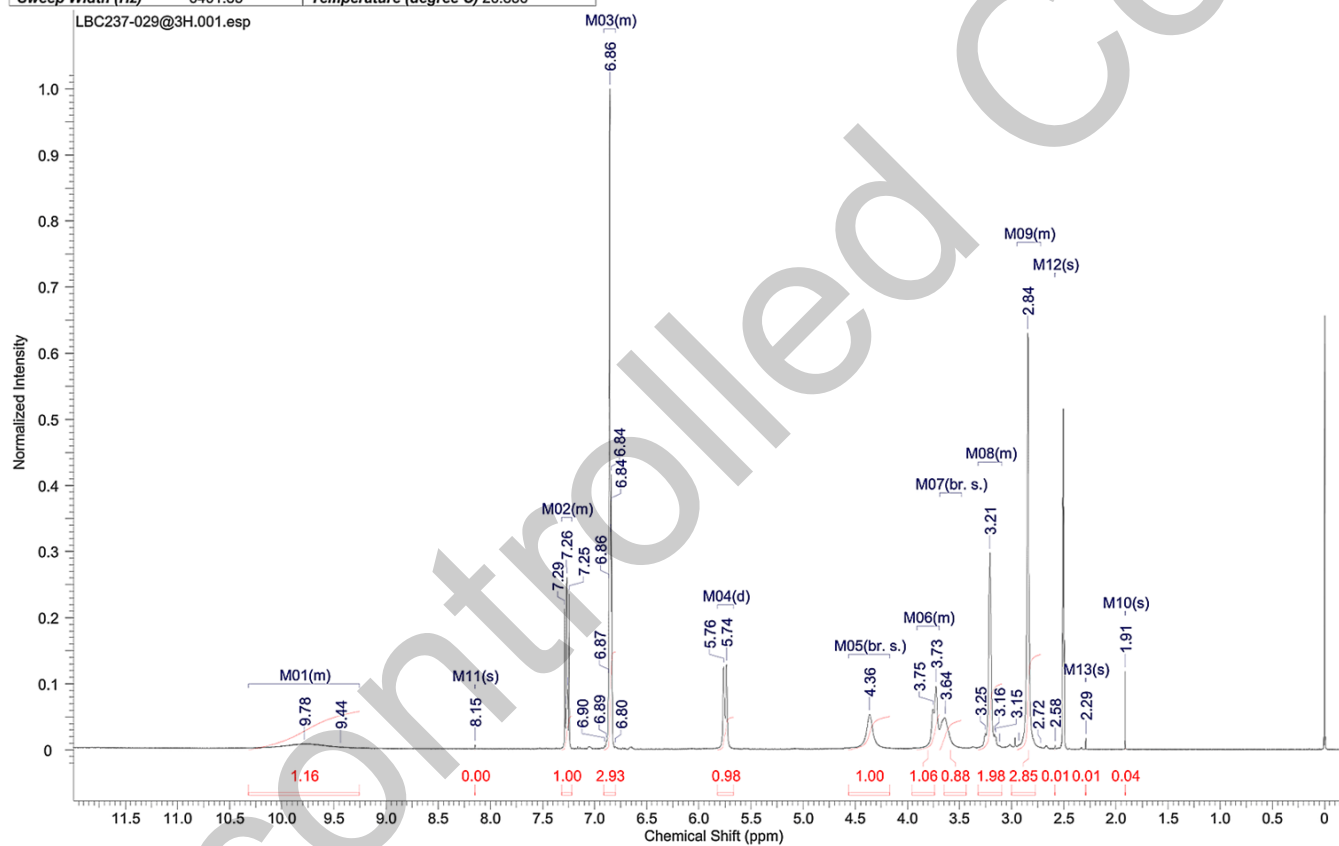
The identity of this product was established using the following analyses:

Ia. ¹H NMR Spectrum

Conditions: 400 MHz, DMSO-d₆

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC237-029@3H 1H DMSO (E:\data\external\epichem) cygoh 9		
Date	18 May 2016 08:51:12	Date Stamp	18 May 2016 08:51:12		
File Name	\NAPHTHALENE\Company\NMR files\LBC237-029@3H1\fid		Frequency (MHz)	400.13	
Nucleus	1H	Number of Transients	8	Origin	spect
Owner	nmr	Points Count	32768	Pulse Sequence	zg
SW(cyclical) (Hz)	6402.05	Solvent	DMSO-d6	Spectrum Offset (Hz)	2799.0972
Sweep Width (Hz)	6401.85	Temperature (degree C)	26.836	Receiver Gain	90.50
				Spectrum Type	STANDARD



EPL-AA88 Batch 10

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

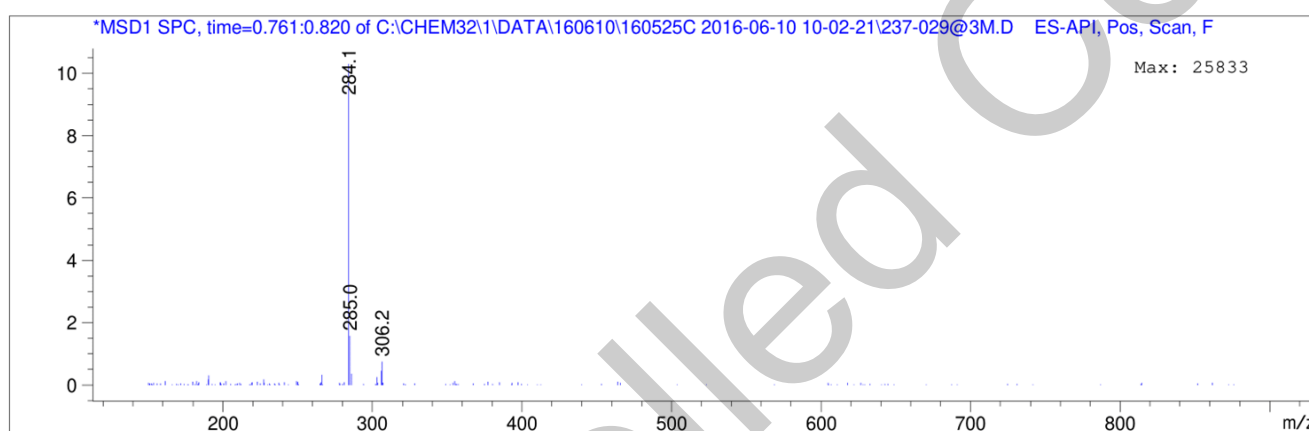
ABN 80 106 769 902

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
0.796	229758	285.05 I 284.15 I
1.682	1784084	553.20 I 267.15 I 266.10 I



Theoretical value: 284.1 [M-OH]⁺.

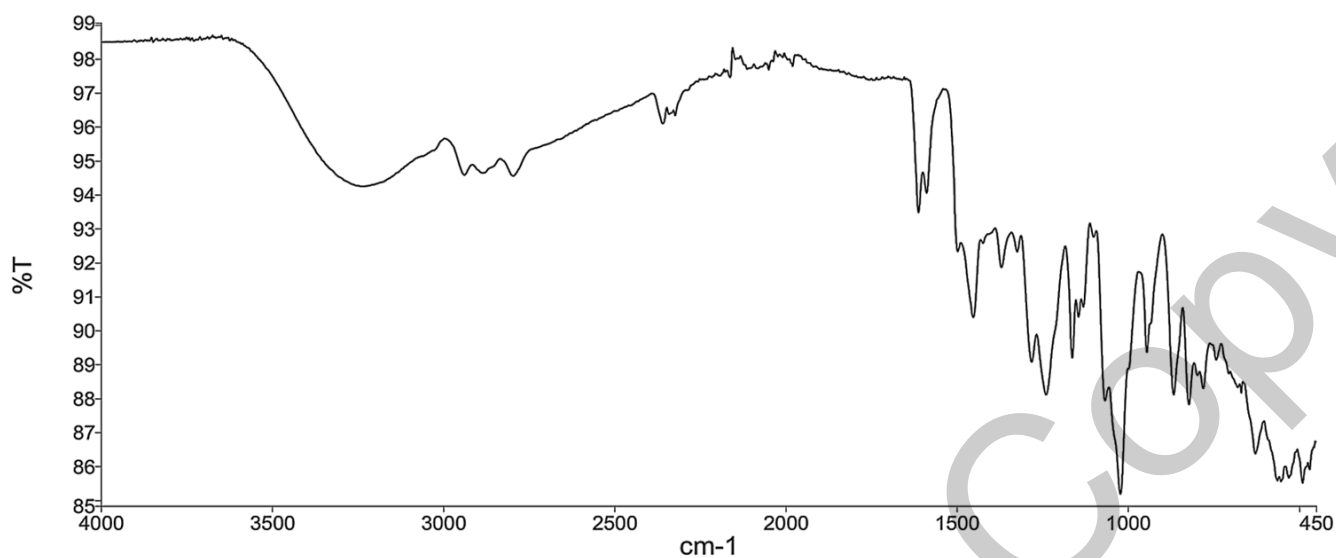
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

EPL-AA88 Batch 10

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 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.

EPL-AA88 Batch 10

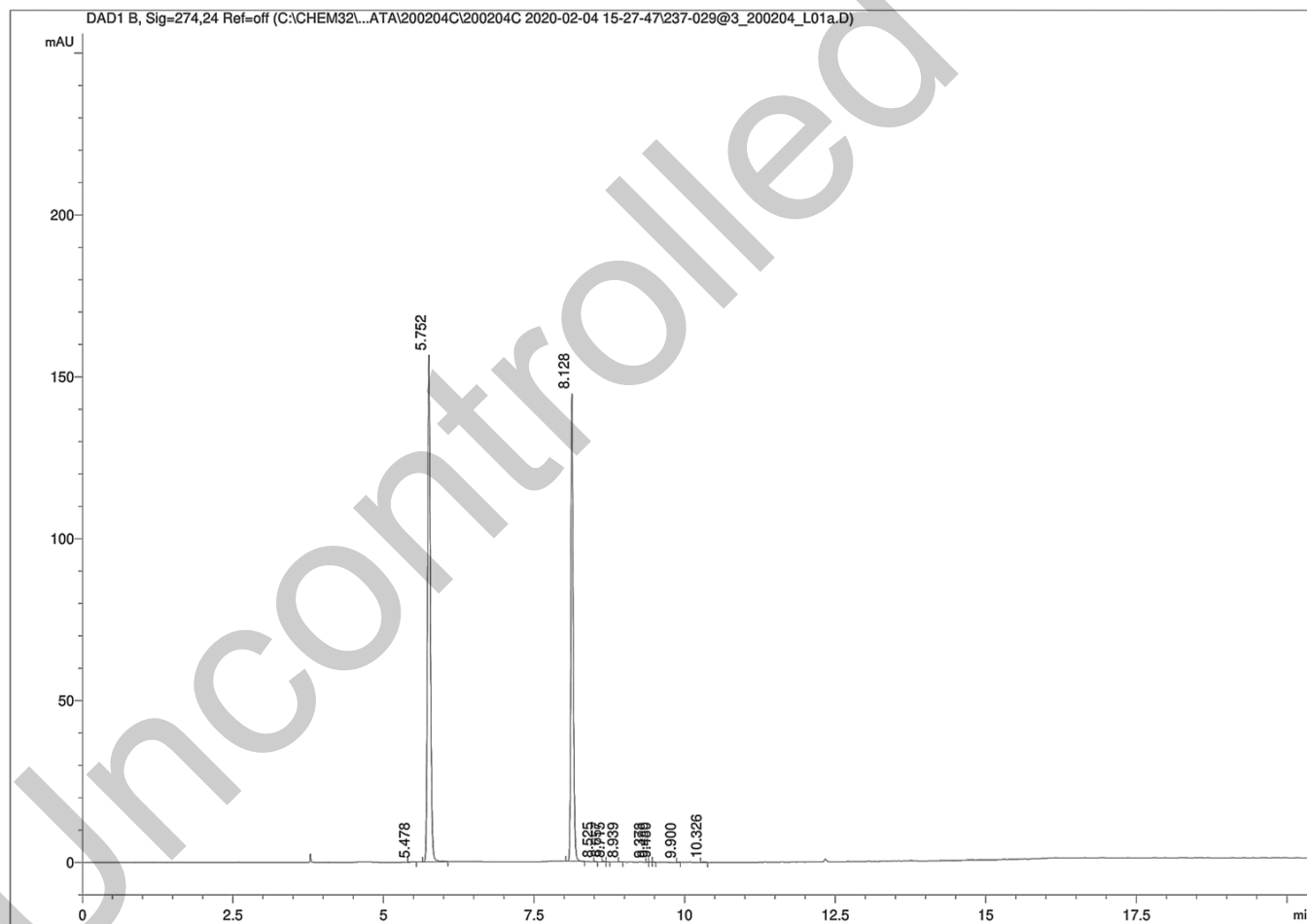
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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 4.6 x 100mm 3 micron	25°C				DAD 274nm	Auto 2.0 µL 1.5mg/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	99.5	0.5	1.0		
	0.50	99.5	0.5	1.0		
	5.25	90	10	1.0		
	13.75	5	95	1.0		
	18.75	5	95	1.0		
	19.75	99.5	0.5	1.0		
	25.75	99.5	0.5	1.0		



EPL-AA88 Batch 10

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

Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	5.48	0.14	0.02
2	5.75	505.06	56.22
3	8.13	391.17	43.54
4	8.52	0.12	0.01
5	8.66	0.35	0.04
6	8.72	0.13	0.01
7	8.94	0.04	0.00
8	9.38	0.07	0.01
9	9.44	0.36	0.04
10	9.48	0.25	0.03
11	9.90	0.12	0.01
12	10.33	0.55	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 99.7% (average of 10 duplicate analyses)

EPL-AA88 Batch 10

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

III. Water Content

Method: Karl-Fischer titration using in-house EM005.WI04.

Results:

Average 0.3%

IV. Ash Content

Method: BP 2016 Ash (Appendix XI J) WS 001/28505

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹H NMR

Result:

Contains 0.3% acetic acid by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.7%
Water content	0.3%
Ash content	<0.1%
Residual solvents	0.3%
Purity*	99.1%

This purity is assessed to be 99.1%.

Product Reviewed By:

Product Released By:

John Moursounidis, PhD
Head Reference Standards

Boon Tan
Quality Manager

Release Date: 5 February 2020

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

The calculation of the purity follows the formula:

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

EPL-AA88 Batch 10

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