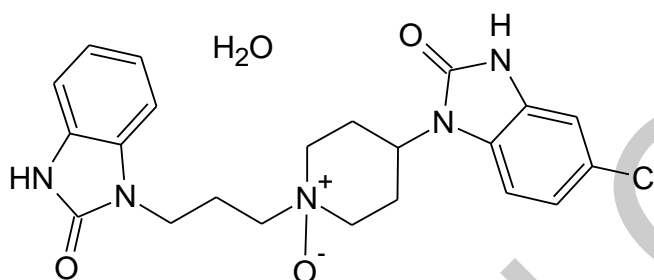


Reference Material Product Information Sheet

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



Name	domperidone- <i>N</i> -oxide monohydrate
BP/EP Name	Domperidone Impurity C
USP Name	Not Listed
Synonym(s)	5-chloro-1-(1-oxido-1-(3-(2-oxo-2,3-dihydro-1 <i>H</i> -benzimidazol-1-yl)propyl)piperidin-4-yl)-1 <i>H</i> -benzimidazol-2(3 <i>H</i>)-one monohydrate
Epichem Item #	EPL-AA55 Batch 1
CAS #	2575516-36-6
Molecular Formula	C ₂₂ H ₂₄ ClN ₅ O ₃ .H ₂ O
Molecular Weight	459.94 g/mol
Appearance	White solid
Melting Point	176.5-181.0°C (decomposition)
Combustion Analysis	Required (%): C:57.4; H:5.7; N:15.2. Found (%): C:55.8; H:5.9; N:14.4.
Purity*	95.7%
Date of Manufacture	30 November 2009
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)

* NATA accreditation does not cover the performance of this service

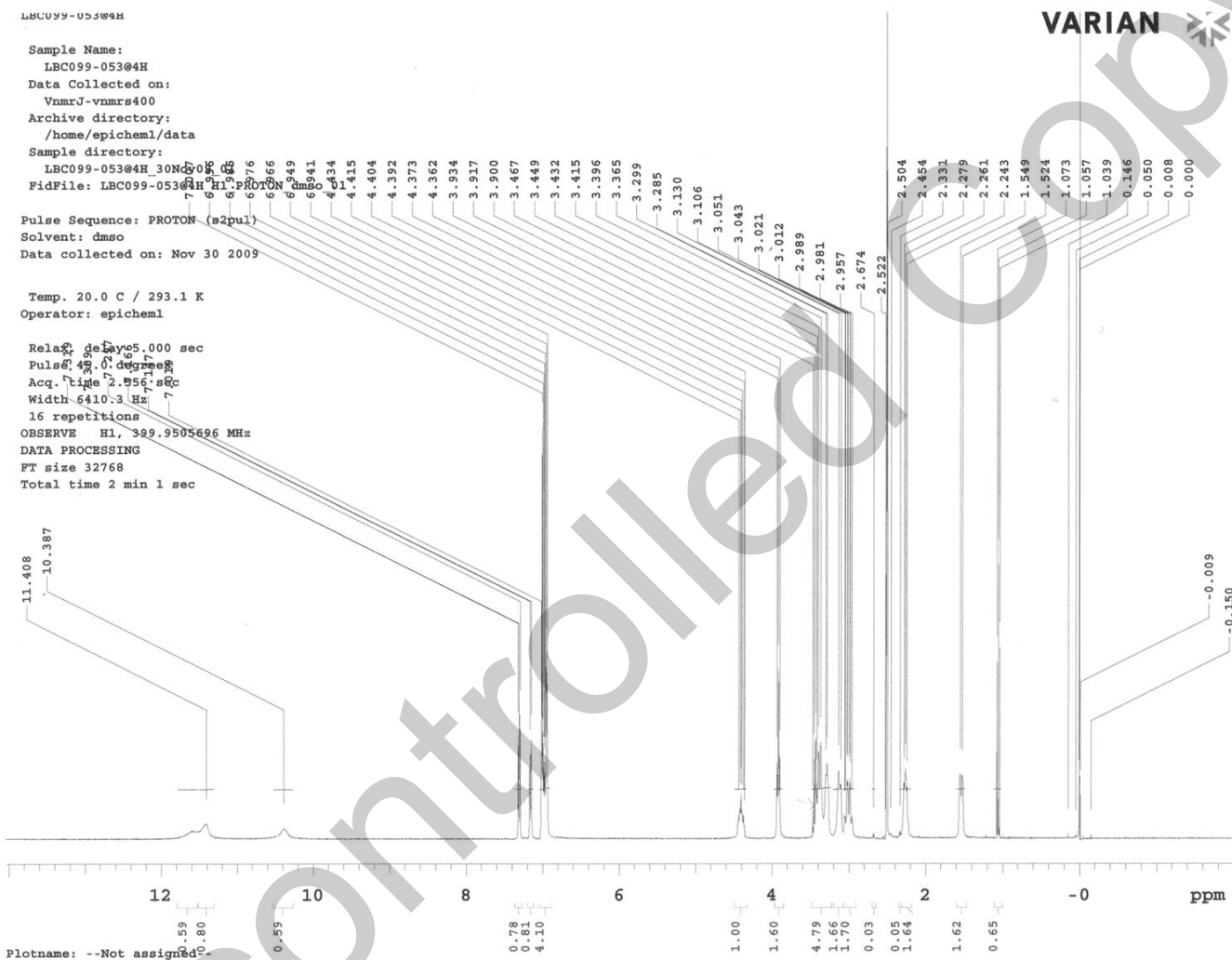
I. Identity

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.



EPL-AA55 Batch 1

Revision 2

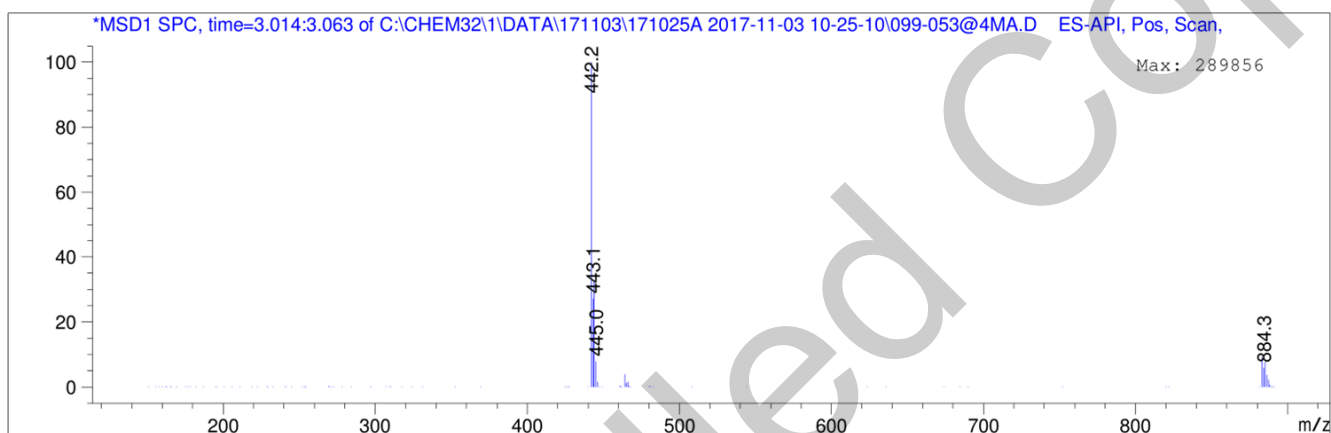
Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

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
3.041	2995195	444.15 I
		443.15 I
		442.20 I

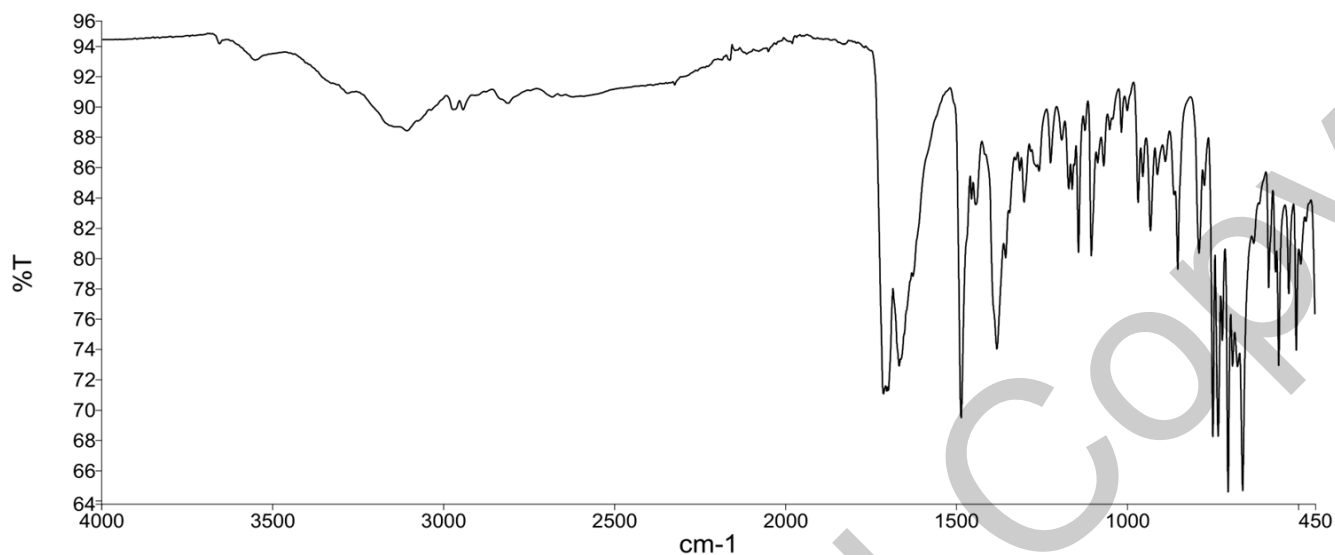


Theoretical values: 442.2 [M+H]⁺.

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

Ic. IR Spectrum

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



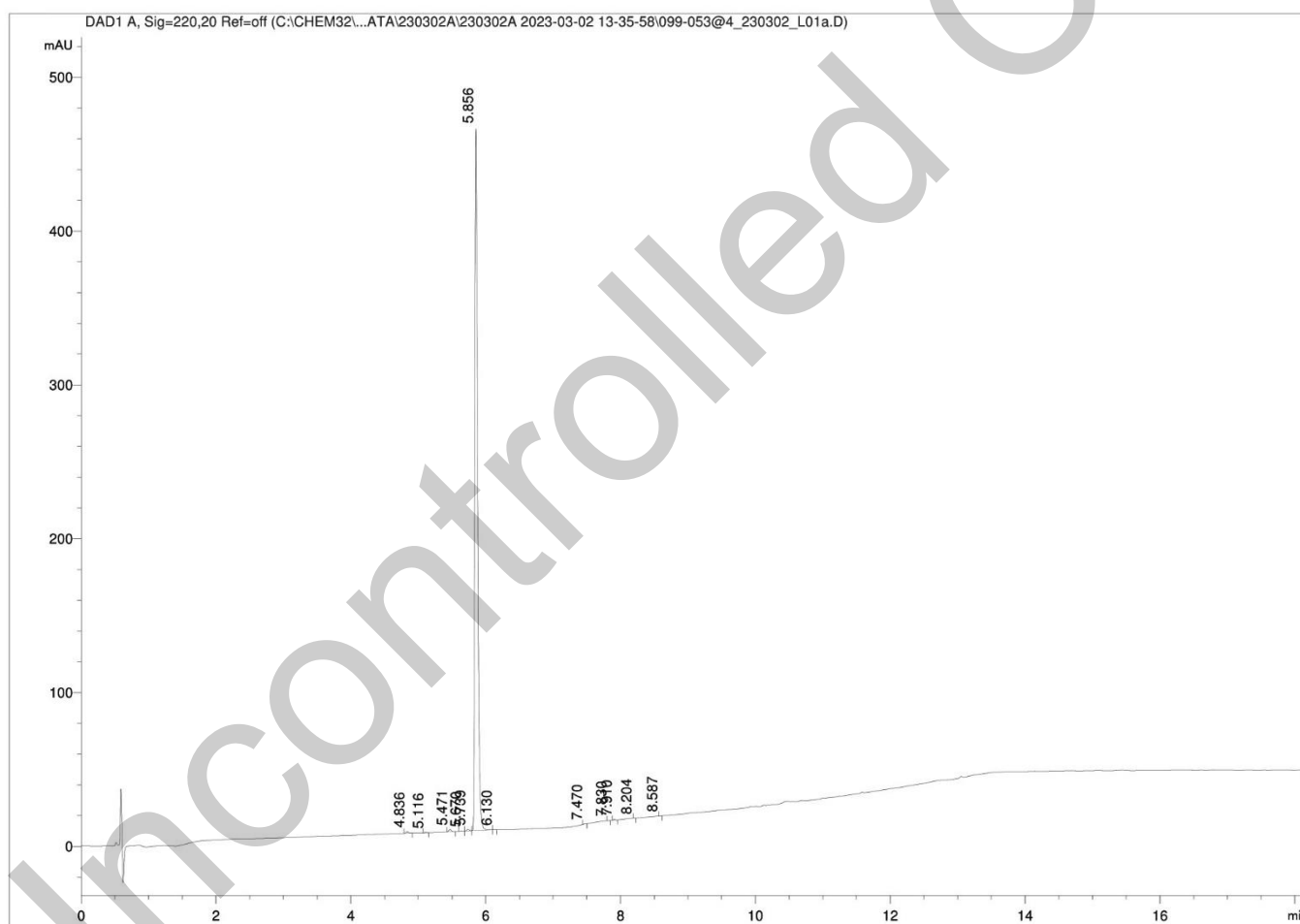
The interpretation of the signals of the Fourier-Transform Infrared Spectrum is consistent with the structural formula.

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
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
Agilent Poroshell 120 EC-C18	25°C				DAD 220nm	Auto
4.6 x 50mm	0.00	85	15	1.0		1.0 µL
2.7 micron	6.00	65	35	1.0		0.4 mg/mL in 50% acetonitrile 50% water (+0.1% TFA)
	12.00	5	95	1.0		
	17.00	5	95	1.0		
	18.00	85	15	1.0		
	21.00	85	15	1.0		



EPL-AA55 Batch 1

Revision 2

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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.84	2.53	0.19
2	5.12	0.51	0.04
3	5.47	3.98	0.30
4	5.67	0.24	0.02
5	5.74	2.45	0.19
6	5.86	1300.96	99.13
7	6.13	0.18	0.01
8	7.47	0.24	0.02
9	7.83	0.14	0.01
10	7.91	0.98	0.07
11	8.20	0.05	0.00
12	8.59	0.08	0.01
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 99.1% (average of 10 duplicate runs)

III. Water Content

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

Results:

Average 4.6%

IV. Ash Content

Method: Combustion adjuvant added.

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹H NMR

Result:

Contains 2.7% ethanol by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.1%
Water content	4.6% (consistent with monohydrate at 3.9% + 0.7% water)
Ash content	<0.1%
Residual solvents	2.7%
Purity*	95.7%

This purity is assessed to be 95.7%.

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Jason Chaplin, PhD
Principal Chemist

Release Date: 9 March 2023

**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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