



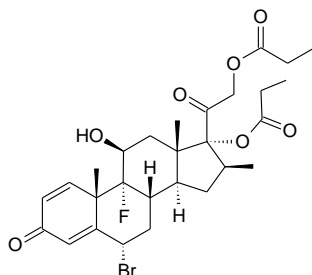
Accredited for compliance with ISO 17034.  
 Accreditation Number 20126  
 NATA is a signatory to the ILAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of testing, medical testing, calibration, inspection, proficiency testing scheme providers and reference materials producers reports and certificates.  
**This document shall not be reproduced except in full.**



*Our Formula. Your Success.*

## Reference Material Product Information Sheet

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



<b>Name</b>	6 $\alpha$ -bromo-9-fluoro-11-hydroxy-16-methyl-17,21-bis(1-oxopropoxy)-(11 $\beta$ ,16 $\beta$ )-pregna-1,4-diene-3,20-dione
<b>BP/EP Name</b>	Betamethasone dipropionate Impurity H
<b>USP Name</b>	Not Listed
<b>Synonym(s)</b>	6 $\alpha$ -Bromobetamethasone dipropionate
<b>Epichem Item #</b>	EPL-AA253 Batch 1
<b>CAS #</b>	2575516-37-7
<b>Molecular Formula</b>	C <sub>28</sub> H <sub>36</sub> BrFO <sub>7</sub>
<b>Molecular Weight</b>	583.50 g/mol
<b>Appearance</b>	White powder
<b>Melting Point</b>	188.6-191.4°C (decomposition)
<b>Combustion Analysis</b>	Required (%): C:57.6, H:6.2. Found (%): C:57.4, H:6.1.
<b>Purity*</b>	98.2%
<b>Date of Manufacture</b>	5 December 2019
<b>Storage Requirements</b>	Protect from heat, light and moisture.
<b>Special Precautions</b>	<b>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.</b>
<b>Intended Use</b>	This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
<b>Date of Shipment</b>	TBA This certificate is valid for one year from the date of shipment provided the substance is unopened and stored under the recommended conditions.
<b>Retest Date</b>	TBA (Proper Storage and Handling Required)

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

EPL-AA253 Batch 1

Revision 1

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

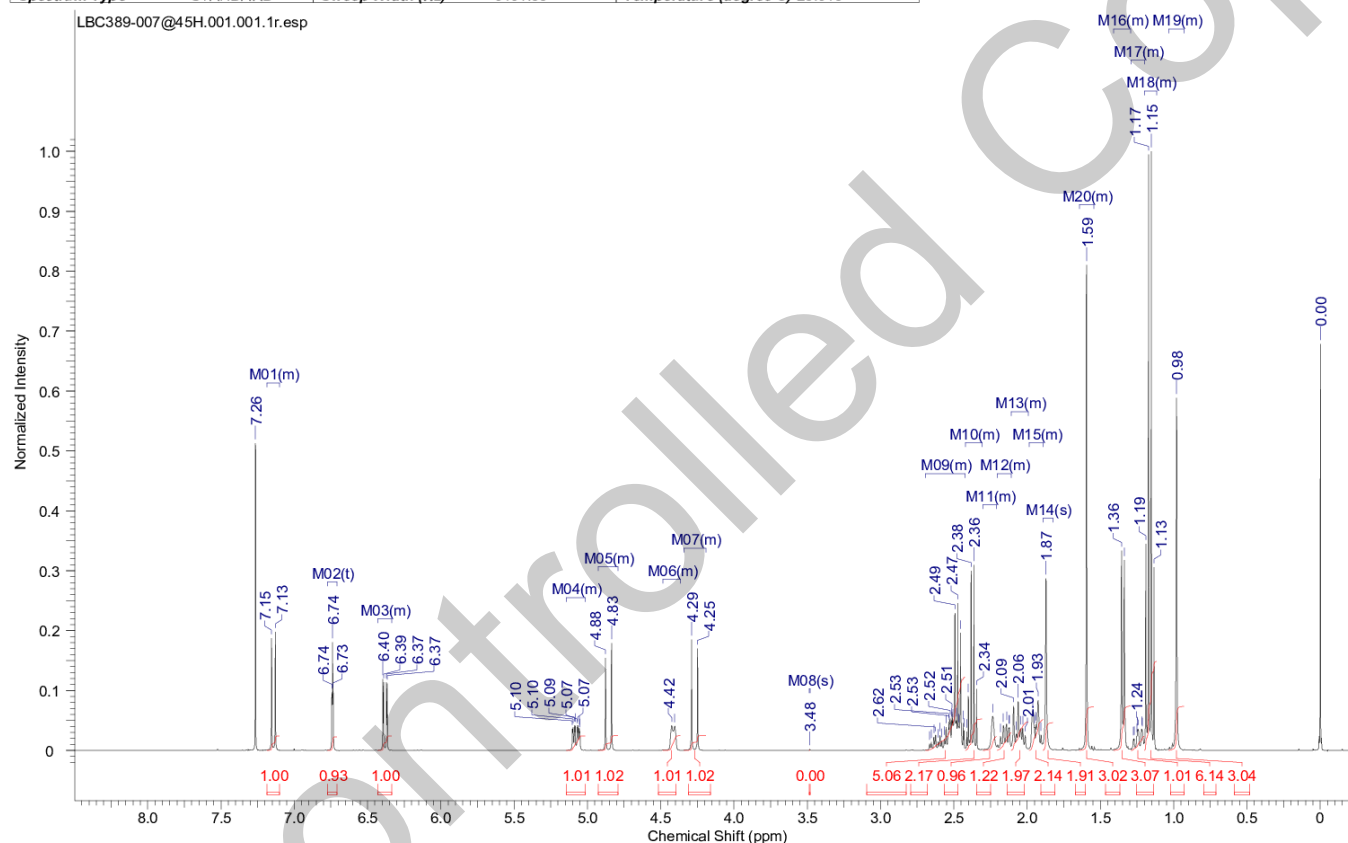
The identity of this product was established using the following analyses:

### Ia. <sup>1</sup>H NMR Spectrum

Conditions: 400 MHz, CDCl<sub>3</sub>

<sup>1</sup>H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC389-007@45H 1H CDCl3 (E:\data\external\epichem}\cygoh 14				
Date	29 Nov 2019 17:42:24	Date Stamp	29 Nov 2019 17:42:24				
File Name	\NAPHTHALENE\Company\NMR files\LBC389-007@45H1\pdata\11r		Frequency (MHz)	400.13			
Nucleus	1H	Number of Transients	16	Origin	spect	Original Points Count	24038
Owner	nmr	Points Count	32768	Pulse Sequence	zg	Receiver Gain	128.00
SW(cyclical) (Hz)	6402.05	Solvent	CHLOROFORM-d	Spectrum Offset (Hz)	2792.8069		
Spectrum Type	STANDARD	Sweep Width (Hz)	6401.85	Temperature (degree C)	25.645		



EPL-AA253 Batch 1

Revision 1

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

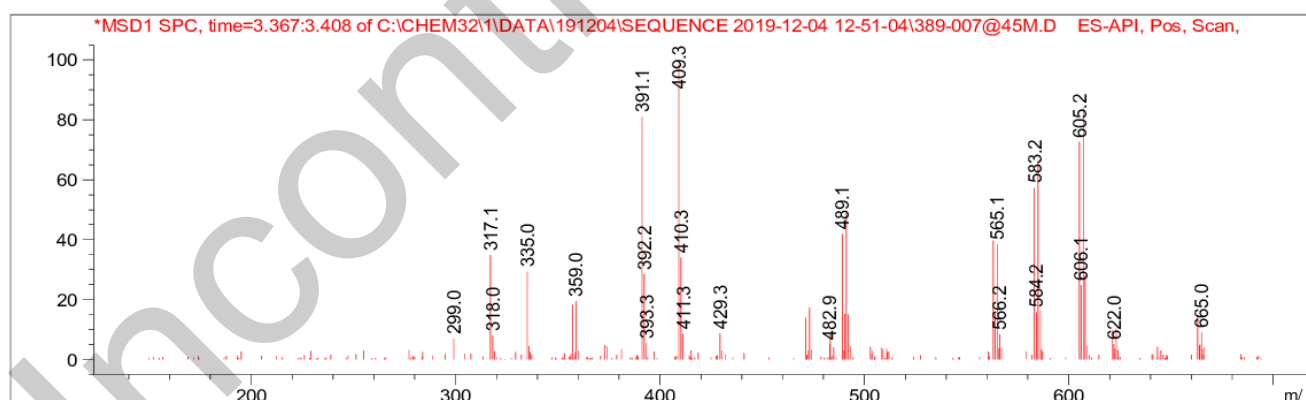
ABN 80 106 769 902

## Ib. Mass Spectrum

The mass spectrum of this material was analysed by Liquid Chromatography Mass Spectroscopy (LCMS) using in-house EM005.WI08.

Method: ACN/water gradient (+ 0.1% formic acid).  
ZORBAX SB-C8, 4.6 x 30 mm, 3.5 micron.

Retention Time (MS)	MS Area	Mol. Weight or Ion
3.380	901965	663.15 I
		623.10 I
		608.05 I
		607.15 I
		606.10 I
		605.15 I
		586.00 I
		585.10 I
		584.15 I
		583.15 I
		565.10 I
		564.00 I
		563.15 I
		492.00 I
		491.15 I
		490.25 I
		489.10 I
		473.10 I
		471.10 I
		410.25 I
		409.25 I
		392.20 I
		391.15 I
		359.00 I
		357.10 I
		335.05 I
		317.15 I



Theoretical values: 585.1 / 583.2 [M+H]<sup>+</sup>.

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

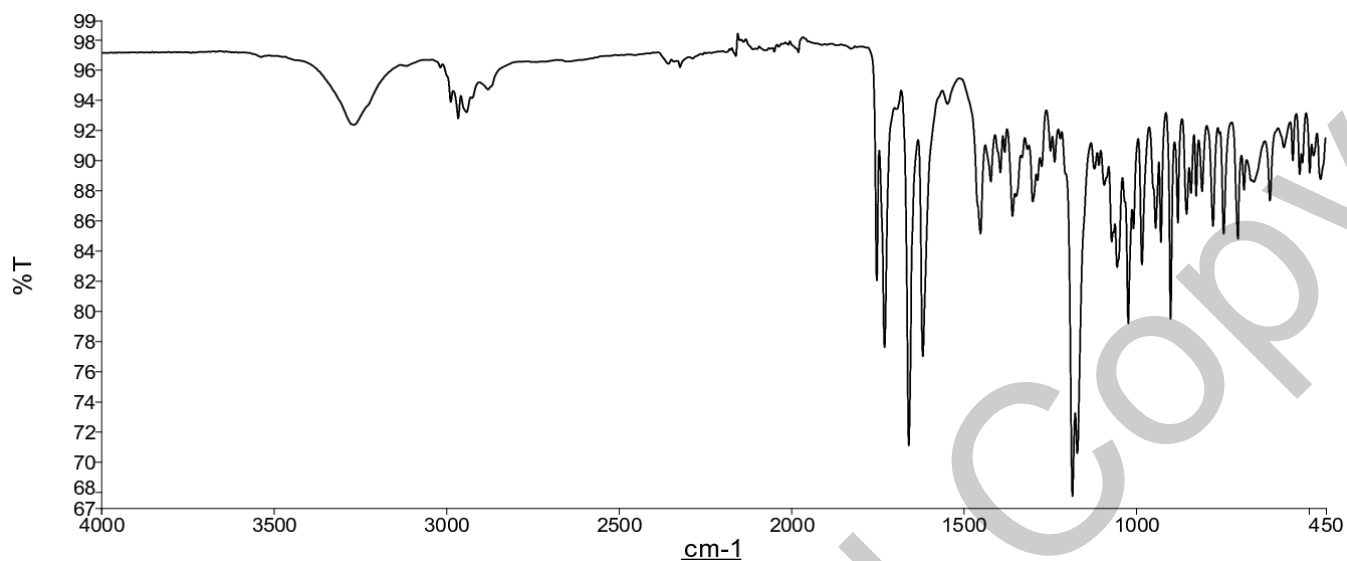
EPL-AA253 Batch 1

Revision 1

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-AA253 Batch 1

Revision 1

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](http://www.epichem.com.au)

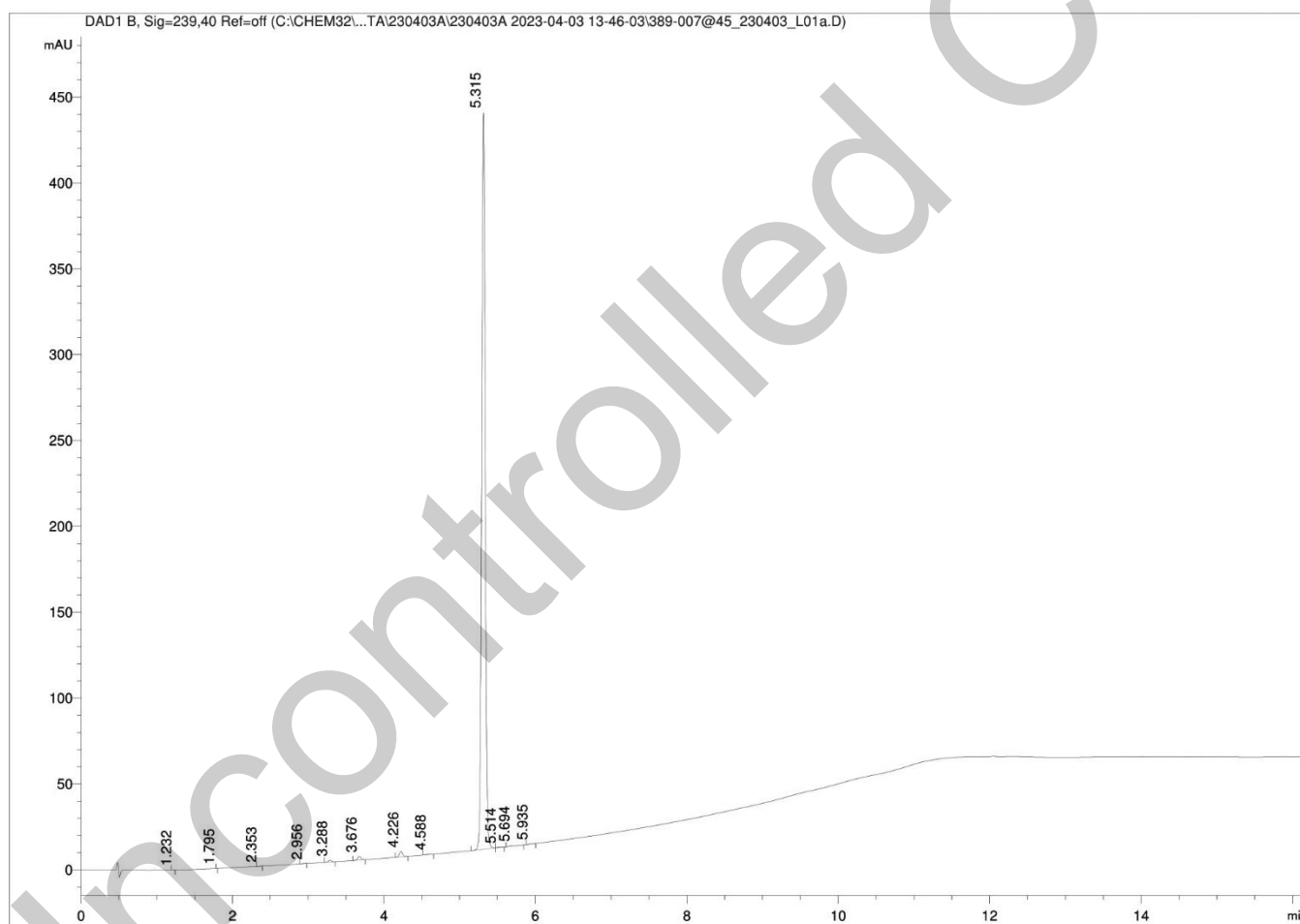
ABN 80 106 769 902

## 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
Agilent Poroshell 120 EC-C18  4.6 x 50mm  2.7 micron	25°C				DAD 239nm	Auto 1.0 µL  1.2 mg/mL in 100% acetonitrile (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	55	45	1.0		
	10.00	5	95	1.0		
	15.00	5	95	1.0		
	16.00	55	45	1.0		
19.00	55	45	1.0			



EPL-AA253 Batch 1

Revision 1

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	1.23	0.09	0.01
2	1.80	0.03	0.00
3	2.35	0.09	0.01
4	2.96	0.26	0.02
5	3.29	3.05	0.22
6	3.68	6.25	0.45
7	4.23	9.51	0.68
8	4.59	1.27	0.09
9	5.31	1371.63	98.32
10	5.51	0.87	0.06
11	5.69	1.68	0.12
12	5.93	0.39	0.03
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 98.3% (average of 10 duplicate runs)

### III. Water Content

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

**Results:**

Average 0.1%

### IV. Ash Content

Method: BP 2019 Appendix XIJ Method II

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>H NMR

**Result:**

Contains <0.1 methanol by <sup>1</sup>H NMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	98.3%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	98.2%

This purity is assessed to be 98.2%

Product Reviewed By:

Product Released By:

Jacob Heppell, PhD  
Chemist

Carol Worth, PhD  
Quality Manager

Release Date: 11 April 2023

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

The calculation of the purity follows the formula:

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

EPL-AA253 Batch 1

Revision 1

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