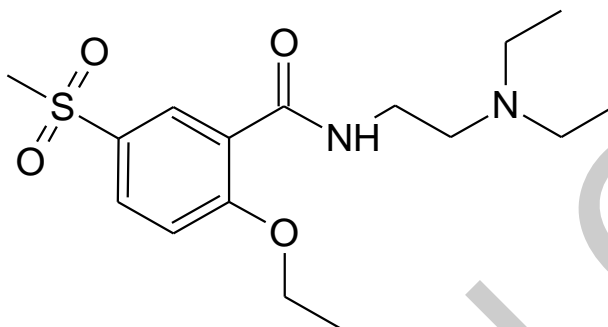


## Reference Material Product Information Sheet

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



<b>Name</b>	N-(2-(diethylamino)ethyl)-2-ethoxy-5-(methylsulfonyl)benzamide
<b>Synonym(s)</b>	Tiapride Ethoxy Impurity
<b>Epichem Item #</b>	EPL-AA206 Batch 1
<b>CAS #</b>	Not available
<b>Molecular Formula</b>	C <sub>16</sub> H <sub>26</sub> N <sub>2</sub> O <sub>4</sub> S
<b>Molecular Weight</b>	342.45 g/mol
<b>Appearance</b>	White crysalline powder
<b>Melting Point</b>	119.7-121.5°C
<b>Combustion Analysis</b>	Required (%): C:56.1; H:7.6; N:8.2. Found (%): C:56.2; H:7.8; N:8.2.
<b>Purity*</b>	99.9%
<b>Date of Manufacture</b>	13 September 2016
<b>Storage Requirements</b>	Store in tightly closed vessel. 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-AA206 Batch 1

Revision 2

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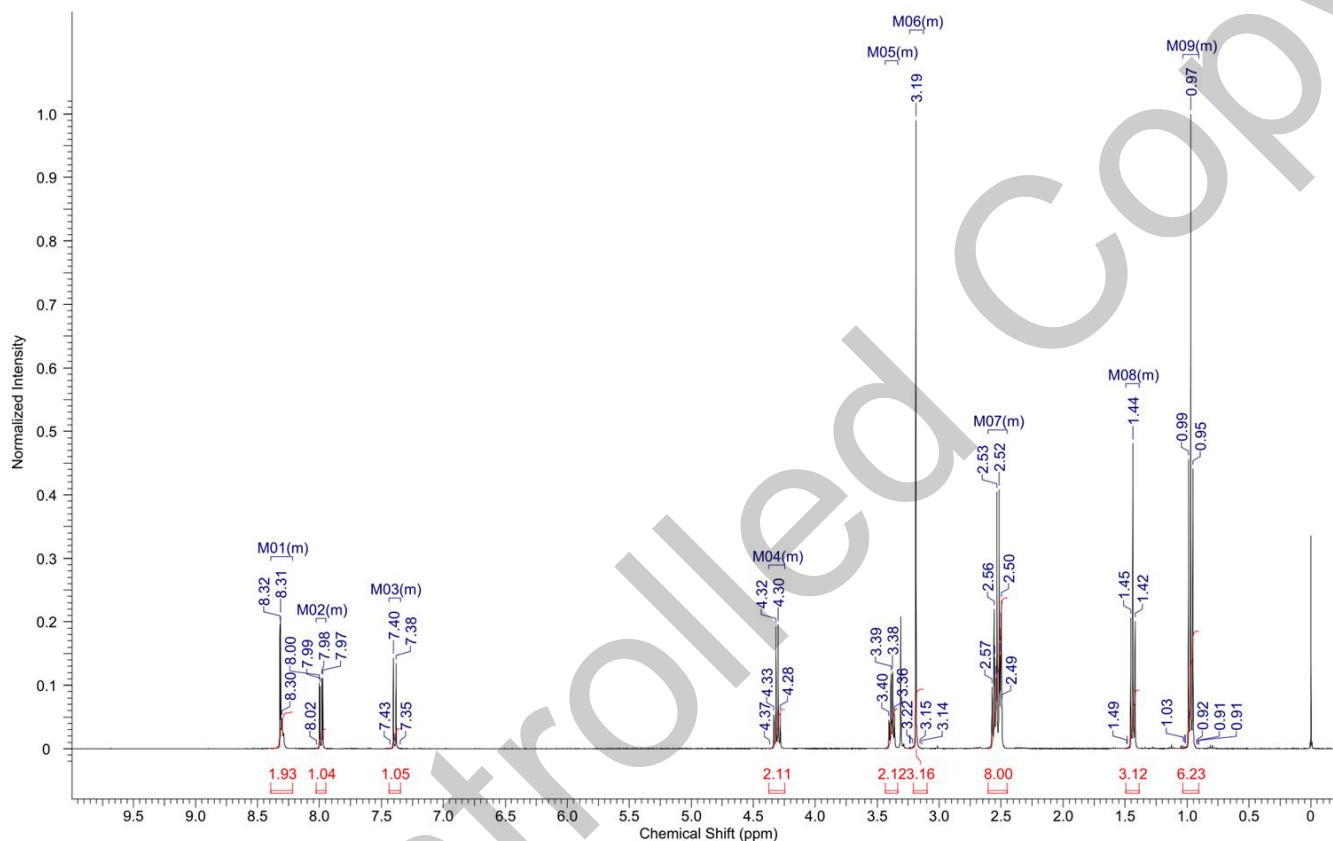
## I. Identity

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

### Ia. <sup>1</sup>HNMR Spectrum

Conditions: 400 MHz, DMSO-d<sub>6</sub>

<sup>1</sup>HNMR spectrum consistent with chemical structure.



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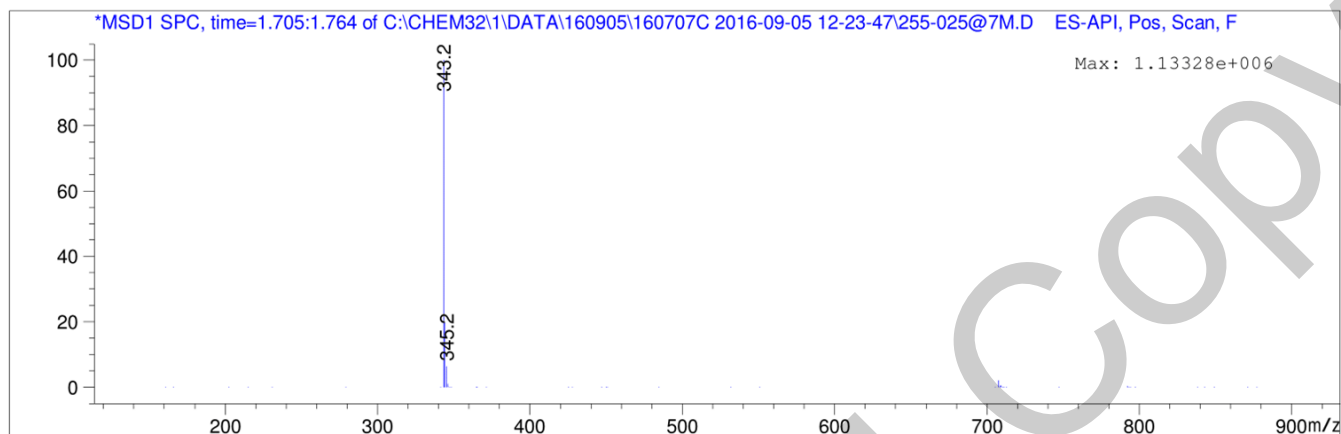
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## Ib. Mass Spectrum

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)  
Poroshell 120 EC-C18, 4.6 x 50 mm, 2.7 micron



Theoretical value: 343.2 [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.

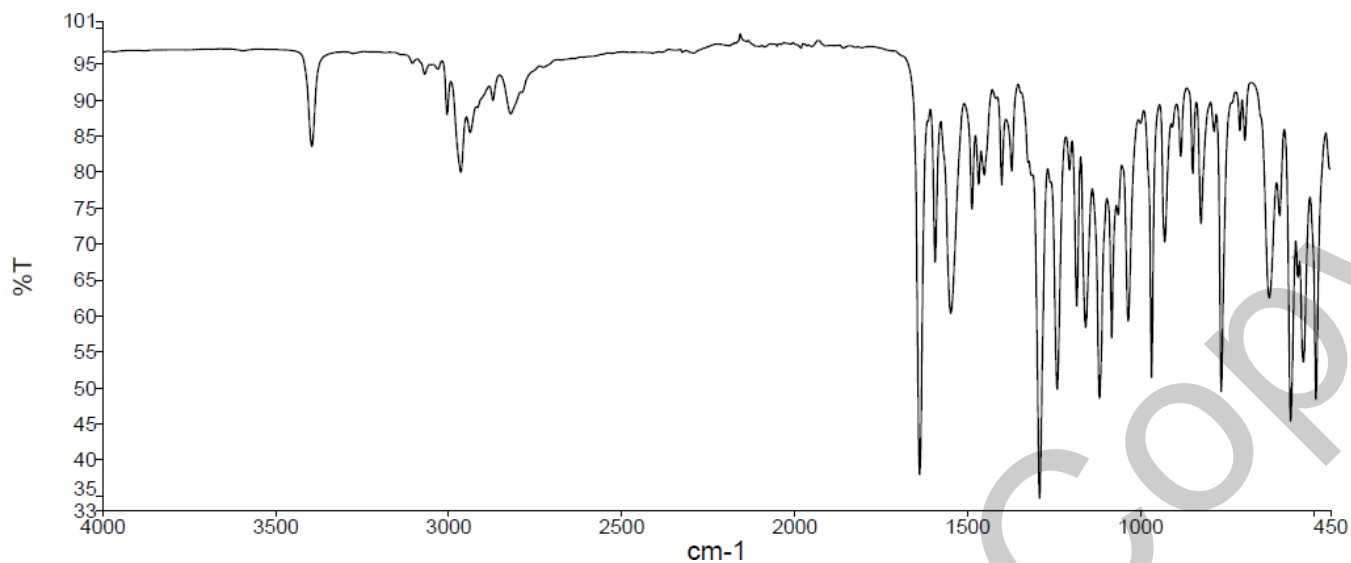
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### Ic. IR Spectrum

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



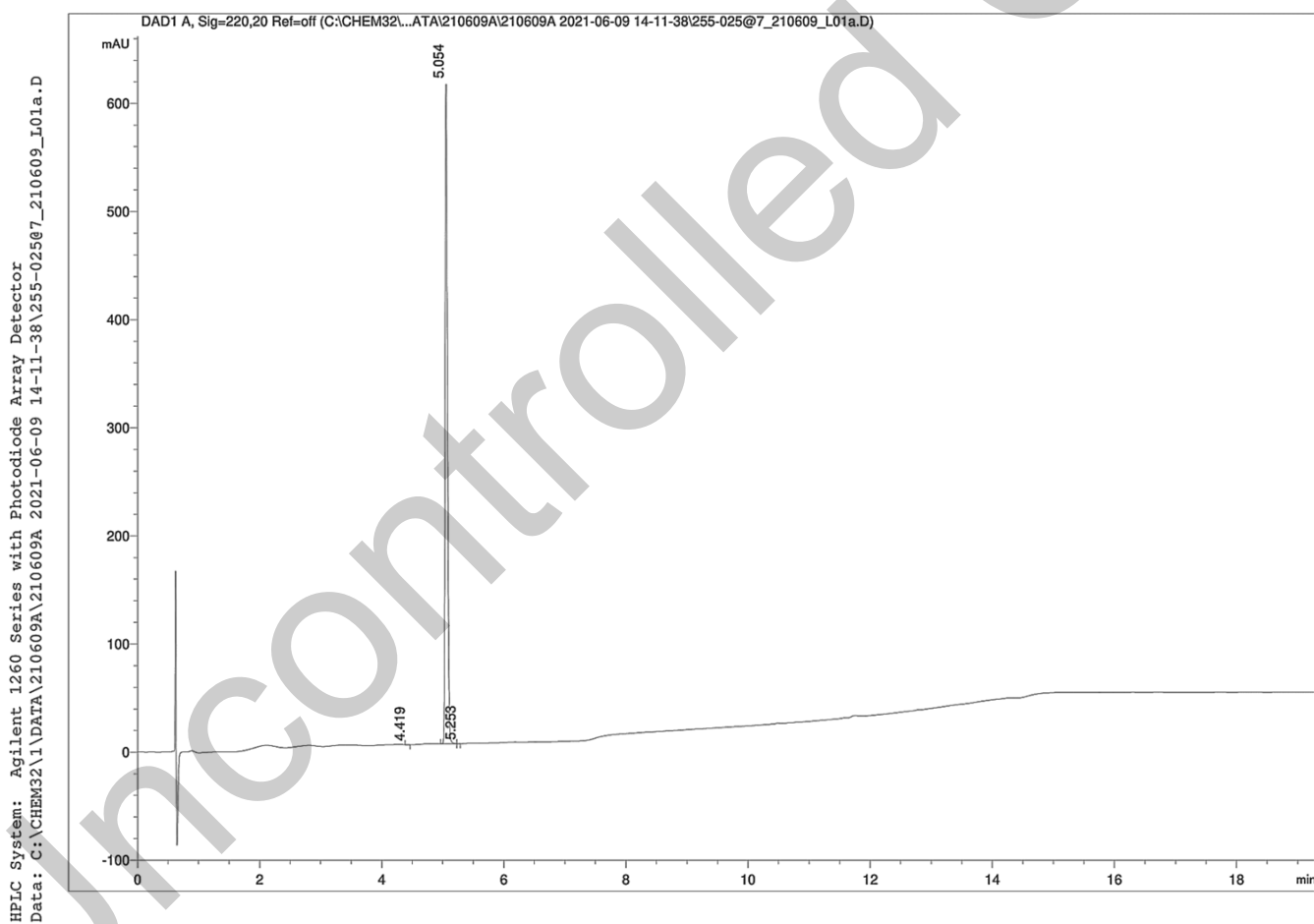
The interpretation of the signals of the Fourier-Transform Infrared Spectrum is consistent with the structural formula.

## 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
Agilent Poroshell 120 EC-C18  4.6 x 50mm  2.7 micron	25°C				DAD 220nm	Auto 1.0 µL 0.35 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	94	6	1.0		
	6.00	76	24	1.0		
	13.10	5	95	1.0		
	18.10	5	95	1.0		
	19.10	94	6	1.0		
	24.10	94	6	1.0		



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### Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	4.42	0.17	0.01
2	5.05	1593.67	99.98
3	5.25	0.15	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 100.0% (average of 10 duplicate analyses)

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### III. Water Content

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

**Results:**

Average 0.1%

### IV. Ash Content

Method: BP2016 Ash (Appendix XI J) as per WS001/C29372

**Result:**

Contains <0.1% ash.

### V. Residual Solvents

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

**Result:**

No significant impurities detected by <sup>1</sup>H NMR analysis.

### VI. Final Result

Chromatographic purity (HPLC)	100.0%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	99.9%

This purity is assessed to be 99.9%.

Product Reviewed By:

Product Released By:

James Rixson, PhD  
Head of Production

Boon Tan  
Quality Manager

Release Date: 21 June 2021

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

The calculation of the purity follows the formula:

$$\text{Purity(\%)} = \frac{((\text{Chromatographic purity[HPLC]}) \times (100 - (\text{water content} + \text{ash content} + \text{volatile contents})))}{100}$$

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