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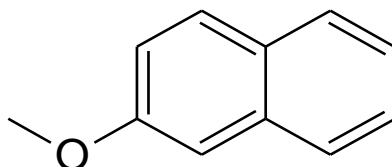
The results of the tests, calibrations and/or measurements included in this document are traceable to Australia/national standards.  
NATA is a signatory to the APLAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of reference materials certificates.



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## 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>                 | 2-methoxynaphthalene  |
| <b>BP Name</b>              | Naproxen Impurity M   |
| <b>Synonym(s)</b>           | Nerolin; 2-naphthyl methyl ether; $\beta$ -methoxynaphthalene   |
| <b>Epichem Item #</b>       | EPL-AA186 Batch 1   |
| <b>CAS #</b>                | 93-04-9   |
| <b>Molecular Formula</b>    | C <sub>11</sub> H <sub>10</sub> O   |
| <b>Molecular Weight</b>     | 158.20 g/mol  |
| <b>Appearance</b>           | White crystals  |
| <b>Melting Point</b>        | 73.0-74.6°C   |
| <b>Combustion Analysis</b>  | Required (%): C:83.5; H:6.4; N:0.0. Found (%): C:83.4; H:6.3; N:0.0.  |
| <b>Purity*</b>              | 99.9%   |
| <b>Date of Manufacture</b>  | 3 February 2016   |
| <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 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-AA186 Batch 1

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## I. Identity

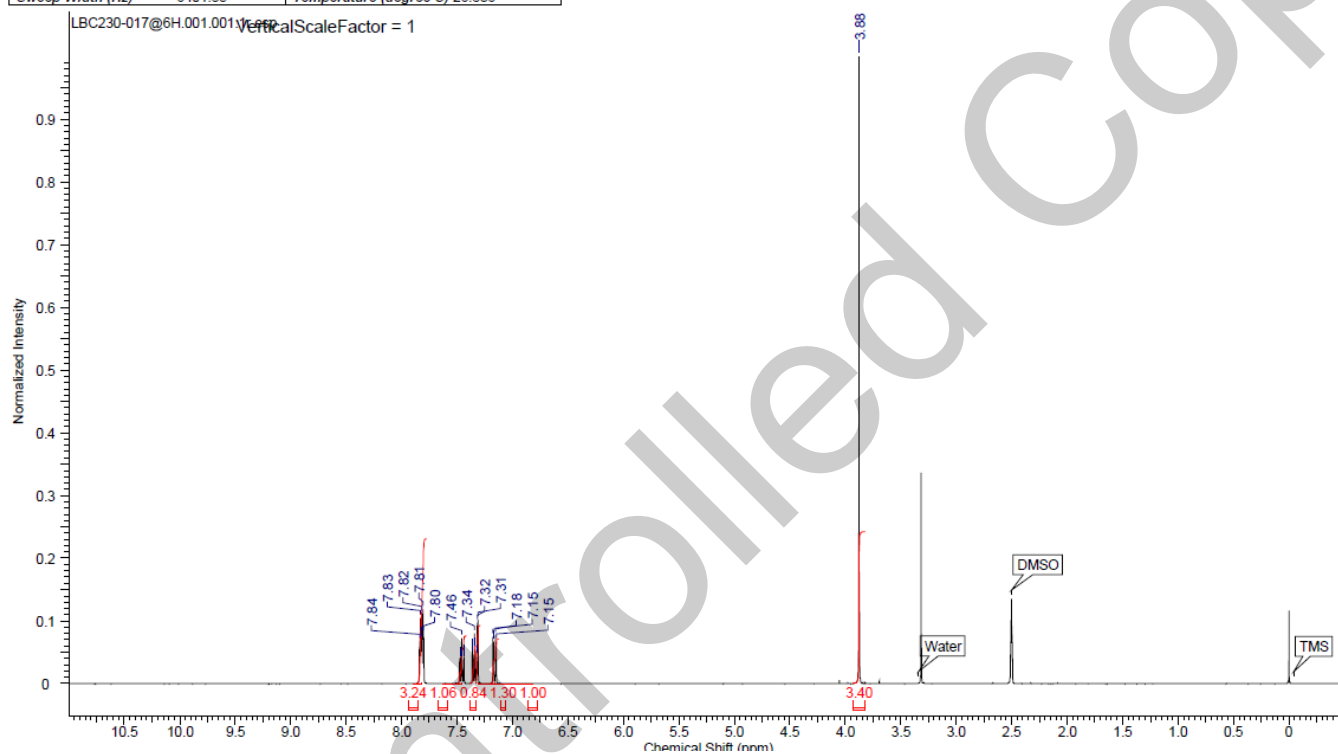
The identity of this product was established using the following analyses:

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

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

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

|                        |   |                        |  |
|------------------------|---|------------------------|--|
| Acquisition Time (sec) | 3.7547  | Comment                | LBC230-017@6H 1H DMSO (E:\data\external\epichem) cygoh 1 |
| Date                   | 11 Dec 2015 18:27:12                                      | Date Stamp             | 11 Dec 2015 18:27:12                                     |
| File Name              | \\NAPHTHALENE\Company\NMR files\LBC230-017@6H\1\data\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          | 128.00   |
| SW(cyclical) (Hz)      | 6402.05   | Solvent                | DMSO-d6  |
| Spectrum Offset (Hz)   | 2798.3408   | Spectrum Type          | STANDARD   |
| Sweep Width (Hz)       | 6401.85   | Temperature (degree C) | 26.836   |



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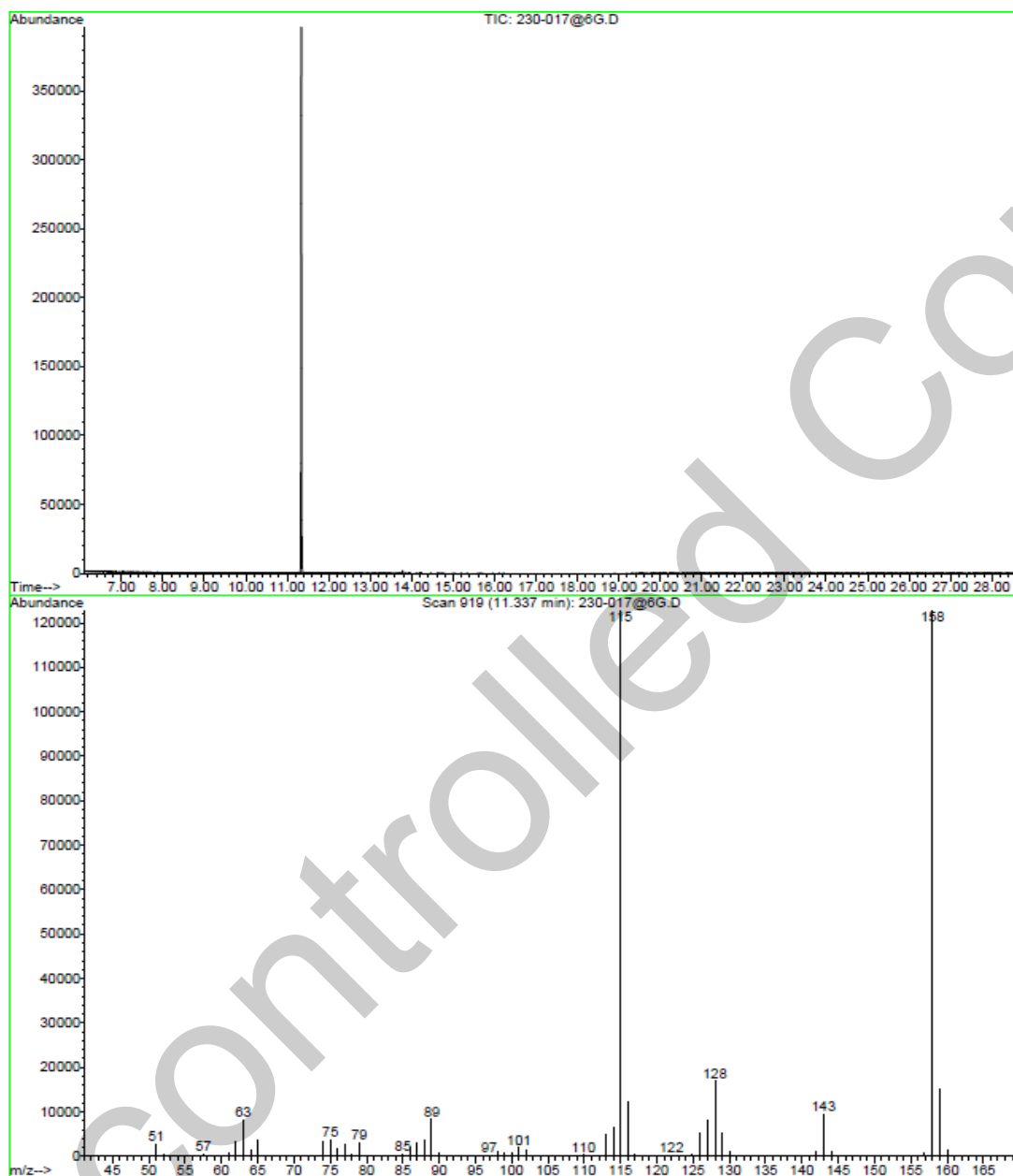
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## Ib. GC-Mass Spectrum\*

The mass spectrum of this material was analysed by Gas Chromatography Mass Spectroscopy (GC MS) using in-house method.



Theoretical value: 158 [M]<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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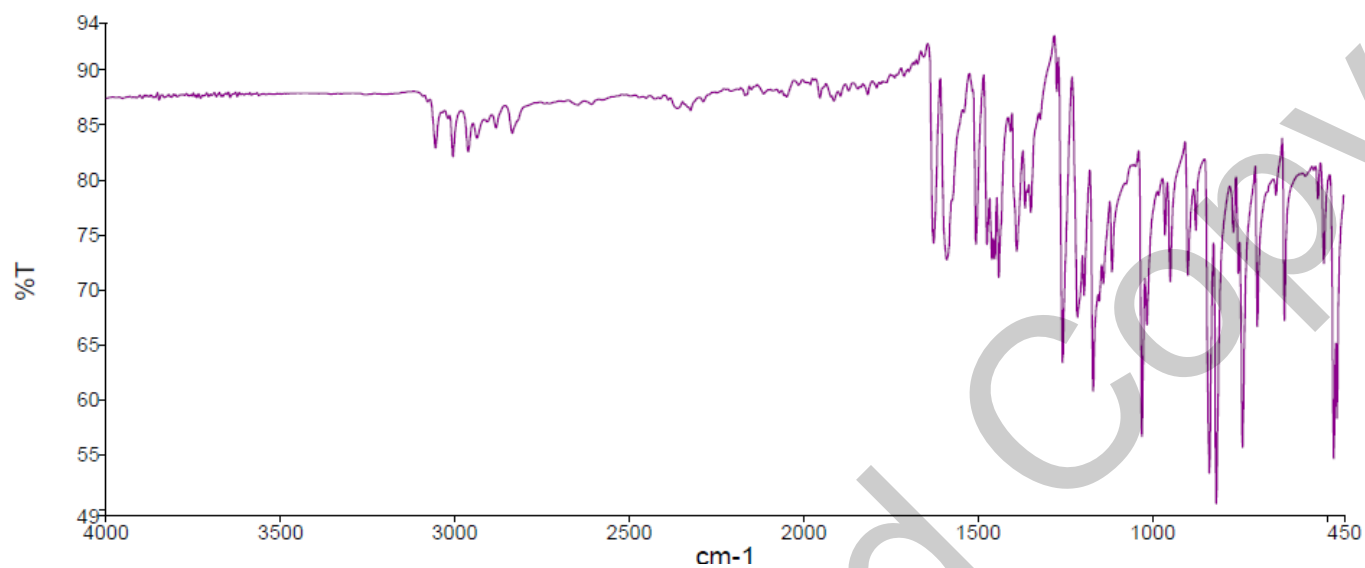
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### Ic. IR Spectrum

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

Method: Fourier Transform Infrared (FTIR) Spectroscopy



The signals of the IR spectrum and their interpretation are consistent with the structural formula.

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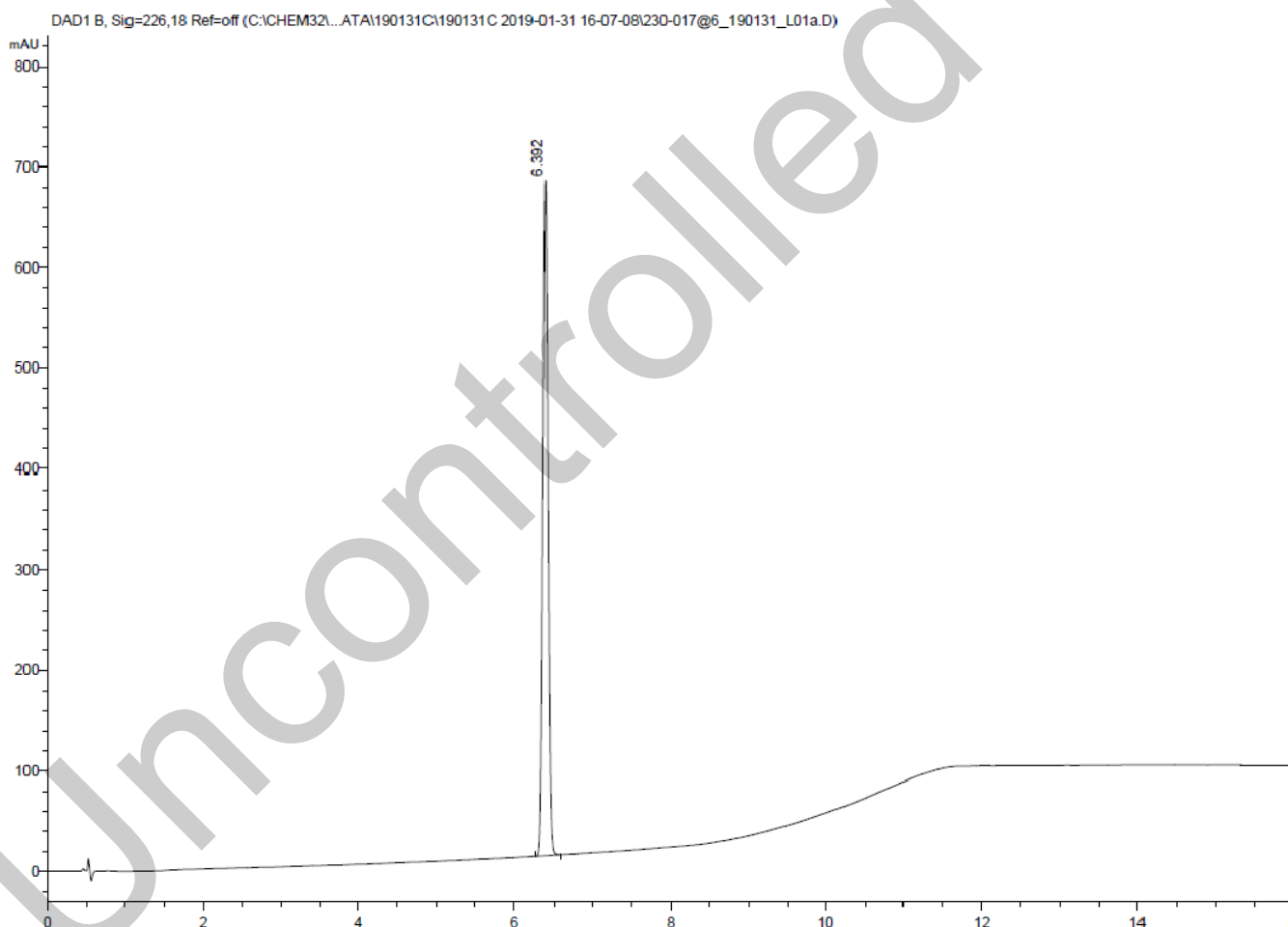
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## II. Purity

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<br>120 EC-C18<br>4.6 x 50mm<br>2.7 micron | 25°C       |                                   |  |                    | DAD<br>226nm | Auto<br>1.0 µL<br>0.15 mg/mL in 100%<br>acetonitrile |
|   | Time (min) | % Line A (Water + 0.1% (v/v) TFA) | % Line B (Acetonitrile + 0.1% (v/v) TFA) | Flow rate (mL/min) |              |  |
|   | 0.00       | 70                                | 30                                       | 1.0                |              |  |
|   | 7.00       | 35                                | 65                                       | 1.0                |              |  |
|   | 10.00      | 5                                 | 95                                       | 1.0                |              |  |
|   | 15.00      | 5                                 | 95                                       | 1.0                |              |  |
|   | 16.00      | 70                                | 30                                       | 1.0                |              |  |
|   | 19.00      | 70                                | 30                                       | 1.0                |              |  |



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### Area Percent Report – Sorted by Signal

| Peak Number | Retention Time (rounded) | Area    | Area % (rounded) |
|-------------|--------------------------|---------|------------------|
| 1           | 6.39                     | 2876.00 | 100.00           |
| Totals      |                          | 2876.00 | 100.0            |

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 runs)

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### III. Water Content

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

#### Results:

Average 0.1%

### IV. Ash Content

Method: BP2015 Ash (Appendix XI-J) WS001/27170

#### Result:

Contains <0.1% ash.

### V. Residual Solvents

Method: <sup>1</sup>HNMR

#### Result:

Contains: <0.1%

### 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:

John Moursounidis, PhD  
Head Reference Standards

Boon Tan  
Quality Manager

Release Date: 8 February 2019

\*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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