



# CERTIFICATE OF ANALYSIS

(Nicotine)

|                       |                   |                   |                       |
|-----------------------|-------------------|-------------------|-----------------------|
| No.                   | : 106/2016        | Date of Issuing   | : 20/05/2016          |
| Product Name          | : <b>NICOTINE</b> | Batch Number      | : <b>469102705051</b> |
| Date of Manufacturing | : 11/05/2016      | Batch Size        | : 300.052 Liter       |
| Date of Expiry        | : 10/05/2021      | Dispatch Quantity | : 300.000 Liter       |

Analytical Protocol Reference: 4691/E-Rev.08

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| <u>Test</u>  | <u>Specification</u>   | <u>Result</u>                                       |  |
|--|--|---|--|
| <b>Character</b>   |  |   |  |
|  | <b>Appearance</b> (Visual test)<br>Colourless or brownish viscous liquid, volatile, hygroscopic  | Colourless viscous liquid, volatile, hygroscopic    |  |
|  | <b>Solubility</b> (Visual test)<br>Soluble in water<br>Miscible with anhydrous ethanol   | Soluble in water<br>Miscible with anhydrous ethanol |  |
| <b>Identification</b>  |  |   |  |
|  | <b>Specific optical rotation</b> ( $\alpha$ ) <sup>20</sup> <sub>D</sub> (Polarimeter)<br>Should conform                                       | Conforms  |  |
|  | <b>IR Spectrum</b> (IR spectrophotometer)<br>Corresponding to reference spectrum   | Corresponds to reference spectrum                   |  |
| <b>Appearance of solution</b> (Limit test)<br>The solution is clear and not more intensely coloured than reference solution Y <sub>5</sub> , BY <sub>5</sub> or R <sub>5</sub> |  |   | The solution is clear and not more intensely coloured than reference solution Y <sub>5</sub> |
| <b>Related substances</b> (Liquid Chromatography)  |  |   |  |
|  | Anatabine (EP Impurity A) : NMT 0.3%   | Less than 0.05%*                                    |  |
|  | $\beta$ -nicotyrine (EP Impurity B) : NMT 0.3%   | Less than 0.05%*                                    |  |
|  | Cotinine (EP Impurity C) : NMT 0.3%  | Less than 0.05%*                                    |  |
|  | Myosmine (EP Impurity D) : NMT 0.3%  | Less than 0.05%*                                    |  |
|  | Nicotine-N-Oxide (EP Impurity E) : NMT 0.3%  | Less than 0.05%*                                    |  |
|  | Nornicotine (EP Impurity F) : NMT 0.3%   | Less than 0.05%*                                    |  |
|  | Anabasine (EP Impurity G) : NMT 0.3%   | Less than 0.05%*                                    |  |
|  | Unspecified impurities (for each impurity) : NMT 0.10%   | Less than 0.05%*                                    |  |
|  | Total impurities : NMT 0.8%  | Less than 0.05%*                                    |  |
|  | <b>Specific optical rotation</b> ( $\alpha$ ) <sup>20</sup> <sub>D</sub> (Polarimeter)<br>(-140° to (-)152°<br>(calculated on anhydrous basis) | (-)147.9°   |  |
|  | <b>Water</b> (Karl Fischer titration)<br>NMT 0.5%  | 0.07%   |  |
|  | <b>Assay</b> (Potentiometer)<br>99.0% to 101.0%<br>(calculated on anhydrous basis)   | 99.6%   |  |

\* Disregard limit of impurity is 0.05%

**Evaluation:** Product corresponds with the requirements of current European Pharmacopoeia.

**Storage Conditions:** Store under nitrogen in well closed containers below 20 °C protected from light and moisture.

**Transportation Temperature:** Below 30°C.

Prepared by

20/05/16

Checked by

Manager Q.C.

**Alchem International Private Limited (Formerly – Alchem International Limited)**

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# CERTIFICATE OF ANALYSIS

(Nicotine EP)

No. : 106/2016 Date of Issuing : 20/05/2016  
Product Name : **NICOTINE EP** Batch Number : **469102705051**  
Date of Manufacturing : 11/05/2016 Batch Size : 300.052 Liter  
Date of Expiry : 10/05/2021 Dispatch Quantity : 300.000 Liter

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| Test   | Specification  | Result   |
|--|--|--|
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| <b>Solubility</b> (Visual test)  | Soluble in water<br>Miscible with anhydrous ethanol  | Soluble in water<br>Miscible with anhydrous ethanol  |
| <b>Identification</b>  |  |  |
| <b>Specific optical rotation</b> ( $\alpha$ ) <sup>20</sup> <sub>D</sub> (Polarimeter) | Should conform   | Conforms   |
| <b>IR Spectrum</b> (IR spectrophotometer)  | Corresponding to reference spectrum  | Corresponds to reference spectrum  |
| <b>Appearance of solution</b> (Limit test)   |  |  |
|  | The solution is clear and not more intensely coloured than reference solution Y <sub>5</sub> , BY <sub>5</sub> or R <sub>5</sub> | The solution is clear and not more intensely coloured than reference solution Y <sub>5</sub> |
| <b>Related substances</b> (Liquid Chromatography)                                      |  |  |
| Anatabine (EP Impurity A)  | : NMT 0.3%   | Less than 0.05%*   |
| β-nicotyrine (EP Impurity B)   | : NMT 0.3%   | Less than 0.05%*   |
| Cotinine (EP Impurity C)   | : NMT 0.3%   | Less than 0.05%*   |
| Myosmine (EP Impurity D)   | : NMT 0.3%   | Less than 0.05%*   |
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| <b>Water</b> (Karl Fischer titration)  | NMT 0.5%   | 0.07%  |
| <b>Assay</b> (Potentiometer)   | 99.0% to 101.0%<br>(calculated on anhydrous basis)   | 99.6%  |

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**Evaluation:** Product corresponds with the requirements of current European Pharmacopoeia.

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