



# CERTIFICATE OF ANALYSIS

(Nicotine)

No.	: 290/2015	Date of Issuing	: 03/11/2015
Product Name	: <b>NICOTINE</b>	Batch Number	: <b>469102610109</b>
Date of Manufacturing	: 26/10/2015	Batch Size	: 300.052 Liter
Date of Expiry	: 25/10/2020	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)	Colourless or brownish viscous liquid, volatile, hygroscopic	Colourless viscous liquid, volatile, hygroscopic
<b>Solubility</b> (Visual test)	Soluble in water Miscible with anhydrous ethanol	Soluble in water Miscible with anhydrous ethanol
<b>Identification</b>		
<b>Specific optical rotation</b> ( $\alpha$ ) <sub>D</sub> <sup>20</sup> (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%*
$\beta$ -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%*

*Prepared by*  
03/11/15

*Checked by*  
03/11/15

*Checked by*  
03/11/15

*Manager Q.C.*  
03/11/15

**Prepared by**

**Checked by**

**Manager Q.C.**

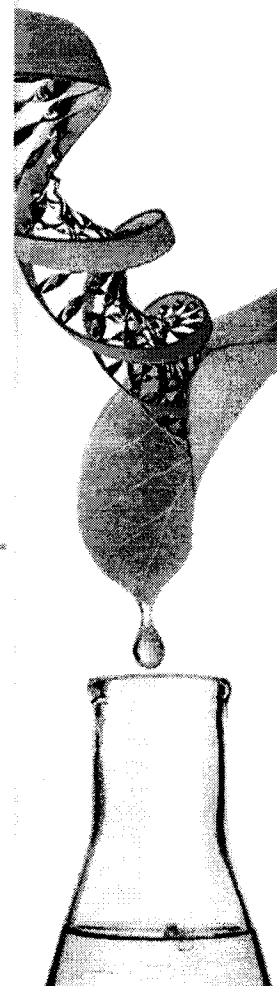
**Alchem International Private Limited (Formerly – Alchem International Limited)**

**Factory:** 25/2, Main Mathura Road, Village Kaili, Ballabgarh, Faridabad – 121 004, Haryana, India

**Registered Office:** 301, Avalon Apartment, Mangla Puri, Mehrauli-Gurgaon Road, New Delhi – 110 030, India

**Contact:** Telephone – 91-129-4266 000 Fax – 91-129-230 9990, 230 9991, 230 7971

**E-mail:** contact@alcheminternational.com





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<u>Test</u>	<u>Specification</u>	<u>Result</u>
<b>Specific optical rotation (<math>\alpha</math>)<sup>20</sup><sub>D</sub> (Polarimeter)</b> (-) <sup>140</sup> ° to (-) <sup>152</sup> ° (calculated on anhydrous basis)		(-) <sup>147.3</sup> °
<b>Water (Karl Fischer titration)</b> NMT 0.5%		0.06%
<b>Assay (Potentiometer)</b> 99.0% to 101.0% (calculated on anhydrous basis)		100.1 %

\* 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

Checked by

Manager Q.C.

Manager Q.C.

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# CERTIFICATE OF ANALYSIS

(Nicotine EP)

No. : 290/2015 Date of Issuing : 03/11/2015  
Product Name : **NICOTINE EP** Batch Number : **469102610109**  
Date of Manufacturing : 26/10/2015 Batch Size : 300.052 Liter  
Date of Expiry : 25/10/2020 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 (Visual test)</b> Colourless or brownish viscous liquid, volatile, hygroscopic	Colourless viscous liquid, volatile, hygroscopic	
	<b>Solubility (Visual test)</b> Soluble in water Miscible with anhydrous ethanol	Soluble in water Miscible with anhydrous ethanol	
<b>Identification</b>			
	<b>Specific optical rotation (<math>\alpha</math>)<sub>D</sub><sup>20</sup> (Polarimeter)</b> Should conform	Conforms	
	<b>IR Spectrum (IR spectrophotometer)</b> Corresponding to reference spectrum	Corresponds to reference spectrum	
<b>Appearance of solution (Limit test)</b> 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 (Liquid Chromatography)</b>			
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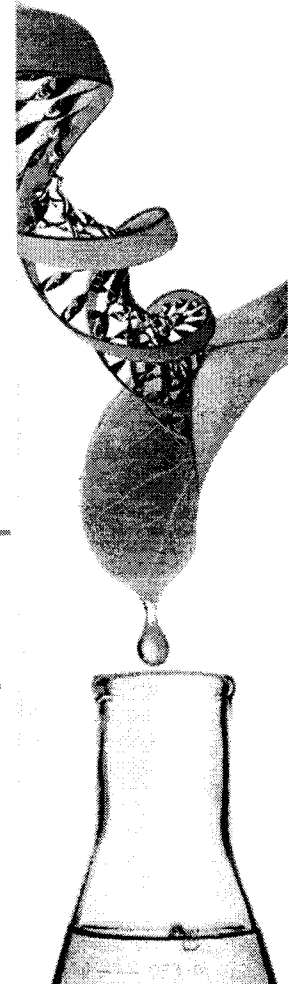
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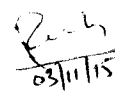
<u>Test</u>	<u>Specification</u>	<u>Result</u>
<b>Specific optical rotation (<math>\alpha</math>)<sup>20</sup><sub>D</sub> (Polarimeter)</b> (-)140° to (-)152° (calculated on anhydrous basis)		(-)147.3°
<b>Water (Karl Fischer titration)</b> NMT 0.5%		0.06%
<b>Assay (Potentiometer)</b> 99.0% to 101.0% (calculated on anhydrous basis)		100.1%

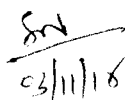
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