

# CERTIFICATE OF ANALYSIS

(Nicotine EP)

No.	: 001/2017	Date of Issuing	: 27/01/2017
Product Name	: <b>NICOTINE EP</b>	Batch Number	: <b>469102712122</b>
Date of Manufacturing	: 29/12/2016	Batch Size	: 620.000 Liter
Date of Expiry	: 28/12/2021	Dispatch Quantity	: 600.000 Liter

Analytical Protocol Reference: 4691/E-Rev.08

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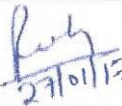
<u>Test</u>	<u>Specification</u>	<u>Result</u>
<b>Character</b>		
	<b>Appearance (Visual test)</b>	
	Colourless or brownish viscous liquid, volatile, hygroscopic	Colourless viscous liquid, volatile, hygroscopic
	<b>Solubility (Visual test)</b>	
	Soluble in water	Soluble in water
	Miscible with anhydrous ethanol	Miscible with anhydrous ethanol
<b>Identification</b>		
	<b>Specific optical rotation (<math>\alpha</math>)<sup>20</sup><sub>D</sub> (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>		
	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%    0.06%
	Nicotine-N-Oxide (EP Impurity E)	: NMT 0.3%    Less than 0.05%*
	Nornicotine (EP Impurity F)	: NMT 0.3%    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%    0.12%
	<b>Specific optical rotation (<math>\alpha</math>)<sup>20</sup><sub>D</sub> (Polarimeter)</b>	
	(-140° to (-)152° (calculated on anhydrous basis)	(-)145.4°
	<b>Water (Karl Fischer titration)</b>	
	NMT 0.5%	0.06%
	<b>Assay (Potentiometer)</b>	
	99.0% to 101.0% (calculated on anhydrous basis)	100.0%

\* 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*  
  
 27/01/17  
**Prepared by**

*Checked by*  
  
 27/01/17  
**Checked by**

*Secondary*  
  
 27/01/17

*Manager Q.C.*  
  
 27/01/17  
**Manager Q.C.**