

CERTIFICATE OF ANALYSIS

(Nicotine EP)

No.	: 001/2017	Date of Issuing	: 27/01/2017
Product Name	: NICOTINE EP	Batch Number	: 469102712122
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>
Character		
	Appearance (Visual test)	
	Colourless or brownish viscous liquid, volatile, hygroscopic	Colourless viscous liquid, volatile, hygroscopic
	Solubility (Visual test)	
	Soluble in water	Soluble in water
	Miscible with anhydrous ethanol	Miscible with anhydrous ethanol
Identification		
	Specific optical rotation (α)²⁰_D (Polarimeter)	
	Should conform	Conforms
	IR Spectrum (IR spectrophotometer)	
	Corresponding to reference spectrum	Corresponds to reference spectrum
Appearance of solution (Limit test)		
	The solution is clear and not more intensely coloured than reference solution Y ₅ , BY ₅ or R ₅	The solution is clear and not more intensely coloured than reference solution Y ₅
Related substances (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% 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%
	Specific optical rotation (α)²⁰_D (Polarimeter)	
	(-140° to (-)152° (calculated on anhydrous basis)	(-)145.4°
	Water (Karl Fischer titration)	
	NMT 0.5%	0.06%
	Assay (Potentiometer)	
	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

Checked by

 27/01/17

Secondary

 27/01/17

Manager Q.C.

 27/01/17