

CERTIFICATE OF ANALYSIS

(Nicotine)

No. : 167/2015 Date of Issuing : 18/06/2015
Product Name : NICOTINE Batch Number : 469102605054
Date of Manufacturing : 29/05/2015 Batch Size : 280.052 Liter
Date of Expiry : 28/05/2020 Dispatch Quantity : 280.000 Liter

Analytical Protocol Reference: 4691/E-Rev.08

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Test	Specification	Result
Specific optical rotation (α) _D ²⁰ (Polarimeter) (-)-140° to (-)-152° (calculated on anhydrous basis)		(-)-146.1°
Water (Karl Fischer titration) NMT 0.5%		0.07%
Assay (Potentiometer) 99.0% to 101.0% (calculated on anhydrous basis)		100.2%

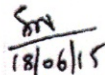
* Disregard limit of impurity is 0.05%

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.


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Prepared by


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Checked by


18/06/15
Manager Q.C.

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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 Miscible with anhydrous ethanol	Soluble in water Miscible with anhydrous ethanol
Identification		
Specific optical rotation (α)_D²⁰ (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 _s , BY _s or R _s	The solution is clear and not more intensely coloured than reference solution Y _s
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%	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%*

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