

# CERTIFICATE OF ANALYSIS

(Nicotine EP)

T.C. No.	: 096/2025	Date of Release	: 23/04/2025
Product Name	: <b>NICOTINE EP</b>	Batch Number	: <b>4691B03604022</b>
CAS No	: <b>54-11-5</b>	Batch Size	: 1263.510 Kg (1251.000 Liter)
Date of Manufacturing	: 02/04/2025	Dispatch Quantity	: 1212.000 Kg (1200.000 Liter)
Date of Expiry	: 01/04/2030		

Analytical Protocol Reference: 4691B/E-Rev.00

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Test	Specification	Result
<b>Character</b>		
	<b>Appearance</b> (Visual test) Colourless or yellowish 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> ( $\alpha$ ) <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%*
$\beta$ -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%	0.08%
Nicotine-N-Oxide (EP Impurity E)	: NMT 0.3%	Less than 0.05%*
Normicotine (EP Impurity F)	: NMT 0.3%	0.06%
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%	0.14%
<b>Specific optical rotation</b> ( $\alpha$ ) <sup>20</sup> <sub>D</sub> (Polarimeter) (-140° to (-)152° (calculated on anhydrous basis)		
		(-)147.9°
<b>Water</b> (Karl Fischer titration) NMT 0.5%		
		0.10%
<b>Assay</b> (Potentiometer) 99.0% to 101.0% (calculated on anhydrous basis)		
		100.2%

\* Disregard limit of impurity is 0.05%

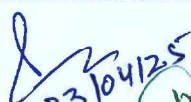
**Evaluation:** Product corresponds with the requirements of current European Pharmacopoeia.

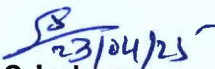
**NOTES**® [NicSelect Organoleptic Test Score] : Not more than 2.1 Conforms

**Long Term Storage Conditions (>6 months):** Store at refrigerated condition (below 8°C) under nitrogen in well closed containers protected from light and moisture.

**Transportation & Short Term Storage Conditions (<6 months):** Below 30°C.

  
23/04/25  
Prepared by

  
23/04/25  
Checked by

  
23/04/25  
Q.C. Incharge

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Annexure: AIL/COAFP/19/13/23

