

CERTIFICATE OF ANALYSIS

Product Name	: Nicotine	CAS No.	: 54 – 11 – 5
Batch No.	: NI008/14	Mfg. Date	: 04/2014
Batch size	: 456.0 Kg.	Expiry Date	: 04/2019

Sr. No.	Tests	Specifications	Results
1.	Description	Colorless to brownish viscous liquid	Slightly Yellowish viscous liquid
2.	Solubility	Soluble in water , miscible with anhydrous alcohol	Complies
3.	Identification a) By U.V.	U.V.absorption spectrum of the test solution and the standard solution exhibits maxima and minima at the same wavelength.	Complies
	b) By IR	The I.R.spectrum of the test sample should match with the IR spectrum of Ph.Eur.reference spectrum of Nicotine.	Complies
	c) By Specific Optical Rotation	It should comply with the test for specific optical rotation	Complies
4.	Specific Optical Rotation at 25°C ±0.5°C	Between -130° and -143°	-139°
	Specific Optical Rotation at 20°C ±0.5°C	Between -140° and -152°	-144°
5.	Water content	Not more than 0.5 % w/w	0.1 %w/w
6.	Appearance of Solution	The solution should be clear and not more intensely colored than reference solution Y ₅ ,BY ₅ or R ₅	Complies
7.	Heavy Metals	Not more than 0.002 %	Complies
8.	Related Substances By HPLC		
	Specified Impurities		
	Anatabine	Not more than 0.30 %	≤ 0.0067 %
	β- Nicotyrine	Not more than 0.30 %	≤ 0.0304 %
	Cotinine	Not more than 0.30 %	≤ 0.0035 %
	Myosmine	Not more than 0.30 %	≤ 0.0018 %
	Nicotine N'oxide	Not more than 0.30 %	≤ 0.0019 %
	Nornicotine	Not more than 0.30 %	≤ 0.0307 %
Anabasine	Not more than 0.30 %	≤ 0.0044 %	

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	Any Unspecified Impurities(Single greatest)	Not more than 0.10%	Not detected
	Sum of Impurities (Identified & Unidentified)	Not more than 0.80 %	Not detected
9.	Assay by Potentiometer on anhydrous basis	Not less than 99.0 % and not more than 101.0 %	100.4 %
Additional Tests			
10.*	Total Viable Count a) Total Bacterial Count b)Total Fungal Count	NMT 2000 cfu/gm NMT 200 cfu/gm	N./A.
11.	Pathogens Test a. E.coli b. Salmonella species c. Pseudomonas aeruginosa d. S.aureus e. Bile Tolerant Gram Negative Bacteria f. Candida albicans	a. Should be absent b. Should be absent c. Should be absent d. Should be absent e. Should be absent f. Should be absent	N./A.
* Additional tests to be performed for once in five batches.			

Batch Complies with respect to above Specifications.