

BGP HEALTHCARE PVT. LTD.

CERTIFICATE OF ANALYSIS

Product Name	: Nicotine USP	Item code	: FP101-00
Batch No.	: NI009/13	Mfg. Date	: 04/2013
Batch size	: 300.0 Kg.	Retest Date	: 04/2018
CAS No.	: 54 - 11 - 5		

Sr. No.	Tests	Specifications	Results
1.	Description	Colorless to brownish viscous liquid	Colorless viscous liquid
2.	Identification by U.V.	U.V.absorption spectrum of the test solution and the standard solution exhibits maxima and minima at the same wavelength.	Complies
3.	Specific Optical Rotation at 25°C ±0.5°C	Between -130° and -143°	-135°
4.	Water content	Not more than 0.5 % w/w	0.1 %w/w
5.	Heavy Metals	Not more than 0.002 %	Complies
6.	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 %
	Normicotine	Not more than 0.30 %	≤ 0.0307 %
	Anabasine	Not more than 0.30 %	≤ 0.0044 %
	Any Unspecified Impurities(Single greatest)	Not more than 0.10%	Not detected
	Sum of Impurities (Identified & Unidentified)	Not more than 0.80 %	Not detected
7.	Assay by Potentiometer on anhydrous basis	Not less than 99.0 % and not more than 101.0 %	100.1 %
Additional Tests			
8.*	Total Viable Count		
	a) Total Bacterial Count	NMT 2000 cfu/gm	Not Applicable
	b) Total Fungal Count	NMT 200 cfu/gm	

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CERTIFICATE OF ANALYSIS

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Sr. No.	Tests	Specifications	Results
10.*	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	Not Applicable

* Additional tests to be performed for once in five batches.

\$ Test carried out as per EP which meets USP requirements as well.

Batch Complies with respect to above Specifications.

Released By:



Mrs.Sonal Shah
Quality Assurance

Released On: 29/04/2013