



BGP HEALTHCARE PVT. LTD.

CERTIFICATE OF ANALYSIS

Product Name	: Nicotine Resinate EP (Contains 20% Nicotine)	Item code	: FP104-00
Batch No.	: NP015/17	A.R.No.	: QC/FP/17/033
Batch size	: 200.0 Kg.	Mfg. Date	: 09/2017
CAS No.	: 96055-45-7	Expiry Date	: 09/2022

Sr. No.	Tests	Specifications	Results
1.	Appearance	White or slightly yellowish powder	Off white powder
2.	Solubility	Practically insoluble in water	Complies
3.	Identification a. By IR b. By Nicotine Release	a. The IR spectrum of Nicotine obtained from the test sample should be concordant with Ph.Eur. reference spectrum of Nicotine b. It Complies with the test for Nicotine Release	Complies Complies
4.	Nicotine Release	Not less than 70 % release in 10 minutes	79 %
5.	Loss on Drying	Not more than 7.0% w/w	4.4 % w/w
6.	Related Substances By HPLC Specified Impurities Anatabine β- Nicotyrine Cotinine Myosmine Nicotine N'oxide Nornicotine Anabasine Any Unspecified Impurities(Single greatest) Sum of Impurities (Identified & Unidentified)	 Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.10% Not more than 0.80 %	 ≤ 0.0076 % ≤ 0.0391 % ≤ 0.0039 % ≤ 0.0023 % ≤ 0.0023 % 0.03 % ≤ 0.0075 % Not Detected 0.03 %
7.	Assay by HPLC on dried basis	95.0 % to 115.0 % of labeled value (20%) (19.0% to 23.0% Nicotine content)	108.3 % (21.7 %)

CIN : U24232GJ2007PTC050417

Office & Work : Plot No. : 3707, G.I.D.C. Ankleshwar, Gujarat, India-393002

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Website : www.bgpgroup.biz



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Sr. No.	Tests	Specifications	Results
Additional Tests			
8. *	Particle size test	100 % passes through 300 μ	Complies
9.**	Total Viable Count a) Total Bacterial Count b) Total Fungal Count	NMT 2000 cfu/gm NMT 200 cfu/gm	NA NA
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	NA NA NA NA NA NA
* Additional test to be carried out for each batch			
** Additional tests to be performed for once in five batches.			

Batch Complies with respect to above Specifications.

Released By:


Mr. Balaji Patel
Quality Assurance

Released On: 26/09/2017

CIN : U24232GJ2007PTC050417

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CERTIFICATE OF ANALYSIS

Product Name	: Nicotine EP	Item code	: FP103-00
Batch No.	: NI015/17	A.R.No.	: QC/FP/17/026
Batch size	: 456.0 Kg.	Mfg. Date	: 07/2017
CAS No.	: 54 – 11 – 5	Expiry Date	: 07/2022

Sr. No.	Tests	Specifications	Results
1.	Appearance	Colorless to brownish viscous liquid,volatile,hygroscopic	Colorless viscous liquid
2.	Solubility	Soluble in water, miscible with anhydrous ethanol	Complies
3.	Identification A.By IR B.By Specific Optical Rotation	A. The I.R.spectrum of the test sample should match with the IR spectrum of Ph.Eur.reference spectrum of Nicotine. B. It should comply with the test for specific optical rotation	Complies Complies
4.	Appearance of Solution	The solution should be clear and not more intensely colored than reference solution Y ₅ ,BY ₅ or R ₅	Complies
5.	Specific Optical Rotation at 20°C ±0.5°C	Between -140° and -152°	-146°
6.	Water content	Not more than 0.5 % w/w	0.1 %
7.	Related Substances By HPLC Specified Impurities Anatabine β- Nicotyrine Cotinine Myosmine Nicotine N'oxide Nornicotine Anabasine Any Unspecified Impurities(Single greatest) Sum of Impurities (Identified & Unidentified)	Not more than 0.30 % Not more than 0.30 % Not more than 0.30 % Not more than 0.30 % Not more than 0.30 % Not more than 0.30 % Not more than 0.30 % Not more than 0.10% Not more than 0.80 %	≤ 0.0067 % ≤ 0.0304 % ≤ 0.0035 % ≤ 0.0018 % ≤ 0.0019 % 0.06 % ≤ 0.0044 % Not detected 0.06 %



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Batch size	: 456.0 Kg.	Mfg. Date	: 07/2017
CAS No.	: 54 – 11 – 5	Expiry Date	: 07/2022

Sr. No.	Tests	Specifications	Results
8.	Assay by Potentiometer on anhydrous basis	Not less than 99.0 % and not more than 101.0 %	99.7 %

Additional Tests

9.*	Total Viable Count a) Total Bacterial Count b) Total Fungal Count	NMT 2000 cfu/gm NMT 200 cfu/gm	NA NA
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	NA NA NA NA NA NA

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

Batch Complies with respect to above Specifications.

Released By:

Mr. Balaji Patel
Quality Assurance

Released On: 26/07/2017