

**TYPICAL CERTIFICATE OF ANALYSIS**

Product	: Nicotine Resinate BP/EP (15%)	Page 1 of 1
Reference	: British Pharmacopeia-2022 : European Pharmacopeia -10	
Manufactured By	: Prism Industries Pvt. Ltd.	Product code : NCTP
Batch Size	: 50.00 Kg	Self Life (Retest Date) : 2 years

Sr. No.	Test	Specification	Result
1	Appearance	White or slightly yellowish powder, hygroscopic	White powder
2	Solubility	Practically insoluble in water	Complies
3	Identification A , B	A) IR Spectrophotometer B) Nicotine release (Minimum 70% release in 10 min.)	Complies 73.05%
4	Related Substances By HPLC		
4.1	Nicotine related Compound A	NMT 0.30%	0.07%
4.2	Nicotine related Compound B	NMT 0.30%	0.04%
4.3	Nicotine related Compound C	NMT 0.30%	0.02%
4.4	Nicotine related Compound D	NMT 0.30%	0.02%
4.5	Nicotine related Compound E	NMT 0.30%	0.05%
4.6	Nicotine related Compound F	NMT 0.30%	0.09%
4.7	Nicotine related Compound G	NMT 0.30%	0.08%
4.8	Any Other Unspecified Impurity	NMT 0.10%	0.03%
4.9	Total Impurities	NMT 0.80%	0.40%
5	Loss on drying	NMT 7.0%	2.32%
6	Assay by HPLC	95.0% to 115.0%	104.20%

Additional Test:

7	Assay Nicotine (On dried basis)	14.25 % to 17.25 %	15.74%
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REMARK: As opinion of under signed product is Complies / ~~Does not Complies~~ as per Specifications.

	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
Name	Sohil Darji	Dixit Prajapati	Amit Tamboli
Sign & Date	 14/09/23	 14/09/23	 14/09/23

CIN U24231GJ1992PTC017501**Office** 208, Trivia Complex, Nr. Natubhai Circle,
Race Course, Gujarat, INDIA, Pin-390007**Phone** 0265-3504649/50 **Mob** +91 98250-51262, +91 92274-06992**E-mail** marketing@prismintltd.com**PAN** AABCP7162Q**Factory** Survey No. 637/23/A1, Khambhat Dhuvaran Road, At: Kalamsar,
Ta.: Khambhat, Dist. Anand, Gujarat, INDIA, Pin-388640**Mob** +91 98250-50731, +91 97277-01668**E-mail** info@prismintltd.com