

**TYPICAL CERTIFICATE OF ANALYSIS**

Product : Nicotine Ditartrate Dihydrate BP	Page 1 of 1
Reference : British Pharmacopoeia	
Manufactured By : Prism Industries Pvt Ltd.	Product code : NBD
Self Life (Retest Date) : 2 years	

Sr.No	Tests	Specification	Results
1	Appearance	White Or Almost White Powder	White crystalline powder
2	Solubility	Soluble in water, and in ethanol (96%)	Complies
3	Identification by IR	Infrared absorption Spectrophotometry comparison nicotine Ditartrate dihydrate CRS	Complies
4	pH	3.0 to 3.4	3.29
5	Specific Optical Rotation	+ 21.0° to + 23.0°	+ 22.60°
6	Sulphated ash	Maximum 0.1 %	0.08%
7	Water	6.5% to 8.0%	6.58%
8	Related Substance By HPLC		
8.1	Impurity E	NMT 0.30 %	Not Detected
8.2	Impurity C	NMT 0.30 %	0.01%
8.3	Impurity F	NMT 0.30 %	0.02%
8.4	Impurity A	NMT 0.30 %	0.02%
8.5	Impurity D	NMT 0.30 %	0.15%
8.6	Impurity G	NMT 0.30 %	0.01%
8.7	Impurity B	NMT 0.30 %	0.06%
8.8	Unspecified Impurity	NMT 0.10 %	0.01%
8.9	Total Impurities	NMT 0.80 %	0.30%
9	Assay (Anhydrous Substance)	98.5 % to 101.5%	99.89%
Additional Teat:			
10	Content of free base Nicotine	31 % to 33 %	32.30%
REMARK : As opinion of under signed product is <u>Complies</u> / Does not Complies as per prescribe Specification BP-2024.			

Name	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
Sign & Date	Nitin Solanki <i>N.Solanki</i> 01/01/25	Sohil Darji <i>Sohil</i> 01/01/25	Bhavesh Chauhan <i>Bhavesh</i> 01/01/25

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