

**TYPICAL CERTIFICATE OF ANALYSIS**

Product	: Scopolamine Hydrobromide Hydrate EP/ Hyoscine Hydro bromide BP	
Reference	: European Pharmacopoeia	Page 1 of 1
Manufactured By	: Prism Industries Pvt. Ltd.	Product code : HHBR
Self Life (Retest Date) : 5 years	CAS NO	: 6533-68-2

Sr. No.	Test	Specification	Result
1	Description	White or almost white, crystalline powder or colourless crystals, efflorescent.	Complies
2	Solubility	Freely soluble in water, soluble in ethanol (96 per cent).	Complies
3	Identification A,B,C,D & E	(A) By Specific optical rotation (B) IR test (C) By MP test (Between 188°C to 193°C) (D) By Color test (E) By Bromide test	Complies Complies 191°C Complies Complies
4	pH	Between 4.0 to 5.5	4.34
5	Specific optical rotation (OAB)	Between -24° to -27°	-25.50°
6	Sulphated Ash	NMT 0.10%	0.06%
7	Water Determination	Between 10.0% to 13.0%	12.14%
8	Related substances by HPLC	Imp. A Not more than 0.10% Imp. B Not more than 0.50% Imp. C Not more than 0.10% Imp. D Not more than 0.10% Un. Max. Imp. Not more than 0.10% Total Imp. Not more than 0.70%	0.05% 0.08% ND 0.07% ND 0.20%
9	Assay (OAB)	99.0 % to 101.0%	99.57%

REMARK: As opinion of under signed product is Complies/ does not Comply as per prescribe Standard EP/BP.

	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
Name	Nitin Solanki	Krishna Patel	Bhavesh Chauhan
Sign & Date	 10/01/25	 10/01/25	 10/01/25

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