

**TYPICAL CERTIFICATE OF ANALYSIS**

Product : Hyoscine Butyl Bromide BP/EP	Page 1 of 1
Reference : British Pharmacopoeia-2024/European Pharmacopoeia	
Manufactured By : Prism Industries Pvt Ltd.	Product code : HBBR
Self Life (Retest Date) : 5 years	

Sr.No	Test	Specification	Result
1	Description	White or almost white crystalline powder.	A white crystalline powder
2	Solubility	Freely soluble in water & in methylene chloride, sparingly soluble in anhydrous ethanol.	Complies
3	First identification A, C, F And Second identification A, B,D, E, F	(A) It complies with Specific optical rotation (B) Melting Point : 139 ⁰ C to 141 ⁰ C (C) BY IR (D) A violet colour develops (E) No precipitate is formed (F) Gives reaction (a) of bromides	Complies 140.2 ⁰ C Complies Complies Complies Complies
4	Appearance of solution	Clear & colourless	Complies
5	Acidity or Alkalinity	Not more than 0.5 ml	0.2ml
6	Specific optical rotation	Between -18 ⁰ to -20 ⁰	-19.38 ⁰
7	Related substances by HPLC	Imp. A Not more than 0.15% Un. Max. Imp. Not more than 0.10% Total Imp. Not more than 0.40%	0.02% 0.05% 0.07%
8	Sulphated Ash	Not more than 0.10%	0.07%
9	Loss on Drying	Not more than 2.5%	1.21%
10	Assay by potentiometer (ODB)	98.0% to 101.0%	99.89%
11	Residual solvent (Additional Test) Methanol Acetonitrile Dichloromethane N-Butyl bromide	Not more than 3000 ppm Not more than 410 ppm Not more than 600 ppm Not more than 500 ppm	1068 ppm 51 ppm 74 ppm 97 ppm
12	Microbial test a) Total Aerobic Microbial Count b) Total Yeast & mould Count c) E. Coil d) Salmonella e) S. Aureus f) Pseudomonas	NMT 1000cfu/gm NMT 100cfu/gm Should be Absent per gm Should be Absent per 10 gm Should be Absent per gm Should be Absent per gm NMT 100cfu/gm	Less than 02 cfu/gm Less than 02 cfu/gm Absent Absent Absent Absent Absent

REMARK : As opinion of under signed product is Complies / ~~Does not Comply~~ as per prescribe Specification BP-2024/EP.

	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
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Sign & Date	 10/10/25	 10/10/25	 10/10/25

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