



PRISM INDUSTRIES PVT. LTD.

A WHO-GMP Certified Company
(Formerly known as Prism Industries Ltd.)

TYPICAL CERTIFICATE OF ANALYSIS

| | | |
|------------------------|-----------------------------|--|
| Product | : Hyoscine Butyl Bromide IP | Page 1 of 1 |
| Reference | : Indian Pharmacopeia-2022 | |
| Manufactured By | : Prism Industries Pvt Ltd. | Product code : HBBR |
| Batch Size | : 50 Kg | 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 chloroform, sparingly soluble in anhydrous ethanol. | Complies |
| 3 | Identification A & B | (A) By IR (B) Gives reaction (a) of bromides | Complies Complies |
| 4 | Appearance of solution | Clear & colourless | Complies |
| 5 | pH (5% Solution in water) | Between 5.5 to 6.5 | 6.34 |
| 6 | Specific optical rotation | Between -18.00° to -20.00° | -19.11° |
| 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% | 0.03% 0.06% 0.10% |
| 8 | Sulphated Ash | Not more than 0.10% | 0.07% |
| 9 | Loss on Drying | Not more than 2.5% | 1.10% |
| 10 | Assay by potentiometer (ODB) | 98.00% to 101.00% | 99.88% |
| 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 | 573.72 ppm Not detected Not detected 51.66 ppm |

REMARK: As opinion of under signed product is Complies / Does not Comply as per prescribe Standard IP-2022.

| | Prepared By (QC Chemist) | Checked By (QC Sr. Chemist) | Approved By (QC In charge) |
|------------------------|-------------------------------------|--|---------------------------------------|
| Name | Sohil Darji | Dixit Prajapati | Amit Tamboli |
| Sign & Date | 16/06/23 | 16/06/23 | 16/06/23 |

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