



PRISM INDUSTRIES LIMITED

An ISO 9000:2008, ISO 22000:2005 Compliant and GMP Approved Company

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TYPICAL CERTIFICATE OF ANALYSIS

Product	: Methscopolamine Bromide USP (Hyoscine Methyl Bromide)	Page 1 of 1
Reference	: United States Pharmacopeia-40.	
Manufactured By	: Prism Industries Ltd.	Product code : MSB
Batch Size	: 25.0 Kg	Self Life (Retest Date) : 5 years

Sr.No	TEST	SPECIFICATION	RESULT
1	Description	White to off white crystalline powder.	Complies
2	Solubility	Freely soluble in water, slightly soluble in alcohol and insoluble in acetone and chloroform.	Complies
3	Identification Test	(A) By IR (B) Gives reaction (a) of bromides	Complies Complies
4	Specific optical rotation	Between -21° to -25°	-23.40°
5	Chromatographic purity by HPLC	Tropic Acid :NMT 0.1% Scopolamine Hydro bromide :NMT 0.1% Methyl atropine bromide :NMT 0.1% Apomethscopolamine bromide :NMT 0.1 % Un. Impurity :NMT 0.1 % Total Impurity :NMT 0.5 %	Not detected 0.04 % 0.03 % Not detected 0.04 % 0.19 %
6	Residue on Ignition	Not more than 0.1 %	0.07 %
7	Loss on Drying	Not more than 2.0 %	0.24 %
8	Assay by (HPLC)	97.0% to 103 %	99.85 %
9*	*Residual solvent (Additional Test) Methanol Acetonitrile Chloroform	Not more than 3000 ppm Not more than 410 ppm Not more than 60 ppm	251 ppm 30 ppm Not detected

REMARK: As opinion of under signed product is Complies/ does not Comply as per prescribe Standard USP-40.

	Tested By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
Name	Milun Mistry	Poojesh Paritosh	Suthar Ramesh
Sign & Date	 30/07/19	 30/07/19	 30/07/19