



RAKSHIT DRUGS PRIVATE LIMITED.,

425/3RT, Door No. 7-1-621/328, Sanjeeva Reddy Nagar, Hyderabad-500038, Telangana, INDIA.

Phones: 91-40-23810385, 23705066, 23818158, Fax: 91-40-23812709, 23801673

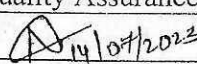
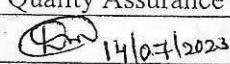
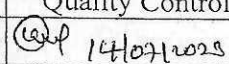
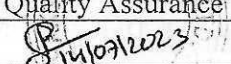
E-mail: sales@rakshidrugspvtltd.com/ purchase@rakshidrugspvtltd.com,

CIN No.: U24230TG2000PTC034018

CERTIFICATE OF ANALYSIS

Product Name	PIHENTOLAMINE MESYLATE USP		
Reference	USP/IN-HOUSE	Mfg. Date	26/06/2023
Batch No.	DB/PTM/2307001	Retest / Expiry Date	25/06/2026
Date of Analysis	28/06/2023	Dispatch / Sample Qty.	1.00Kg
Name of the Customer	---	Specification Ref. No.	STP/S/FP/6027/001-00

S. No.	Test	Specification	Result
1.	Description	White to off white crystalline powder	Off white crystalline powder
2.	Solubility	Freely soluble in Water and in Ethanol, Practically insoluble in Methylene chloride.	Complies
3.	Identification by		Complies
	a) By IR Spectroscopy	The IR spectrum of sample should exhibit maxima only at the same wavelengths as that of a similar preparation of the corresponding USP reference standard	
	b) By HPLC	The retention time of the major peak of test sample solution chromatogram should correspond to that of the standard chromatogram, as obtained in the Assay by HPLC.	
	c) By UV Spectroscopy	The absorbance maxima of the UV absorption spectrum of sample should be matches with standard	
4.	Loss on Drying (% w/w, at 60°C under vacuum for 4hrs)	Not more than 0.50	0.34
5.	Residue on ignition (%w/w)	Not more than 0.10	0.06
6.	Sulfates (%)	Not more than 0.20	Complies

	Prepared By	Reviewed By		Approved By
Department	Quality Assurance	Quality Assurance	Quality Control	Quality Assurance
Sign & Date	 14/07/2023	 14/07/2023	 14/07/2023	 14/07/2023

Page 1 of 2

RAKSHIT STANDS FOR ASSURED QUALITY

WORKS: UNIT-III: Sy. No: 156, 157, 158, 187, 189, 190 and 261 (Plot No.4), JNPC, Parawada, Thadi, Anakapalli Dist., AP-531021, India.
Format No.: QAD/028-F10-05-12/04/2023



RAKSHIT DRUGS PRIVATE LIMITED.,

425/3RT, Door No. 7-1-621/328, Sanjeeva Reddy Nagar, Hyderabad-500038, Telangana, INDIA.
Phones: 91-40-23810385, 23705066, 23818158, Fax: 91-40-23812709, 23801673
E-mail: sales@rakshitdrugsprivltd.com/ purchase@rakshitdrugsprivltd.com,
CIN No.: U24230TG2000PTC034018

CERTIFICATE OF ANALYSIS

Product Name	PHENTOLAMINE MESYLATE USP		
Reference	USP/IN-HOUSE	Mfg. Date	26/06/2023
Batch No.	DB/PTM/2307001	Retest / Expiry Date	25/06/2026
Date of Analysis	28/06/2023	Dispatch / Sample Qty.	1.00Kg
Name of the Customer	---	Specification Ref. No.	STP/S/FP/6027/001-00

S. No.	Test	Specification	Result
7.	Related substance by HPLC (%w/w)		
	Phentolamine Keto analog	Not more than 0.15	0.03
	Related compound-A	Not more than 0.15	0.07
	Any unspecified impurity	Not more than 0.10	0.06
	Total Impurities	Not more than 1.0	0.16
8.	Assay by HPLC (%w/w, On dried basis)	Not less than 98.0 and Not more than 102.0	99.6
9.	Residual solvents by GC-MS (ppm)		
	a) Acetone	Not more than 5000	Not Detected
	b) Iso propyl alcohol	Not more than 5000	823 ppm
	c) Dichloromethane	Not more than 600	Not Detected
	d) Methyl tert-butyl ether	Not more than 5000	Not Detected
	e) Ethyl acetate	Not more than 5000	Not Detected
	f) Cyclohexane	Not more than 3880	Not Detected
	g) Toluene	Not more than 890	Not Detected
	h) Methanol	Not more than 3000	5 ppm
	i) Ethanol	Not more than 5000	Not Detected

Note / Remarks: The material complies as per above specification.



	Prepared By	Reviewed By		Approved By
Department	Quality Assurance	Quality Assurance	Quality Control	Quality Assurance
Sign & Date	<i>[Signature]</i> 14/07/2023	<i>[Signature]</i> 14/07/2023	<i>[Signature]</i> 14/07/2023	<i>[Signature]</i> 14/07/2023

