



Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP10.0**
 Batch No. : HPHCPO010
 Date of manufacture : MAY 2020 Quantity : 210kgs (25kgsX 7,15kgs x1&10kgs x2)
 Date of Expiry : APRIL 2025 Nature of Packing: HDPE DRUMS

C E R T I F I C A T E O F A N A L Y S I S

S.No	TEST	RESULTS	SPECIFICATION
1.	Characters Appearance	White Crystalline Powder	White or faintly yellowish Crystalline powder.
	Solubility	Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride.	Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride.
	Melting point	It melts at about 222.3 ⁰ C with decomposition	It melts at about 222 ⁰ C with decomposition
2.	Identification		
	Test A. IR absorption spectrum	Complies	The infra-red absorption spectrum is concordant with the reference spectrum of Promethazine Hydrochloride.
	Test B. By TLC	Complies	Shall comply Identification test for phenothiazines by thin-layer chromatography.
	Test C. Test with Nitric acid	Complies	The solution becomes orange and an orange-red precipitate is formed.
	Test D. Test for chlorides	Complies	Shall comply the test
3.	pH		
	10% w/v solution	4.29	4.0 to 5.0

HARIKA DRUGS PRIVATE LIMITED

Office : 5-5-35/145/NR, Plot No. 110, Prasanth Nagar, Kukatpally, Hyderabad - 500 072. Telangana, INDIA.

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Factory : Sy. No 165 A & 165/E, Gummadidala Village, Sangareddy District, Telangana State. Tel : +91-08458-275369, ✉ : harikasite@yahoo.com



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S.No	TEST	RESULTS	SPECIFICATION
4.	Related substances by HPLC: Impurity A Impurity B Impurity C Impurity D Unspecified Impurities Total Impurities	Not detected 0.21% 0.10% Not detected 0.03% 0.34%	Not more than 0.1% Not more than 0.8% Not more than 0.2% Not more than 0.1% Not more than 0.10% Not more than 1.2%
5.	Loss on drying at 105°C	0.20%	Not more than 0.5%
6.	Sulphated Ash	0.03%	Not more than 0.1%
7.	Assay (on dried substance)	99.9%	99.0% to 101.0%
8.	Residual solvents Class 1 Solvents Class 2 Solvents o-Xylene Class 3 Solvents Isopropyl alcohol	Nil 1719 ppm 409 ppm	Not used in our manufacturing process ICH Limits: 2170 ppm ICH Limits: 5000 ppm
9.	Microbial Limits Total Bacterial Count Total Fungal Count Pathogens: E.Coli Salmonella Pseudomonas Staphylococcus	55 cfu/gm Less than 10cfu/gm Absent/gm Absent/gm Absent/gm Absent/gm	NMT 1000 cfu/gm NMT 100 cfu/gm Should be absent Should be absent Should be absent Should be absent
RESULT : The sample complies with prescribed standards as per EP10.0			


Analyst
 Date: 12-05-2021


QC In Charge
 Date: 12-05-2021

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