



Name of the Product : **PROMETHAZINE HYDROCHLORIDE Ph.Eur10.0**

Batch No. : HPHCPQ078

Date of manufacture : DECEMBER 2022 Quantity : 300kgs (25kgsX 12)

Date of Expiry : NOVEMBER 2027 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	White Crystalline Powder Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride. It melts at about 222.2 ⁰ C with decomposition	White or faintly yellowish Crystalline powder. Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride. 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	It complies with the identification test for phenothiazines.
	Test C. Test for Nitric acid	Complies	The solution becomes orange and an orange-red precipitate is formed.
	Test D. Test for chlorides [Reaction (b)]	Complies	Shall comply the test.
3.	pH 10% w/v solution	4.33	4.0 to 5.0

HARIKA DRUGS PRIVATE LIMITED

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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 0.25% 0.09% Not detected 0.02% 0.36%	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	0.18%	Not more than 0.5%
6.	Sulphated Ash	0.03%	Not more than 0.1%
7.	Assay (on dried substance)	100.1%	99.0% to 101%
8.	Residual solvents Class 1 Solvents Class 2 Solvents o-Xylene Class 3 Solvents Isopropyl alcohol	Nil 826 ppm 971 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	Less than 10 cfu/gm Less than 10cfu/gm Absent Absent Absent Absent	Not more than 1000 cfu/ gm Not more than 100 cfu/gm Shall be absent Shall be absent Shall be absent Shall be absent

RESULT : The sample complies with prescribed standards as per Ph.Eur10.0

Analyst

Date: 23-12-2022

QC In Charge

Date: 23-12-2022

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