

## METAPHARMACEUTICAL

N DE LOTE:

0201022



31/10/2022

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

Batch No. : **HPHCPP022**

Date of manufacture : **MAY 2021** Quantity : **100kgs (25kgsX 2 & 10kgs x5)**

Date of Expiry : **APRIL 2026** 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 222.3°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 °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	4.27	4.0 to 5.0

**HARIKA DRUGS PRIVATE LIMITED**

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Factory : Sy. No 165 A &amp; 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 0.17% 0.09% Not detected 0.04% 0.30%	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)	99.9%	99.0% to 101%
8.	Residual solvents Class 1 Solvents Class 2 Solvents o-Xylene Class 3 Solvents Isopropyl alcohol	Nil  1582 ppm  1076 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: 25-08-2021

  
QC In Charge

Date: 25-08-2021

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