



Name of the Product : **PROMETHAZINE HYDROCHLORIDE Ph.Eur8.0**  
 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	White Crystalline Powder  Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride.  It melts at about 222.3 <sup>0</sup> 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 <sup>0</sup> 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	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




Batch NO : HPHCPO010

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.	Heavy Metals	Less than 10 ppm	Not more than 10 ppm
6.	Loss on drying at 105°C	0.20%	Not more than 0.5%
7.	Sulphated Ash	0.03%	Not more than 0.1%
8.	Assay (on dried substance)	99.9%	99.0% to 101%
9.	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
10.	Microbial Limits  Total Bacterial count Total Fungal count Pathogens: E.Coli Salmonella Pseudomonas Staphylococcus	  55 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.Eur8.0			

  
Analyst

Date: 17-06-2020

  
QC In Charge  
Date: 17-06-2020

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