

**METAPHARMACEUTICAL**

CIN No. : U24230TG1989PTC010584

N DE LOTE:

0300625

25/06/2025

Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP**

Batch No. : HPHCPT014

Date of manufacture : APRIL 2025


Date of Expiry : MARCH 2030

Quantity : 30 kgs (15kgs x2)

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 (a)]	Complies	Shall comply the test.
3.	pH (10% w/v solution)	4.36	4.0 to 5.0
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 0.04% 0.35%	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	0.22%	Not more than 0.5%
6.	Sulphated Ash	0.04%	Not more than 0.1%
7.	Assay (on dried substance)	100.0%	99.0% to 101%
8.	Residual solvents o-Xylene Isopropyl alcohol	390 ppm 1298 ppm	ICH Limits: 2170 ppm ICH Limits: 5000 ppm
RESULT : The sample complies with prescribed standards as per IP			

Analyst   
Date: 06-06-2025QC In charge   
Date: 06-06-2025**HARIKA DRUGS PRIVATE LIMITED**

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

☎ : +91-40-2381 4863, +91-40-23700915, Fax : +91-40-23700731, ✉ : harikadrugs@yahoo.co.in, info@harikadrugs.com

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