



Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP8.0**
Batch No. : **HPHCPI011**
Date of manufacture : **APRIL 2014** Quantity : **350.0kgs(25kgsX 12 & 10kgs x 5)**
Date of Expiry : **MARCH 2019** 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 222.6°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	Complies	Shall comply the test.
3.	pH 10% w/v solution	4.36	4.0 to 5.0

HARIKA DRUGS PRIVATE LIMITED

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Factory : Gummadidala, Medak District, Andhra Pradesh, INDIA. Tel : +91-08458-275369, ✉ : harikasite@yahoo.com



Batch NO : HPHCP1011

S.No	TEST	RESULTS	SPECIFICATION
4.	Related substances by HPLC: Impurity A Impurity B Impurity C Impurity D Unspecified Impurities Total Impurities	Below disregard limit 0.13% 0.12% Below disregard limit 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.	Heavy Metals	Less than 10 ppm	Not more than 10 ppm
6.	Loss on drying at 105°C	0.17%	Not more than 0.5%
7.	Sulphated Ash	0.05%	Not more than 0.1%
8.	Assay (on dried substance)	100.0%	99.0% to 101%
9.	Residual solvents Class 1 Solvents Class 2 Solvents o-Xylene Class 3 Solvents Isopropyl alcohol	Nil 1075 ppm 324 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	40cfu/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 EP8.0			

Analyst

Date: 11-06-2014

QC In Charge

Date: 11-06-2014

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