



lote: 0J50314

Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP7.0**
Batch No. : **HPHCPH033**
Date of manufacture : **SEPTEMBER 2013** Quantity : **350.0kgs(25kgsX 14)**
Date of Expiry : **AUGUST 2018** 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 222.5°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	4.32	4.0 to 5.0

HARIKA DRUGS PRIVATE LIMITED

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Factory : Gummadidala, Medak District, Andhra Pradesh, India. Tel : 08458-275339



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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	Below disregard limit 0.20% 0.06% Below disregard limit 0.02% 0.27%	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	0.15%	Not more than 0.5%
7.	Sulphated Ash	0.05%	Not more than 0.1%
8.	Assay (on dried substance)	99.8%	99.0% to 101%
9.	Residual solvents Class 1 Solvents Class 2 Solvents o-Xylene Class 3 Solvents Isopropyl alcohol	Nil 1191 ppm 255 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	30cfu/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 EP7.0			

Analyst *[Signature]*
Date: 30-09-2013

QC In Charge *[Signature]*
Date: 30-09-2013

INVOICE NO : 148

DT : 30-09-2013

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