

HARIKA DRUGS PRIVATE LIMITED

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Lot: C030212

ID 196562

021/12

Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP7.0**
Batch No. : **HPHCPE034**
Date of manufacture : **NOVEMBER 2010** Quantity : 100.0kgs (25kgs X4)
Date of Expiry : **OCTOBER 2015** 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

No	TEST	RESULTS	SPECIFICATION
	Characters	White Crystalline Powder Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride. It melts at about 222.4 °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
	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.
	pH 10% w/v solution	4.32	4.0 to 5.0

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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 0.11% 0.04% Below disregard limit 0.04% 0.19%	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	0.12%	Not more than 0.5%
7.	Sulphated Ash	0.02%	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 1246 ppm 539 ppm	Not used in our manufacturing process ICH Limits: 2170 ppm ICH Limits: 5000 ppm
RESULT : The sample complies with prescribed standards as per EP 7.0			


Analyst

Date: 24-12-2010


QC In Charge
Date: 24-12-2010

INVOICE No. : 147

DT : 24-12-2010