



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

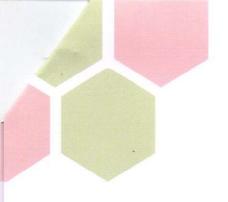
APRIL 2025 Nature of Packing: HDPE DRUMS

CERTIFICATE OF ANALYSIS

S.No	TEST	RESULTS	SPECIFICATION
1.	Characters	White Crystalline Powder	White or faintly yellowish Crystalline powder.
		Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride.	Very soluble in water, freely soluble in ethanol (96%) and in methylene chloride.
		It melts at about 222.3°C with decomposition	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.	рН		
	10% w/v solution	4.29	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	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 proces ICH Limits: 2170 ppm ICH Limits: 5000 ppm
10.	Microbial Limits		
	Total Bacterial count	55 cfu/gm	Not more than 1000 cfu/ gm
	Total Fungal count Pathogens:	Less than 10cfu/gm	Not more than 100 cfu/gm
	E.Coli	Absent	Shall be absent
	Salmonella	Absent	Shall be absent
	Pseudomonas	Absent	Shall be absent
	Staphylococcus	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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HARIKA DRUGS PRIVATE LIMITED