



Name of the Product

PROMETHAZINE HYDROCHLORIDE Ph.Eur10.0

Batch No.

HPHCPP022

Date of manufacture

MAY 2021

Quantity

: 100kgs (25kgsX 2 & 10kgs x5)

Date of Expiry

APRIL 2026

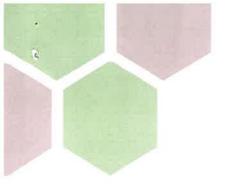
Nature of Packing: HDPE DRUMS

<u>CERTIFICATE OF ANALYSIS</u>

TEST	RESULTS	SPECIFICATION
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
Identification		
	Complies	The infra-red absorption spectrum is
spectrum	Complics	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 (b)]	Complies	Shall comply the test.
pH		
10% w/v solution	4.27	4.0 to 5.0
	Identification Test A. IR absorption spectrum Test B. By TLC Test C. Test for Nitric acid Test D. Test for chlorides [Reaction (b)] pH	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 Test A. IR absorption spectrum Complies Test B. By TLC Complies Test C. Test for Nitric acid Complies Test D. Test for chlorides [Reaction (b)] PH

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S.No	TEST	RESULTS	SPECIFICATION
4.	Related substances by HPLC:		
	Impurity A	Not detected	Not more than 0.1%
	Impurity B	0.17%	Not more than 0.8%
	Impurity C	0.09%	Not more than 0.2%
	Impurity D	Not detected	Not more than 0.1%
	Unspecified Impurities	0.04%	Not more than 0.10%
	Total Impurities	0.30%	Not more than 1.2%
5.	Loss on drying at 105°C	0.18%	Not more than 0.5%
6.	Sulphated Ash	0.03%	Not more than 0.1%
7.	Assay (on dried substance)	99.9%	99.0% to 101%
8.	Residual solvents		
	Class 1 Solvents	Nil	Not used in our manufacturing process
	Class 2 Solvents	1-0-	701111 11 0170
	o-Xylene	1582 ppm	ICH Limits: 2170 ppm
	Class 3 Solvents	1076 nnm	ICH Limits: F000 ppm
	Isopropyl alcohol	1076 ppm	ICH Limits: 5000 ppm
9.	Microbial Limits		
	Total Bacterial count	Less than 10 cfu/gm	Not more than 1000 cfu/ gm
	Total Fungal count	Less than 10cfu/gm	Not more than 100 cfu/gm
	Pathogens:		
	E.Coli	Absent	Shall be absent
	Salmonella	Absent	Shall be absent
	Pseudomonas	Absent	Shall be absent
	Staphylococcus	Absent	Shall be absent

Analyst

Date: 25-08-2021

QC In Charge

Date: 25-08-2021

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