

CIN No.: U24230TG1989PTC010584



## **METAPHARMACEUTICAL**

N DE LOTE: 0230721

Name of the Product

Batch No.

PROMETHAZINE HYDROCHLORIDE EP10.0

HPHCPO010

Date of manufacture

Quantity

: 210kgs /25kgsX 7,15kgs x1&10kgs x2)

Date of Expiry

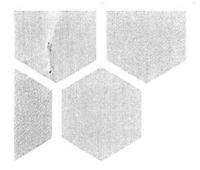
MAY 2020 APRIL 2025

Nature of Packing: HDPE DRUMS

## T E OF A N A L Y S I S CERTIFICA

S.No	TEST	RESULTS	SPECIFICATION
1.	Characters		
	Appearance	White Crystalline Powder	White or faintly yellowish Crystalline powder.
	Solubility	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.
	Melting point	It melts at about 222.3°C with decomposition	It melts at about 222 °C with decomposition
2.	Identification		
	Test A. IR absorption	Complies	The infra-red absorption spectrum is
	spectrum	*	concordant with the reference spectrum of Promethazine Hydrochloride.
	Test B. By TLC	Complies	Shall comply Identification test for phenothiazines by thin-layer chromatography.
	Test C. Test with 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	4.29	4.0 to 5.0

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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	0.21%	Not more than 0.8%
	Impurity C	0.10%	Not more than 0.2%
	Impurity D	Not detected	Not more than 0.1%
	Unspecified Impurities	0.03%	Not more than 0.10%
	Total Impurities	0.34%	Not more than 1.2%
5.	Loss on drying at 105°C	0.20%	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 101.0%
8.	Residual solvents		
	Class 1 Solvents	Nil	Not used in our manufacturing process
	Class 2 Solvents		
	o-Xylene	1719 ppm	ICH Limits: 2170 ppm
	Class 3 Solvents		27 11
	Isopropyl alcohol	409 ppm	ICH Limits: 5000 ppm
9.	Microbial Limits		
	Total Bacterial Count	55 cfu/gm	NMT 1000 cfu/gm
	Total Fungal Count	Less than 10cfu/gm	NMT 100 cfu/gm
	Pathogens:		
	E.Coli	Absent/gm	Should be absent
	Salmonella	Absent/gm	Should be absent
	Pseudomonas	Absent/gm	Should be absent
	Staphylococcus	Absent/gm	Should be absent

Analyst Date: 12-05-2021

QC In Charge Date: 12-05-2021

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