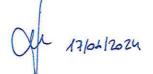
METAPHARMACEUTICAL

N DE LOTE:





CIN No.: U24230TG1989PTC010584

Name of the Product : PROMETHAZINE HYDROCHLORIDE Ph.Eur11.0

Batch No.

: HPHCPR104

Date of manufacture: MARCH 2024

Quantity

: 80kgs (25kgsX 3& 5kgs x1)

Date of Expiry

: FEBRUARY 2029

Nature of Packing: HDPE DRUMS

CERTIFICATE OF A N

S.No	TEST	RESULTS	SPECIFICATION
1.	Characters	White Crystalline Powder	White or faintly yellowish Crystalline powder.
£1	٠	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 30C 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 a orange-red precipitate is formed.
	Test D. Test for chlorides [Reaction (a)]	Complies	Shall comply the test.
3.	рН		
É	10% w/v solution	4.30	4.0 to 5.0

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HARIKA DRUGS PRIVATE LIMITED



Batch N0: HPHCPR104

S.No	TEST	RESULTS	SPECIFICATION
4.	Related substances by HPLC:		
	Impurity A	Not detected	Not more than 0.1%
i	Impurity B	0.29%	Not more than 0.8%
	Impurity C	0.08%	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	0.41%	Not more than 1.2%
5.	Loss on drying at 105°C	0.20%	Not more than 0.5%
6.	Sulphated Ash	0.04%	Not more than 0.1%
7.	Assay (on dried substance)	99.9%	99.0% to 101%
8.	Residual solvents		
	Class 1 Solvents Class 2 Solvents	Nil	Not used in our manufacturing proces
	o-Xylene	 1178 ppm	ICH Live II - 2470
	Class 3 Solvents	1170 ppm	ICH Limits: 2170 ppm
	Isopropyl alcohol	1491 ppm	ICH Limits: 5000 ppm
9.	Microbial Limits		тем сострый
	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:		200 cra/gm
	E.Coli	Absent	Shall be absent
	Salmonella	Absent	Shall be absent
	Pseudomonas	Absent	Shall be absent
	Staphylococcus	Absent	
		Ausent	Shall be absent

Analyst

Date: 14-03-2024

QC In Charge Date: 14-03-2024

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