

METAPHARMACEUTICAL

CIN No. : U24230TG1989PTC010584

N DE LOTE:


0070525

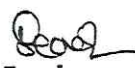
Algarbio
07/05/2025

Name of the Product : **PROMETHAZINE HYDROCHLORIDE EP**
Batch No. : HPHCPS105
Date of manufacture : MARCH 2025 Quantity : 45kgs (15kgs x3)
Date of Expiry : FEBRUARY 2030 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

S.No	TEST	RESULTS	SPECIFICATION
1.	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
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 [Reaction (a)]	Complies	Shall comply the test.
3.	pH (10% w/v solution)	4.34	4.0 to 5.0
4.	Related substances by HPLC: Impurity A Impurity B Impurity C Impurity D Unspecified Impurities Total Impurities	Not detected 0.23% 0.09% Not detected 0.05% 0.37%	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.	Loss on drying at 105°C	0.21%	Not more than 0.5%
6.	Sulphated Ash	0.02%	Not more than 0.1%
7.	Assay (on dried substance)	99.9%	99.0% to 101%
8.	Residual solvents o-Xylene Isopropyl alcohol	1206 ppm 818 ppm	ICH Limits: 2170 ppm ICH Limits: 5000 ppm
RESULT : The sample complies with prescribed standards as per EP			

Analyst 
Date: 11-04-2025

QC In charge 
Date: 11-04-2025

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