

PROMETHAZINI HYDROCHLORIDUM 25 g

Lot No.: 24C12-AP24079

Autorisation :	1890IR05496	Date Of Analysis :	12/03/2024
Analytical Reference :	Ph.Eur (04/2021:0524)	Production Number :	260324-0020324
CNK :	3679-156	Expiry Date :	04/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white slightly hygroscopic crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with promethazine hydrochloride CRS	Complies
Identification D	Reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
pH	4.0 – 5.0	4.0
Related substances		
Impurity B	≤ 0.8%	Not detected
Impurity C	≤ 0.2%	0.12%
Impurity A	≤ 0.1%	< 0.05%
Impurity D	≤ 0.1%	< 0.05%
Unspecified Impurities	≤ 0.10%	< 0.10%
Total	≤ 1.2%	0.24
Loss on drying	≤ 0.5%	0.03%
Sulfated ash	≤ 0.1%	< 0.01%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	100.8%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: