

CHLORPHENAMINI MALEAS 25 g

Lot No.: 23D12-APR23212

Autorisation :	1890R05408	Date Of Analysis :	17/03/2023
Analytical Reference :	Ph. Eur. 11.0 [01/2017 :0386]	Production Number :	050723-GS23024
CNK :	3489-994	Expiry Date :	11/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	130 °C to 135 °C	134.3 °C
Identification B	Spectrum complies with the spectrum obtained with chlorphenamine maleate CRS	Complies
Identification C	- 0.10° to + 0.10°	+ 0.02°
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution BY ₆	Complies
Optical rotation	- 0.10° to + 0.10°	+ 0.02°
Related substances		
Impurity A	≤ 0.2%	< 0.05%
Impurity B	≤ 0.1%	< 0.05%
Impurity C	≤ 0.1%	< 0.05%
Impurity D	≤ 0.1%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Loss on drying	≤ 0.5%	0.2%
Sulfated ash	≤ 0.1%	0.08%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.0 % to 101.0 % (dried substance)	99.5%
Manufacturer identification code: S/GS/032		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: