

PHENYLEPHRINI HYDROCHLORIDUM 25 g

Lot No.: 22G04-APR22195

Authorisation:	1890R05433	Date Of Analysis:	13/06/2022
Analytical Reference:	Ph. Eur. 10.6 [01/2008:0632] Corr. 10.3	Production Number:	070722-GS22065
CNK:	3490-711	Expiry Date:	11/2025

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	– 43 to – 47 (dried substance)	Complies
Identification C	The spectrum complies with the spectrum obtained with <i>phenylephrine hydrochloride CRS</i>	Complies
Identification E	Reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	≤ 0.4 mL of 0.01 M hydrochloric acid	Complies
Specific optical rotation	– 43 to – 47 (dried substance)	- 46
Related substances		
Impurity C	≤ 0.1%	< 0.05%
Impurity E	≤ 0.1%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.2%	< 0.05%
Sulfates	≤ 500 ppm	Complies
Loss on drying	≤ 1.0%	0.2%
Sulfated ash	≤ 0.1%	0.06%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.5% to 101.0% (dried substance)	100.2%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: