

PHENYLEPHRINI HYDROCHLORIDUM 5 g

Lot No.: 24H14-F240098

Authorisation:	1890R05433	Date Of Analysis:	05/09/2024
Analytical Reference:	Ph.Eur. [01/2008 :0632]	Production Number:	290824-G240033
CNK:	3490-729	Expiry Date:	02/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	– 43 to – 47 (dried substance)	– 46
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)	Complies
Related substances		
Impurity C	≤ 0.1%	< 0.05%
Impurity E	≤ 0.1%	< 0.05%
Unspecified impurities	≤ 0.10%	0.07%
Total	≤ 0.2%	0.07%
Sulfates	≤ 500 ppm	Complies
Loss on drying	≤ 1.0%	0.08%
Sulfated ash	≤ 0.1%	0.09%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.5% to 101.0% (dried substance)	99.5%
Manufacturer identification code: S/GS/026		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: