

**PENICILLAMINUM 30 g**

Lot No.: 24D26-APR24089

Autorisation :	1890R06239	Date Of Analysis :	12/01/2024
Analytical Reference :	Ph. Eur. 11.2 [07/2021 :0566]	Production Number :	290424-GS23127
CNK :	4797-957	Expiry Date :	07/2026

**ANALYTICAL TESTS**

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder.	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	A 10 g/L solution of the precipitate is dextrorotatory.	Complies
Identification B	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).	Complies
Identification D	A blue colour develops.	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour.	Complies
pH	4.5 to 5.5	4.9
Specific optical rotation	- 65.0 to - 61.0 (dried substance)	-62.6
Ultraviolet-absorbing substances	≤ 0.5% of of penilloic acid	Complies
Impurity A	≤ 1%	0.6%
Impurity B	≤ 0.1 ppm	< 0.1 ppm
Loss on drying	≤ 0.5%	0.1%
Sulfated ash	≤ 0.1%	0.02%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.0% to 101.0% (dried substance)	98.9%
Manufacturer identification code: S/GS/190		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: