

PREDNISONUM 5 g
Lot No.: 24A17-APR24026

Autorisation :	1890R05603	Date Of Analysis :	11/12/2023
Analytical Reference :	Ph. Eur. 11.2 [07/2023:0354]	Production Number :	060224-GS23122
CNK :	3679-131	Expiry Date :	08/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with prednisone CRS	Complies
Identification C	Chromatogram complies	Complies
TESTS	SPECIFICATION	RESULT
Specific optical rotation	+ 183 to + 191 (dried substance)	+ 187
Related substances		
Impurity A	≤ 0.5%	0.1%
Impurity E	≤ 0.2%	0.1%
Impurity D	≤ 0.15%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 1.0%	0.2%
Loss on drying	≤ 1.0%	0.2%
ASSAY	SPECIFICATION	RESULT
LC-UV	97.0% to 102.0% (dried substance)	100.0%

Manufacturer identification code: S/GS/031

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: