

PREDNISONUM 5 g
Lot No.: 22F08-APR22169

Authorisation:	1890R05603	Date Of Analysis:	23/03/2022
Analytical Reference:	Ph. Eur. 10.6 [01/2018:0354]	Production Number:	090622-GS22048
CNK:	3679-131	Expiry Date:	09/2026

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)	+ 190
Related substances		
Impurity A	≤ 0.5%	0.1%
Impurity E	≤ 0.2%	< 0.05%
Impurity D	≤ 0.15%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 1.0%	0.1%
Loss on drying	≤ 1.0%	0.4%
ASSAY	SPECIFICATION	RESULT
LC-UV	97.0% to 102.0% (dried substance)	99.9%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: Maxime Brits
(Signature)
2022.07.04
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