

PREDNISOLONI NATRII PHOSPHAS 1 g

Lot No.: 24G08-APR24126

Autorisation :	1890R06004	Date Of Analysis :	02/05/2024
Analytical Reference :	Ph. Eur. 10.6 [01/2008:0735]	Production Number :	080724-GS24033
CNK :	4315-230	Expiry Date :	09/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, hygroscopic, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the reference spectrum obtained with <i>prednisolone sodium phosphate CRS</i>	Complies
Identification C	The principal spot in the chromatogram obtained with test solution is similar in position, colour in daylight, fluorescence in ultraviolet light at 365 nm and size to the principal spot in the chromatogram obtained with reference solution (a)	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution B ₇	Complies
pH	7.5 to 9.0	7.9
Specific optical rotation	+ 94 to + 100	+96
Related substances		
Any impurity	≤ 2 %	(1) 0.53% (2) 0.22% (3) 0.18% (4) 0.23% (5) 0.07%
Only one peak	> 1 %	Complies
Total	≤ 3 %	1.22%
Inorganic phosphate	≤ 1 %	Complies
Water	≤ 8.0 %	5.0%
ASSAY	SPECIFICATION	RESULT
UV-Vis	96.0 % to 103.0 % (anhydrous substance)	98.1%

Manufacturer identification code: S/GS/004

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: