CERTIFICATE of ANALYSIS

PREDNISOLONE SODIUM PHOSPHATE Ph. Eur. 11.5

BATCH N.: C3841/0 24040 **MAN. DATE:** Sep/24 **RE-TEST DATE:** Sep/26

DESCRIPTION: White or almost white powder, hygroscopic. Freely soluble in water, soluble in methanol, slightly soluble in alcohol and in chloroform, very slightly soluble in acetone and in dioxane.

STORAGE CONDITIONS: Preserve in tight containers, protected from light. Store in a refrigerator (5°C ± 3°C). Silica gel included.

COUNTRY OF ORIGIN: SPAIN

TEST	SPECIFICATIONS	RESULTS
1. Description	White or almost white powder, hygroscopic.	Complies
2. Identification		
IR	Concordant with reference standard	Concordant
TLC	Rf according to reference standard	Concordant
Test A	0.10 – 0.20	0.12
Test D	Positive	Positive
3. Specific optical rotation (anhydrous substance)	+ 94° to + 100° (c=1, water, 20 °C)	+ 98°
4. Appearance of solution	Clear, less colour than B_7	Clear, < B_7
5. pH	7.5 – 9.0 (1 g / 20 ml)	8.4
6. Water	≤ 8.0 %	5.6 %
7. Inorganic phosphate	≤ 1%	< 1 %
8. Related substances	Individual ≤ 2 % 1 % ≤ One ≤ 2 % Total ≤ 3 %	0.15 % None 0.40 %
9. HPLC assay (anhydrous basis)	96.0 – 103.0 %	98.4 %
10. UV assay (anhydrous basis)	96.0 – 103.0 %	102.0 %
11. Residual solvents	Acetone < 3000 ppm Tetrahydrofuran < 720 ppm	21 ppm < LOQ*

GMP Compliance Declaration/Certificate of Compliance: The Company hereby certify that the information contained in this CoA/CoC is authentic and accurate. This batch has been manufactured and packaged at the above mentioned site in full compliance with GMP requirements of the local Regulatory Authority, applicable laws or regulations and tested according to the approved product specification. The Manufacturing Batch Records, packaging and analysis records have been reviewed, released and found to be in compliance with GMP requirements. * LOQ: Limit of quantitation.

CoA No./Rev: 0
Revision release date: 26/Sep/24

BDI 14/11/24

Quality Assurance Department

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