

DEXAMETHASONI NATRII PHOSPHAS 1 g

Lot No.: 24F18-APR24124

Autorisation :	1890R06127	Date Of Analysis :	02/05/2024
Analytical Reference :	Ph. Eur. 10.8 [07/2021:0549]	Production Number :	180624-GS24030
CNK :	4492-708	Expiry Date :	12/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, very hygroscopic powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with dexamethasone sodium phosphate CRS	Complies
Identification D	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 (b)	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution B ₇	Complies
pH	7.5 to 9.5	7.9
Specific optical rotation	+ 75 to + 83 (anhydrous substance)	+78
Related substances		
Impurity A	≤ 0.5%	< 0.05%
Impurity G	≤ 0.3%	< 0.05%
Impurity B	≤ 0.2%	< 0.05%
Impurity C	≤ 0.2%	< 0.05%
Impurity D	≤ 0.2%	< 0.05%
Impurity E	≤ 0.2%	< 0.05%
Impurity F	≤ 0.2%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 1.0%	< 0.05%
Inorganic phosphates	≤ 1%	Complies
Ethanol	≤ 1.5%	Not detected
Water	≤ 10.0%	7.6%
ASSAY	SPECIFICATION	RESULT
LC	97.0% to 102.0% (anhydrous substance)	101.4%

Manufacturer identification code: S/GS/025

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: