

**DEXAMETHASONI NATRII PHOSPHAS 25 g**

Lot No.: 25I08-F250458

Authorisation:	1890R06127	Date Of Analysis:	19/06/2025
Analytical Reference:	Ph.Eur. [07/2021:0549]	Production Number:	100925-G250107
CNK:	4492690	Expiry Date:	12/2028

**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 the reference solution	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution B <sub>7</sub>	Complies
pH	7.5 to 9.5	8.1
Specific optical rotation	+ 75 to + 83 (anhydrous substance)	+ 81
Related substances		
Impurity A	≤ 0.5%	0.1%
Impurity G	≤ 0.3%	< 0.1%
Impurity B	≤ 0.2%	Not detected
Impurity C	≤ 0.2%	< 0.1%
Impurity D	≤ 0.2%	Not detected
Impurity E	≤ 0.2%	Not detected
Impurity F	≤ 0.2%	Not detected
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 1.0%	0.1%
Inorganic phosphates	≤ 1%	Complies
Ethanol	≤ 1.5%	< 0.1%
Water	≤ 10.0%	7.7%
ASSAY	SPECIFICATION	RESULT
Liquid chromatography	97.0% to 102.0% (anhydrous substance)	100.8%

Manufacturer identification code: G.GS/025

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: