

Geldig van 30 DEC 2021
tot 30 DEC 2024

QUALITY CONTROL DEPARTMENT

DEXAMETHASONI NATRII PHOSPHAS

ANALYSIS REPORT: 22A20-APR22044

AUTHORISATION	1890R06127	DATE OF ANALYSIS	29/12/2021
LOT NUMBER	22A20-APR22044	EXPIRY DATE	08/2025
PRODUCTION NUMBER	020222-GS21114	ANALYTICAL REFERENCE	PH. EUR. 10.5 [07/2021:0549]

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	8.6
Specific optical rotation	+ 75 to + 83 (anhydrous substance)	+ 81
Related substances		
Impurity A	≤ 0.5 %	0.06 %
Impurity G	≤ 0.3 %	Not detected
Impurity B	≤ 0.2 %	Not detected
Impurity C	≤ 0.2 %	< 0.05 %
Impurity D	≤ 0.2 %	< 0.05 %
Impurity E	≤ 0.2 %	< 0.05 %
Impurity F	≤ 0.2 %	0.08 %
Unspecified impurities	≤ 0.10 %	< 0.05 %
Total	≤ 1.0 %	0.14 %
Inorganic phosphates	≤ 1 %	Complies
Ethanol	≤ 1.5 %	0.4 %
Water	≤ 10.0 %	4.9 %
ASSAY	SPECIFICATION	RESULT
LC	97.0 % to 102.0 % (anhydrous substance)	98.1 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

Maxime Brits
(Signature)
2022.03.23
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