We certify that the delivered batch conforms to CEP Version R1-CEP 2013-142-Rev 00 and current EP.
This batch has been manufactured, tested, packaged and released in accordance with the current GMP guideline.

CERTIFICATE OF ANALYSIS

Rev.05（230901）

Product	**Dexamethasone Sodium Phosphate**	Manufacturing date	2025.01.16
		Report date	2025.02.12
Batch No.	NCEDNa250201	Retest date	2027.01.16
Criteria	CEP		
	Specification		Batch result
Appearance	White or almost white, very hygroscopic powder		White powder, very hygroscopic powder
Identification	A(IR), D(HPLC)		Conforms
Solution S.	1.0g / 20ml water		Conforms
Appearance of solution	Clear and not more intensely colored than reference solution B7		Conforms
pH	7.5 ~ 9.5		8.2
Specific optical rotation	+75° ~ +83°		+79°
Related substances	Impurity A: ≤ 0.5% Impurity G: ≤ 0.3% Impurity B ≤ 0.2% Impurity C ≤ 0.2% Impurity D ≤ 0.2% Impurity E ≤ 0.2% Impurity F ≤ 0.2% Unspecified impurities: ≤ 0.10% Total impurities ≤ 1.0%		A: 0.07% G: <0.05% B: <0.05% C: <0.05% D: <0.05% E: <0.05% F: <0.05% Conforms Total: 0.07%
Inorganic phosphates	≤ 1.0%		Conforms
Ethanol	≤ 1.5%		0.014%
Water	≤ 10.0%		4.6%
Assay*	97.0% ~ 102.0%		100.3%
Residual solvents	Methanol ≤ 3000ppm		172ppm
Batch size	95.1kg		
Conclusion	The above product conforms to CEP		

*Calculated on anhydrous basis

Checked by: Zhang Jinling 张

Approved by: Jia Yuping 贾

March 26, 2025

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