



津药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.



CERTIFICATE OF ANALYSIS

Rev.05 (230901)

Product	Dexamethasone Sodium Phosphate	Manufacturing date	2024.08.25
		Report date	2024.09.12
Batch No.	NCEDNa240901	Retest date	2026.08.25
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	8.5	
Specific optical rotation	+75° ~ +83°	+80°	
Related substances	Impurity A: ≤ 0.5%	A: <0.05%	
	Impurity G: ≤ 0.3%	G: <0.05%	
	Impurity B ≤ 0.2%	B: <0.05%	
	Impurity C ≤ 0.2%	C: <0.05%	
	Impurity D ≤ 0.2%	D: <0.05%	
	Impurity E ≤ 0.2%	E: <0.05%	
	Impurity F ≤ 0.2%	F: <0.05%	
	Unspecified impurities: ≤ 0.10%	Conforms	
	Total impurities ≤ 1.0%	Total: <0.05%	
Inorganic phosphates	≤ 1.0%	Conforms	
Ethanol	≤ 1.5%	0.013%	
Water	≤ 10.0%	6.6%	
Assay*	97.0% ~ 102.0%	100.0%	
Residual solvents	Methanol ≤ 3000ppm	36ppm	
Batch size	95.1kg		
Conclusion	The above product conforms to CEP		

*Calculated on anhydrous basis

Checked by: Zhang Jinling

Approved by: Jia Yuping

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