



津药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

CERTIFICATE OF ANALYSIS



Rev.05 (220210)

Product	Dexamethasone	Manufacturing date	2022.12.02
Batch No.	NUD221202	Report date	2022.12.26
Criteria	CEP	Retest date	2026.12.02
	Specification	Batch result	
Appearance	White or almost white, crystalline powder	White crystalline powder	
Identification	A(IR), B(TLC)	Conforms	
Specific optical rotation	+86 ~ +92	+89	
Related substances	Total impurities ≤ 0.5% Impurity G: ≤ 0.3% Impurity B: ≤ 0.15% Impurity F: ≤ 0.15% Impurity J: ≤ 0.15% Impurity K: ≤ 0.15% Any unspecified impurities ≤ 0.10%	Total: <0.05% <0.05% <0.05% <0.05% <0.05% <0.05% Max: <0.05%	
Loss on drying	≤ 0.5%	0.14%	
Assay*	97.0% ~ 103.0%	99.8%	
Residual solvent	Methanol ≤ 3000ppm Chloroform ≤ 60ppm N, N-Dimethylformamide ≤ 880ppm	62 ppm ND ND	
Particle size	99% < 30 μm By microscope	Conforms	
Batch size	25.1kg		
Conclusion	The above product conforms to CEP		

*Calculated on the dried basis

Checked by: Cheng Jianqiao

Approved by: Jia Yuping

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