



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

Lot: 0020414

CERTIFICATE OF ANALYSIS

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Product	Dexamethasone	Manufacturing date	2014.02.25
Batch No.	NUD 140302	Report date	2014.03.10
Criteria	EP8.1	Expiration date	2019.02.25
	Specification	Batch result	
Appearance	White or almost white, crystalline powder	White crystalline powder	
Identification	First: B, C	Conforms	
Specific optical rotation	+86° ~ +92°	+88°	
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: 0.13% <0.05% 0.07% <0.05% 0.06% <0.05% Max: <0.05%	
Loss on drying	≤ 0.5%	0.32%	
Assay*	97.0% ~ 103.0%	99.3%	
Residual solvent	Methanol ≤ 3000ppm	173 ppm	
Particle size	Micronized	Conforms	
Batch size	50.01 kg		
Quantity	1 kg		
Conclusion	The above product conforms to EP8.1.		

*Storage conditions: Protected from light

*Calculated on the dried basis

Checked by: 许静超 2014.7.16

Approved by: 贾晓萍 2014.7.16



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