



TJPC

天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

CERTIFICATE OF ANALYSIS

Page: 1 / 1

Product	Dexamethasone	Manufacturing date	2015.04.13
Batch No.	NUD 150502	Report date	2015.04.29
Criteria	EP8.4	Retest date	2017.04.13
	Specification	Batch result	
Appearance	White or almost white, crystalline powder	White crystalline powder	
Identification	First: B, C	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: 0.08% <0.05% 0.08% <0.05% <0.05% <0.05%	
Loss on drying	≤ 0.5%	0.26%	
Assay*	97.0% ~ 103.0%	99.4%	
Residual solvent	Methanol ≤ 3000ppm	162ppm	
Particle size	Micronized	Conforms	
Batch size	60 kg		
Quantity	60 kg		
Conclusion	The above product conforms to EP8.4.		

*Storage conditions: Protected from light

*Calculated on the dried basis

Checked by: 孙静 2015.6.8

Approved by: 贾晓萍 2015.6.8



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