



# 天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.



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Product	<b>Dexamethasone</b>	Manufacturing date	2016.09.27
Batch No.	NUD 161003	Report date	2016.10.25
Criteria	<b>Current EP</b>	Retest date	2018.09.27
	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: 0.09% <0.05% <0.05% <0.05% <0.05% <0.05% Max: 0.09%
Loss on drying	≤ 0.5%		0.08%
Assay*	97.0% ~ 103.0%		99.5%
Residual solvent	Methanol ≤ 3000ppm Chloroform ≤ 60ppm N, N-Dimethylformamide ≤ 880ppm		304 ppm ND ND
Particle size	Micronized		Conforms
Batch size	53.5 kg		
Quantity	2 kg		
Conclusion	The above product conforms to current EP		

\*Storage conditions: Protected from light

\*Calculated on the dried basis

Checked by: *齐明强* 2016.11.3

Approved by: *贾毓萍* 2016.11.3



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