



天津天药药业股份有限公司
TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

CERTIFICATE OF ANALYSIS

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Product	Dexamethasone	Manufacturing date	2018.11.27
Batch No.	NUD 181201	Report date	2018.12.21
Criteria	Current EP	Retest date	2020.11.27
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 $\leq 0.5\%$ Impurity G: $\leq 0.3\%$ Impurity B: $\leq 0.15\%$ Impurity F: $\leq 0.15\%$ Impurity J: $\leq 0.15\%$ Impurity K: $\leq 0.15\%$ Unspecified impurities $\leq 0.10\%$		Total: 0.22% $<0.05\%$ $<0.05\%$ $<0.05\%$ $<0.05\%$ $<0.05\%$ Max: 0.08%
Loss on drying	$\leq 0.5\%$		0.14%
Assay*	97.0% ~ 103.0%		99.3%
Residual solvent	Methanol $\leq 3000\text{ppm}$ Chloroform $\leq 60\text{ppm}$ N, N-Dimethylformamide $\leq 880\text{ppm}$		114 ppm ND ND
Particle size	99% $< 30\text{ }\mu\text{m}$ By microscope		Conforms
Batch size	55 kg		
Quantity	5 kg		
Conclusion	The above product conforms to current EP		

*Storage conditions: Protected from light

*Calculated on the dried basis

Checked by: *[Signature]* 2018.12.21

Approved by: *[Signature]* 2018.12.21



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