



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

(date: 008)214



Page: 1 / 1

Product	Dexamethasone	Manufacturing date	2014.05.20
Batch No.	NUD 140602	Report date	2014.06.17
Criteria	EP8.1	Expiration date	2019.05.20
	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%		Total: 0.16%
	Impurity G: ≤ 0.3%		<0.05%
	Impurity B: ≤ 0.15%		0.06%
	Impurity F: ≤ 0.15%		<0.05%
	Impurity J: ≤ 0.15%		<0.05%
	Impurity K: ≤ 0.15%		<0.05%
	Any unspecified impurities ≤ 0.10%		Max: 0.06%
Loss on drying	≤ 0.5%		0.22%
Assay*	97.0% ~ 103.0%		99.4%
Residual solvent	Methanol ≤ 3000ppm		346 ppm
Particle size	Micronized		Conforms
Batch size	55 kg		
Quantity	1kg		
Conclusion	The above product conforms to EP8.1.		

*Storage conditions: Protected from light

*Calculated on the dried basis

Checked by: 张立 2014.11.24

Approved by: 贾毓 2014.11.24



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