



Lote: 0051015

CERTIFICATE OF ANALYSIS

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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%		Total: 0.08%
	Impurity G: ≤ 0.3%		<0.05%
	Impurity B: ≤ 0.15%		0.08%
	Impurity F: ≤ 0.15%		<0.05%
	Impurity J: ≤ 0.15%		<0.05%
	Impurity K: ≤ 0.15%		<0.05%
	Any unspecified impurities ≤ 0.10%		Max: <0.05%
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	1 kg		
Conclusion	The above product conforms to EP8.4.		

*Storage conditions: Protected from light

*Calculated on the dried basis

Checked by: 张芳 2015-9.16

Approved by: 贾晓萍 2015-9.16

