



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

CERTIFICATE OF ANALYSIS

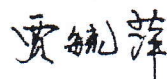
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Product	Prednisone	Manufacturing date	2015.04.22
Batch No.	NUPD 150503	Report date	2015.05.05
Test criteria	Current EP	Retest date	2017.04.22
Specifications			Result
Appearance	A white to almost white crystalline powder		White crystalline powder
Identification	A, B		Positive
Specific optical rotation	+167° ~ +175°		+169°
Related substances	Cortisone ≤ 0.25%		0.07%
	Dimmer 1 ≤ 0.25%		0.05%
	Dimmer 2 ≤ 0.25%		0.05%
	Each single unknown ≤ 0.10%		Conforms
	Total impurities ≤ 0.75%		0.21%
Loss on drying	≤ 1.0%		0.08%
Assay*	97.0% ~ 103.0%		98.7%
Residual solvents	Acetone ≤ 2000ppm		279 ppm
Particle size	99% < 20 μm		Conforms
Batch size	101.567 kg		
Quantity	100 kg		
Conclusion	The above product conforms to current EP.		

*Storage conditions: Preserve in well-closed containers, protected from light, T ≤ 25°C.

*Calculated on the dried basis

Checked by:  2015.5.5.

Approved by:  2015.5.5

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15EB-005



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