



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	Prednisolone	Production date	2010.08.22
Batch No.	NEPL 100901	Report date	2011.03.31
Test criteria	EP7.0	Retest date	2013.08.22
Specifications			Result
Appearance	A white or almost white crystalline powder		White crystalline powder
Identification	A, B		Positive
Specific optical rotation	+ 96° ~ + 102°		+ 100°
Related substances	Total impurities ≤ 2.0%		1.28%
	11α-hydroxy-prednisolone ≤ 1.0%		0.44%
	Prednisone ≤ 0.5%		0.27%
	Hydrocortisone ≤ 0.5%		0.36%
	11-deoxyprednisone ≤ 0.5%		0.15%
	Any other detectable impurity ≤ 0.10%		Conforms
Loss on drying	≤ 1.0%		0.34%
Assay*	97.0 ~ 103.0%		98.5%
Particle size	99% < 20μm		Conforms
Residual solvent	Dimethylformamide ≤ 880 ppm		462ppm
Batch size	101.6kg		
Quantity	100kg		
Conclusion	The above product conforms to EP7.0.		

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

*Calculated on the dried basis

Checked by:

2011.3.31

Approved by:

2011.3.31

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

UD 14-B01

Director Técnico



天津市经济技术开发区西区新业九街 19 号 邮编：300462

No. 19, XINYE 9th Street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China

电话 (Telephone): 86 22 66321554

传真 (FAX): 86 22 66321556