



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.



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Product	Prednisolone	Production date	2012.07.29
Batch No.	NEPL 120802	Report date	2012.08.27
Test criteria	EP7.2	Retest date	2015.07.29
Specifications		Result	
Appearance	A white or almost white, crystalline, hygroscopic powder		White crystalline powder
Identification	A, B		Positive
Specific optical rotation	+ 113° ~ + 119°		+ 117°
Related substances	Total impurities ≤ 1.5%		0.69%
	Impurity A: Hydrocortisone ≤ 1.0%		0.39%
	Impurity F: 11-epi-prednisolone ≤ 0.5%		0.07%
	Impurity B: Prednisone ≤ 0.3%		0.08%
	Impurity C: Prednisolone Acetate ≤ 0.3%		<0.05%
	Impurity J: 11-deoxyprednisolone ≤ 0.3%		0.07%
	Any other unspecified impurity ≤ 0.10%		Conforms
Loss on drying	≤ 1.0%		0.20%
Assay*	96.5 ~ 102.0%		99.2%
Particle size	99% < 20µm		Conforms
Residual solvent	Dimethylformamide ≤ 880 ppm		257ppm
Batch size	101.02kg		
Quantity	100kg		
Conclusion	The above product conforms to EP7.2.		

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

*Calculated on the dried basis

Checked by: 张 莹

2012.11.6

Approved by: 贾 毓 萍

2012.11.6

ChemSwiss AG
 Sihlbruggstrasse 109
 CH-6340 Baar
 Phone: +41 41 766 04 90
 Fax: +41 41 766 04 99
 chemswiss@chemswiss.ch
 www.chemswiss.ch

ChemSwiss

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

BB13-B1a

1007B

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