



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

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

13C14-301

Director Técnico

CERTIFICATE OF ANALYSIS

Page: 1 / 1

Product	Prednisone	Manufacturing date	2012.11.08
Batch No.	NUPD 121101	Report date	2012.11.20
Test criteria	EP7.2	Retest date	2014.11.08
Specifications			Result
Appearance	A white to almost white crystalline powder		White crystalline powder
Identification	A, B		Positive
Specific optical rotation	+167° ~ +175°		+170°
Related substances	Cortisone ≤ 0.25%		0.12%
	Dimmer 1 ≤ 0.25%		0.06%
	Dimmer 2 ≤ 0.25%		0.07%
	Each single unknown ≤ 0.10%		Conforms
	Total impurities ≤ 0.75%		0.35%
Loss on drying	≤ 1.0%		0.24%
Assay*	97.0% ~ 103.0%		98.3%
Residual solvents	Acetone ≤ 2000ppm		182 ppm
Particle size	99% < 20 μm		Conforms
Batch size	103.24 kg		
Quantity	100 kg		
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: 张立 2012.11.29

Approved by: 贾晓萍 2012.11.29



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