



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

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

12C08-B04

Director Técnico S.

Prednisolum



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Product	Prednisone	Manufacturing date	2011.08.15
Batch No.	NUPD 110901	Report date	2011.09.05
Test criteria	EP7.2	Retest date	2013.08.15
Specifications			Result
Appearance	A white to almost white crystalline powder		White crystalline powder
Identification	A, B		Positive
Specific optical rotation	+167° ~ +175°		+172°
Related substances	Cortisone ≤ 0.25%		0.12%
	Dimmer 1 ≤ 0.25%		0.06%
	Dimmer 2 ≤ 0.25%		<0.05%
	Each single unknown ≤ 0.10%		Conforms
	Total impurities ≤ 0.75%		0.23%
Loss on drying	≤ 1.0%		0.26%
Assay*	97.0% ~ 103.0%		99.8%
Residual solvents	Acetone ≤ 2000ppm		133 ppm
Particle size	90% < 10 μm		Conforms
Batch size	103.57 kg		
Quantity	103.57 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: *Y. Zhou*

Approved by:

杨俊俊

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