



Zhejiang Xianju Pharmaceutical Co., Ltd

Certificate of Analysis



Product	PREDNISON	Number of COA	A11 (05) -1005-01
Batch No.	X1-100501	Test Date	2010-05-28
Amounts(Kg)	39.80	Manufacture Date	2010-05-22
According To	EP5 AND CUSTOMER STANDARD	Retest Date	2013-05-22

Test	Specification	Result
CHARACTER	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	ALMOST WHITE CRYSTALLINE POWDER
IDENTIFICATION	(1) COMPLIES BY IR (2) COMPLIES BY TLC	CONFORMS CONFORMS
SPECIFIC ROTATION	+167° TO +175°	+171.5°
RELATED SUBSTANCES	CORTISONE NOT MORE THAN 0.25% IMPURITY A NOT MORE THAN 0.15% IMPURITY B NOT MORE THAN 0.15% IMPURITY C NOT MORE THAN 0.15% PRINCIPAL UNKNOWN IMPURITY NOT MORE THAN 0.10% TOTAL IMPURITY NOT MORE THAN 0.35%	0.16% UNDETECTED UNDETECTED UNDETECTED 0.05% 0.37%
LOSS ON DRYING	NOT MORE THAN 1.0%	0.1%
RESIDUAL ORGANIC SOLVENTS		
METHANOL	NOT MORE THAN 3000ppm	8ppm
ETHANOL	NOT MORE THAN 5000ppm	367ppm
DICHLOROMETHANE	NOT MORE THAN 600ppm	UNDETECTED
CHLOROFORM	NOT MORE THAN 60ppm	UNDETECTED
PARTICLE SIZE	IT SHOULD BE 90% BELOW 25 μm IT SHOULD BE 90% BELOW 15 μm	CONFORMS CONFORMS
ASSAY	CONTAINS 97.6 TO 103.0% OF C ₂₁ H ₂₆ O ₄ CALCULATED ON DRIED BASIS	99.7%

CONCLUSION THE GOODS CONFORMS TO EP5 AND CUSTOMER STANDARD

Analyst :

Checker :

Supervisor :

Date : 2010-05-31

Date : 2010-05-

Date : 2010-05-31



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