

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT	PREDNISOLONE	DATE OF SAMPLING	AUG.10.2013
BATCH NUMBER	K04A20130811	DATE OF RELEASE	MAR.19.2014
BATCH SIZE	239.70Kg	MANUFACTURING DATE: AUG.9.2013 RETEST DATE: JUL.2018	
CRITERIA:		EP7.2	
NAME OF THE TEST	SPECIFICATION	RESULTS	
CHARACTERS	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	QUALIFIED	
IDENTIFICATION	A;B	MEETS TEST	
SPECIFIC OPTICAL ROTATION	+113° ~ +119°	+118°	
RELATED SUBSTANCES	IMPURITY A(HYDROCORTISONE)≤1.0% IMPURITY B(PREDNISONE)≤0.30% IMPURITY C (PREDNISOLONE ACETATE)≤0.30% IMPURITY F(11-EPI-PREDNISOLONE)≤0.50% IMPURITY J(11-DEOXY-PREDNISOLONE)≤0.30% UNSPECIFIED IMPURITY≤0.10% TOTAL≤1.5%	IMPURITY A: 0.51% IMPURITY B: <0.05% IMPURITY C: <0.05% IMPURITY F: <0.05% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.51%	
LOSS ON DRYING	≤1.0%	0.2%	
ASSAY	96.5~102.0% (ON DRIED SUBSTANCE)	99.6%	
CONCLUSION: The above items meet the specifications of EP7.2			
MICRONIZED: 98%<30μm, 80%<15μm			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER

刘爱利 2014.3.19

QC DIRECTOR

王 2014.3.19

ADDRESS: MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRY DEVELOPMENT ZONE, HENAN, CHINA

TEL.: +86-372-2595136

+86-372-3664615

FAX: +86-372-2595138