

NOTE ACOFORM: J60544

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT	PREDNISOLONE	DATE OF SAMPLING	JAN.23.2016
BATCH NUMBER	K04I20160118	DATE OF RELEASE	MAR.11.2016
BATCH SIZE	244.10Kg	MANUFACTURING DATE: JAN.23.2016 RETEST DATE: DEC.2020	
CRITERIA: EP8.0			
NAME OF THE TEST	SPECIFICATION	RESULTS	
APPEARANCE	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:B	MEETS TEST	
SPECIFIC OPTICAL ROTATION	+113° ~ +119°	+117°	
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: 0.55% IMPURITY B: <0.05% IMPURITY C: <0.05% IMPURITY F: <0.05% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.55%	
LOSS ON DRYING	≤ 1.0%	0.1%	
ASSAY	96.5 ~ 102.0% (ON DRIED SUBSTANCE)	100.1%	
CONCLUSION: CONFORMS TO EP8.0			
MICRONIZED			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 张秋慧 2016.3.11

QC DIRECTOR 2016.3.11

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