

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT		PREDNISOLONE		DATE OF SAMPLING	OCT.12.2018
BATCH NUMBER		K04I20181008		DATE OF REPORT	DEC.5.2018
BATCH SIZE		243.06 Kg		MANUFACTURING DATE: OCT.12.2018 RETEST DATE: SEP.2023	
CRITERIA: EP9.0					
NAME OF THE TEST (METHOD)		SPECIFICATION		RESULTS	
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER		WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:IR(2.2.24)	CONFORM		CONFORM	
	B:HPLC(2.2.29)	CONFORM		CONFORM	
SPECIFIC OPTICAL ROTATION(2.2.7)		+113° ~ +119°		+118°	
RELATED SUBSTANCES (2.2.29)		IMPURITY A ≤ 1.0% IMPURITY B ≤ 0.30% IMPURITY C ≤ 0.30% IMPURITY F ≤ 0.50% IMPURITY J ≤ 0.30% UNSPECIFIED IMPURITY ≤ 0.10% TOTAL ≤ 1.5%		IMPURITY A: 0.76% IMPURITY B: <0.05% IMPURITY C: <0.05% IMPURITY F: <0.05% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.76%	
LOSS ON DRYING(2.2.32)		≤ 1.0%		0.1%	
ASSAY(2.2.29)		96.5 ~ 102.0% (ON DRIED SUBSTANCE)		99.5%	
CONCLUSION: CONFORMS TO EP9.0					
RESIDUAL SOLVENTS		METHANOL ≤ 700PPM METHYLENE CHLORIDE ≤ 600PPM		29 PPM 85 PPM	
MICRONIZED: 90% < 30μm					
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT					

CHECKER

2018.12.5

QC DIRECTOR

2018.12.5

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