

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20210518EP10.0

PRODUCT	PREDNISOLONE	DATE OF SAMPLING	AUG.04,2021
BATCH NUMBER	K04120210803	DATE OF REPORT	AUG.10,2021
BATCH SIZE	305.38Kg	MANUFACTURING DATE: AUG.02,2021 RETEST DATE: JUL.2026	
CRITERIA:		EP10.0	
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
IDENTIFICATION	A:IR	CONFORM	CONFORM
	B:HPLC	CONFORM	CONFORM
SPECIFIC OPTICAL ROTATION		+113° ~+119°	+117°
RELATED SUBSTANCES		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: 0.65% IMPURITY B: <0.05% IMPURITY C: <0.05% IMPURITY F: <0.05% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.65%
LOSS ON DRYING		≤1.0%	0.1%
ASSAY		96.5~102.0% (ON DRIED SUBSTANCE)	99.2%
CONCLUSION: CONFORMS TO EP10.0			
MICRONIZED			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 王瑞芳 2021.08.10

QC DIRECTOR 王瑞芳 2021.08.10

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