

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20250802EP11.4

PRODUCT		PREDNISOLONE	DATE OF SAMPLING	JUN.13,2025
BATCH NUMBER		K04120250610	DATE OF REPORT	JUN.18,2025
BATCH SIZE		308.46Kg	MANUFACTURING DATE: JUN.10,2025 RETEST DATE: MAY 2030	
CRITERIA:		EP11.4		
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°	+118°	
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: 0.48% IMPURITY B: <0.05% IMPURITY C: <0.05% IMPURITY F: <0.05% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: RRT(1.77)0.05% RRT(3.85)0.05% TOTAL: 0.58%	
LOSS ON DRYING		≤1.0%	0.2%	
ASSAY		96.5%~102.0% (ON DRIED SUBSTANCE)	99.9%	
CONCLUSION: CONFORMS TO EP11.4				
RESIDUAL SOLVENTS		METHANOL≤700PPM METHYLENE CHLORIDE≤600PPM	10 PPM 100 PPM	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 李敏 2025.06.18

QC DIRECTOR 梁张 2025.06.18

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