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HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20200305USP42

PRODUCT		PREDNISONE	DATE OF SAMPLING	AUG.12.2020
BATCH NUMBER		K03F20200818	DATE OF REPORT	OCT.20.2020
BATCH SIZE		114.44 Kg	MANUFACTURING DATE : AUG.9.2020 RETEST DATE: JUL.2025	
CRITERIA:		USP42		
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE TO PRACTICALLY WHITE, CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A: IR<197K>	CONFORM	CONFORM	
	B: CHEMISTRY REACTION	CONFORM	CONFORM	
ASSAY<621>		97.0%~102.0% (ON ANHYDROUS BASIS)	98.2%	
RESIDUE ON IGNITION<281>		NEGLECTIBLE	NEGLECTIBLE	
ORGANIC IMPURITIES <621>		ANY INDIVIDUAL IMPURITY ≤1.5% TOTAL ≤2.0%	THE MAX: 0.38% TOTAL: 1.3%	
OPTICAL ROTATION<781S>		+167° ~+175°	+170°	
WATER<921>		≤1.0%	0.1%	
CONCLUSION: CONFORMS TO USP42				
RESIDUAL SOLVENTS		METHANOL ≤3000PPM ACETONE ≤5000PPM CHLOROFORM ≤60PPM	NOT DETECTED 1252 PPM NOT DETECTED	
MICRONIZED: 90%<10um				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 王 2020.10.20

QC DIRECTOR 2020.10.20

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