

2105000091



# HENAN LIHUA PHARMACEUTICAL CO., LTD.

## CERTIFICATE OF ANALYSIS

COA NO.:20210022USP42

PRODUCT		PREDNISONE	DATE OF SAMPLING	JAN.13,2021
BATCH NUMBER		K03F20210105 ✓	DATE OF REPORT	MAR.02,2021
BATCH SIZE		114.40Kg	MANUFACTURING DATE :JAN.10,2021 ✓ RETEST DATE:DEC.2025 ✓	
CRITERIA: USP42				
NAME OF THE TEST (MATHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE TO PRACTICALLY WHITE, CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:IR	CONFORM	CONFORM	
	B: CHEMISTRY REACTION	CONFORM	CONFORM	
ASSAY		97.0%~102.0% (ON ANHYDROUS BASIS)	98.9%	
RESIDUE ON IGNITION		NEGLIGIBLE	NEGLIGIBLE	
ORGANIC IMPURITIES		ANY INDIVIDUAL IMPURITY ≤1.5% TOTAL ≤2.0%	THE MAX: 0.39% TOTAL: 1.1%	
OPTICAL ROTATION		+167° ~ +175°	+170°	
WATER		≤1.0%	0.1%	
CONCLUSION: CONFORMS TO USP42				
RESIDUAL SOLVENTS		METHANOL ≤3000PPM ACETONE ≤5000PPM CHLOROFORM ≤60PPM	NOT DETECTED 1372PPM NOT DETECTED	
TAMC		<100 CFU/g	QUALIFIED	
TYMC		<10 CFU/g	QUALIFIED	
ENTEROBACTERIA		NOT DETECTABLE/G	QUALIFIED	
SOLUBILITY		VERY SLIGHTLY SOLUBLE IN WATER, SLIGHTLY SOLUBLE IN ALCOHOL, IN CHLOROFORM, IN DIOXANE AND IN METHANOL.	QUALIFIED,	
MICRONIZED: 90% < 10um				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER *2021.03.02*QC DIRECTOR *2021.03.02*

Note: 1. Tested three batches for same product with same process.

ADDRESS: MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRY DEVELOPMENT ZONE,  
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