

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20220764USP43

PRODUCT		PREDNISOLONE		DATE OF SAMPLING	AUG.23,2022
BATCH NUMBER		K04120220812		DATE OF REPORT	AUG.29,2022
BATCH SIZE		304.72Kg		MANUFACTURING DATE: AUG.20,2022 RETEST DATE: JUL.2027	
CRITERIA:		USP43			
NAME OF THE TEST (METHOD)		SPECIFICATION		RESULTS	
APPEARANCE		WHITE TO PRACTICALLY WHITE, CRYSTALLINE POWDER		WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A	CONFORM		CONFORM	
	B	CONFORM		CONFORM	
SPECIFIC ROTATION		+97° ~ +103°		+98°	
LOSS ON DRYING		≤ 1.0%		0.1%	
RESIDUE ON IGNITION		NEGLECTIBLE		NEGLECTIBLE	
SELENIUM		≤ 0.003%		< 0.003%	
CHROMATOGRAM PURITY		ANY PEAK ≤ 1.0% ONLY ONE PEAK > 0.50% TOTAL ≤ 2.0%		HYDROCORTISONE: 0.63% THE MAX OF OTHER IMPURITY: < 0.05% TOTAL: 0.63%	
ASSAY		97.0 ~ 102.0% (ON DRIED SUBSTANCE)		98.7%	
CONCLUSION: CONFORMS TO USP43					
RESIDUAL SOLVENTS		METHANOL ≤ 700PPM METHYLENE CHLORIDE ≤ 600PPM		20 PPM 194 PPM	
SOLUBILITY		SOLUBLE IN METHANOL AND IN DIOXANE, SPARINGLY SOLUBLE IN ACETONE AND IN ETHANOL, SLIGHTLY SOLUBLE IN CHLOROFORM, VERY SLIGHTLY SOLUBLE IN PURIFIED WATER.		QUALIFIED,	
MICRONIZED					
STORAGE: STORE IN AN AIRTIGHT CONTAINER PROTECTED FROM LIGHT					

CHECKER

毛江 2022.08.29

QC DIRECTOR

2022.08.29

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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