

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20210747EP10.0

PRODUCT	PREDNISONE	DATE OF SAMPLING	NOV.04,2021
BATCH NUMBER	K03C20211101M	DATE OF REPORT	NOV.09,2021
BATCH SIZE	286.78Kg	MANUFACTURING DATE: OCT.21,2021 RETEST DATE: SEP.2026	
CRITERIA : EP10.0			
NAME OF THE TEST	SPECIFICATION	RESULTS	
APPEARANCE	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A;C	MEETS TEST	
SPECIFIC OPTICAL ROTATION	+183° ~+191°	+187°	
RELATED SUBSTANCES	IMPURITY A≤0.5% IMPURITY E≤0.2% IMPURITY D≤0.15% UNSPECIFIED IMPURITY≤0.10% TOTAL≤1.0%	IMPURITY A: 0.10% IMPURITY E: <0.05% IMPURITY D: <0.05% UNSPECIFIED IMPURITY: RRT(2.35)0.05% TOTAL: 0.15%	
LOSS ON DRYING	≤1.0%	0.1%	
ASSAY	97.0~102.0% (ON DRIED SUBSTANCE)	99.6%	
RESIDUAL SOLVENTS	METHANOL≤3000PPM ACETONE≤5000PPM CHLOROFORM≤60PPM	NOT DETECTED 322 PPM NOT DETECTED	
PARTICLE DISTRIBUTION (In-house criteria)	≤20μm>98%	100%	
CONCLUSION: CONFORMS TO EP10.0			
MICRONIZED			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER

王瑞芳 2021.11.09

QC DIRECTOR

王瑞芳 2021.11.09

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

TEL.: +86-372-2595136 +86-372-2595137

FAX: +86-372-2595138