

METAPHARMACEUTICAL

N DE LOTE:

0260324

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20231690EP11

Lot Magis-Pharma: BT24005

PRODUCT	PREDNISOLONE	DATE OF SAMPLING	DEC.30,2023
BATCH NUMBER	K04I20231222	DATE OF REPORT	JAN.04,2024
BATCH SIZE	306.80Kg	MANUFACTURING DATE:DEC.29,2023 RETEST DATE: NOV.2028	
CRITERIA:	EP11		
NAME OF THE TEST (METHOD)	SPECIFICATION	RESULTS	
APPEARANCE	WHITE OR ALMOSTWHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A	CONFORM	CONFORM
	B	CONFORM	CONFORM
SPECIFIC OPTICAL ROTATION	+113° ~+119°	+117°	
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: 0.60% IMPURITY B: <0.05% IMPURITY C: <0.05% IMPURITY F: <0.05% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.60%	
LOSS ON DRYING	≤1.0%	0.1%	
ASSAY	96.5%~102.0% (ON DRIED SUBSTANCE)	99.5%	
CONCLUSION: CONFORMS TO EP11			
RESIDUAL SOLVENTS	METHANOL≤700PPM METHYLENE CHLORIDE≤600PPM	13 PPM 120 PPM	
MICRONIZED			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 杨 2024.01.04

QC DIRECTOR 王 2024.01.04

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