

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20250098EP11.0

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	JAN.21,2025
BATCH NUMBER		K06M20250117	DATE OF REPORT	APR.08,2025
BATCH SIZE		102.16 Kg	MANUFACTURING DATE:JAN.17,2025 RETEST DATE: DEC.2029	
CRITERIA : EP11.0				
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A: IR	CONFORM	CONFORM	
	B:HPLC	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION		+158° ~ +167°	+166°	
RELATED SUBSTANCES		IMPURITY A≤ 0.5% IMPURITY B≤ 0.3% IMPURITY C≤ 0.6% IMPURITY D≤ 0.3% IMPURITY E≤ 0.3% IMPURITY G≤ 0.15% UNSPECIFIED IMPURITY≤ 0.10% TOTAL≤ 1.5%	IMPURITY A: <0.05% IMPURITY B: <0.05% IMPURITY C: 0.06% IMPURITY D: <0.05% IMPURITY E: 0.06% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.12%	
LOSS ON DRYING		≤0.5%	0.1%	
ASSAY		97.0%~102.0% (ON DRIED SUBSTANCE)	99.8%	
CONCLUSION: CONFORMS TO EP11.0				
RESIDUAL SOLVENTS		METHANOL≤3000PPM ACETONE≤5000PPM METHYLENE CHLORIDE≤600PPM	13 PPM 348 PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 杨 2025.04.08

QC DIRECTOR 梁 2025.04.08

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METAPHARMACEUTICAL

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Aljandra

13/05/2025