



HENANLIHUAPHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20250366EP11

PRODUCT		HYDROCORTISONE	DATE OF SAMPLING	MAR.15,2025
BATCH NUMBER		K05M20250319	DATE OF REPORT	MAR.19,2025
BATCH SIZE		167.06Kg	MANUFACTURING DATE: MAR.08,2025 RETEST DATE:FEB.2030	
CRITERIA: EP11				
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		+162° ~+168°	+166°	
RELATED SUBSTANCES		IMPURITY C:≤0.5% IMPURITY D:≤0.5% IMPURITY E:≤0.5% IMPURITY I:≤0.5% IMPURITY F:≤0.3% IMPURITY A:≤0.2% IMPURITY B:≤0.2% IMPURITY G:≤0.4% IMPURITY H:≤0.15% IMPURITY N:≤0.15% UNSPECIFIED IMPURITY≤0.10% TOTAL:≤2.0%	IMPURITY C : <0.05% IMPURITY D : <0.05% IMPURITY E : <0.05% IMPURITY I : <0.05% IMPURITY F : <0.05% IMPURITY A : <0.05% IMPURITY B : <0.05% IMPURITY G : 0.14% IMPURITY H : <0.05 % IMPURITY N : <0.05% UNSPECIFIED IMPURITY: RRT(2.05)0.06% TOTAL: 0.20%	
LOSS ON DRYING		≤0.5%	0.1%	
ASSAY		97.0~103.0% (ON DRIED SUBSTANCE)	100.5%	
CONCLUSION: CONFORMS TO EP11				
RESIDUAL SOLVENTS		METHANOL≤1500PPM ACETONE≤3000PPM DICHLOROMETHANE≤100PPM	23 PPM 1124 PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 杨文 2025.03.19

QC DIRECTOR 梁张 2025.03.19

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

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

METAPHARMACEUTICAL

N DE LOTE:

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Alcandra
9.3/05/2025