

HENANLIHUAPHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20231080EP11

PRODUCT		HYDROCORTISONE	DATE OF SAMPLING	AUG.14,2023
BATCH NUMBER		K05M20230802	DATE OF REPORT	AUG.18,2023
BATCH SIZE		318.78Kg	MANUFACTURING DATE: AUG.12,2023 RETEST DATE:JUL.2028	
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°	+165°	
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 : 0.11% IMPURITY D : <0.05% IMPURITY E : <0.05% IMPURITY I : <0.05% IMPURITY F : <0.05% IMPURITY A : 0.06% IMPURITY B : <0.05% IMPURITY G : 0.24% IMPURITY H : <0.05 % IMPURITY N : <0.05 % UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.41%	
LOSS ON DRYING		≤0.5%	0.1%	
ASSAY		97.0~103.0% (ON DRIED SUBSTANCE)	99.4%	
CONCLUSION: CONFORMS TO EP11				
RESIDUAL SOLVENTS		METHANOL≤1500PPM ACETONE≤3000PPM DICHLOROMETHANE≤100PPM	NOT DETECTED 897 PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 李秋 2023.08.18

QC DIRECTOR 李秋 2023.08.18

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