

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20231504EP11.0

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	NOV.19,2023
BATCH NUMBER		K06M20231106	DATE OF REPORT	NOV.28,2023
BATCH SIZE		101.96 Kg	MANUFACTURING DATE: NOV.15,2023 RETEST DATE: OCT.2028	
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: 0.16% IMPURITY D: <0.05% IMPURITY E: <0.05% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: RRT(3.50)0.05% TOTAL: 0.21%	
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	20 PPM 527 PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 李敏 2023.11.28

QC DIRECTOR 孙少喜 2023.11.28

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