

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20210579EP10

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	AUG.23,2021
BATCH NUMBER		K06M20210801	DATE OF REPORT	AUG.31,2021
BATCH SIZE		99.72Kg	MANUFACTURING DATE: AUG.16,2021 RETEST DATE: JUL.2026	
CRITERIA : EP10.0				
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: 0.06% IMPURITY B: 0.10% IMPURITY C: 0.05% IMPURITY D: <0.05% IMPURITY E: <0.05% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.21%	
LOSS ON DRYING		≤0.5%	0.1%	
ASSAY		97.0%~102.0% (ON DRIED SUBSTANCE)	99.9%	
CONCLUSION: CONFORMS TO EP10.0				
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER

王瑞芳 2021.08.31

QC DIRECTOR

张华 2021.08.31

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