

12/10/2022

METAPHARMACEUTICAL

N DE LOTE:

0081022



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HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20220939EP10

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	SEP.11,2022
BATCH NUMBER		K06M20220902	DATE OF REPORT	SEP.16,2022
BATCH SIZE		100.52 Kg	MANUFACTURING DATE: SEP.06,2022 RETEST DATE: AUG.2027	
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: <0.05% IMPURITY B: <0.05% IMPURITY C: 0.16% IMPURITY D: <0.05% IMPURITY E: <0.05% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.16%	
LOSS ON DRYING		≤ 0.5%	0.1%	
ASSAY		97.0% ~ 102.0% (ON DRIED SUBSTANCE)	99.6%	
CONCLUSION: CONFORMS TO EP10.0				
RESIDUAL SOLVENTS		METHANOL ≤ 3000PPM ACETONE ≤ 5000PPM METHYLENE CHLORIDE ≤ 600PPM	NOT DETECTED 412 PPM NOT DETECTED	
MICRONIZED: 85% ≤ 30μm				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER

3207 2022.09.16

QC DIRECTOR

3207 2022.09.16

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