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METAPHARMACEUTICAL

N DE LOTE:

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HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20210436EP10

PRODUCT	HYDROCORTISONE ACETATE	DATE OF SAMPLING	JUN.27,2021
BATCH NUMBER	K06M20210605	DATE OF REPORT	JUL.29,2021
BATCH SIZE	102.36Kg	MANUFACTURING DATE: JUN.24,2021	RETEST DATE: MAY 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	
	B:HPLC	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: 0.38% IMPURITY D: <0.05% IMPURITY E: <0.05% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: RRT(1.60)0.05% TOTAL: 0.48%	
LOSS ON DRYING	≤0.5%	0.1%	
ASSAY	97.0%~102.0% (ON DRIED SUBSTANCE)	99.9%	
CONCLUSION: CONFORMS TO EP10.0			
RESIDUAL SOLVENTS	METHANOL ≤ 3000PPM ACETONE ≤ 5000PPM METHYLENE CHLORIDE ≤ 600PPM	NOT DETECTED 549 PPM NOT DETECTED	
MICRONIZED: 85% < 30μm			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER

王瑞华 2021.07.29

QC DIRECTOR

YAH/15 2021.07.29

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