

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	NOV.25.2018
BATCH NUMBER		K06M20181103	DATE OF REPORT	DEC.13.2018
BATCH SIZE		101.44 Kg	MANUFACTURING DATE: NOV.25.2018 RETEST DATE: OCT.2023	
CRITERIA : EP9				
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:IR(2.2.24)	CONFORM	CONFORM	
	B:HPLC	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION (2.2.7)		+158° ~ +167°	+166°	
RELATED SUBSTANCES(2.2.29)		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: 0.06% IMPURITY D: <0.05% IMPURITY E: <0.05% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: RRT(1.44)0.06% TOTAL: 0.17%	
LOSS ON DRYING(2.2.32)		≤0.5%	0.1%	
ASSAY(2.2.29)		97.0% ~ 102.0% (ON DRIED SUBSTANCE)	99.4%	
CONCLUSION: CONFORMS TO EP9				
RESIDUAL SOLVENTS		METHANOL ≤ 3000PPM ACETONE ≤ 5000PPM METHYLENE CHLORIDE ≤ 600PPM DMF ≤ 880PPM	NOT DETECTED 700 PPM NOT DETECTED 360 PPM	
MICRONIZED: 90% < 20μm				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER

2018.12.13

QC DIRECTOR

2018.12.13

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