

HENANLIHUAPHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT		HYDROCORTISONE	DATE OF SAMPLING	MAR.24.2017
BATCH NUMBER		K05M20170317	DATE OF REPORT	MAR.29.2017
BATCH SIZE		161.30Kg	MANUFACTURING DATE: MAR.24.2017 RETEST DATE: FEB.2022	
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(2.2.29)	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION(2.2.7)		+162° ~ +168°	+165°	
RELATED SUBSTANCES(2.2.29)		IMPURITY C: ≤0.5% IMPURITY D: ≤0.5% IMPURITY E: ≤0.5% IMPURITY I: ≤0.5% IMPURITY F: ≤0.3% IMPURITY A: ≤0.2% IMPURITY B: ≤0.2% IMPURITY G: ≤0.4% IMPURITY H: ≤0.15% IMPURITY N: ≤0.15% UNSPECIFIED IMPURITY ≤0.10% TOTAL: ≤2.0%	IMPURITY C: <0.05% IMPURITY D: 0.06% IMPURITY E: <0.05% IMPURITY I: <0.05% IMPURITY F: <0.05% IMPURITY A: <0.05% IMPURITY B: <0.05% IMPURITY G: 0.13% IMPURITY H: <0.05% IMPURITY N: <0.05% UNSPECIFIED IMPURITY: RRT(1.40) 0.06% TOTAL: 0.25%	
LOSS ON DRYING(2.2.32)		≤0.5%	0.1%	
ASSAY(2.2.25)		97.0~103.0% (ON DRIED SUBSTANCE)	98.4%	
CONCLUSION: CONFORMS TO EP9				
RESIDUAL SOLVENTS		METHANOL ≤1500PPM ACETONE ≤3000PPM DICHLOROMETHANE ≤100PPM	41PPM 1370PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 张秋慧 2017.3.29

QC DIRECTOR 张秋慧 2017.3.29

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