

Lot: 0020417

HENANLIHUAPHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT		HYDROCORTISONE	DATE OF SAMPLING	JAN.19.2017
BATCH NUMBER		K05X20170107	DATE OF RELEASE	MAR.22.2017
BATCH SIZE		131.42 Kg	MANUFACTURING DATE: JAN.19.2017 RETEST DATE: DEC.2021	
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°	+164°	
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 : 0.07% IMPURITY E : <0.05% IMPURITY I : <0.05% IMPURITY F : < 0.05% IMPURITY A : < 0.05% IMPURITY B : < 0.05% IMPURITY G : 0.10% IMPURITY H : <0.05% IMPURITY N : < 0.05% UNSPECIFIED IMPURITY: < 0.05% TOTAL: 0.17%	
LOSS ON DRYING(2.2.32)		≤1.0%	0.1%	
ASSAY(2.2.25)		97.0~103.0% (ON DRIED SUBSTANCE)	98.6%	
CONCLUSION: CONFORMS TO EP9				
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 张秋慧 2017.3.22

QC DIRECTOR 2017.3.22

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