

Lot: 0060517

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	FEB.24.2017
BATCH NUMBER		K06M20170207M	DATE OF RELEASE	MAR.1.2017
BATCH SIZE		202.94Kg	MANUFACTURING DATE: FEB.19.2017 RETEST DATE: JAN.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	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION (2.2.7)		+158° ~+167°	+164°	
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: 0.08% IMPURITY C: 0.05% IMPURITY D: <0.05% IMPURITY E: 0.09% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.22%	
LOSS ON DRYING(2.2.32)		≤0.5%	0.1%	
ASSAY(2.2.29)		97.0%~102.0% (ON DRIED SUBSTANCE)	98.9%	
CONCLUSION: CONFORMS TO EP9				
RESIDUAL SOLVENTS		METHANOL≤3000PPM ACETONE≤5000PPM METHYLENE CHLORIDE≤600PPM DMF≤880PPM	31PPM 568PPM NOT DETECTED 323PPM	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 张秋慧 2017.3.1

QC DIRECTOR 张秋慧 2017.3.1

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