

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS



PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	OCT.4.2018
BATCH NUMBER		K06B20181001M	DATE OF REPORT	OCT.11.2018
BATCH SIZE		106.22 Kg	MANUFACTURING DATE: SEP.20.2018 RETEST DATE: AUG.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: 0.26% IMPURITY B: <0.05% IMPURITY C: 0.09% IMPURITY D: <0.05% IMPURITY E: 0.09% IMPURITY G: 0.12% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.56%	
LOSS ON DRYING(2.2.32)		≤0.5%	0.1%	
ASSAY(2.2.29)		97.0%~102.0% (ON DRIED SUBSTANCE)	98.6%	
CONCLUSION: CONFORMS TO EP9				
RESIDUAL SOLVENTS		ACETONE≤3000PPM DMF≤880PPM	1120 PPM 403 PPM	
MICRONIZED: 99%<15µm				
STORAGE: STORE IN AN AIRTIGHT CONTAINER. PROTECTED FROM LIGHT				

CHECKER *31524* 2018.10.11

QC DIRECTOR *2018.10.11*

ADDRESS: MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRY DEVELOPMENT ZONE, HE NAN, CHINA

TEL.: +86-372-2595136 +86-372-2595137

FAX: +86-372-2595138