

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT	HYDROCORTISONE ACETATE	DATE OF SAMPLING	JUN.19.2015
BATCH NUMBER	K06B20150601	DATE OF RELEASE	JUN.23..2015
BATCH SIZE	34.00Kg	MANUFACTURING DATE: JUN.19.2015 RETEST DATE: MAY.2020	
CRITERIA : EP8.0			
NAME OF THE TEST	SPECIFICATION	RESULTS	
APPEARANCE	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:B	MEETS TEST	
SPECIFIC OPTICAL ROTATION	+158° ~ +167°	+165°	
RELATED SUBSTANCES	IMPURITY A ≤ 0.40% IMPURITY B ≤ 0.30% IMPURITY C ≤ 0.60% IMPURITY D ≤ 0.30% IMPURITY E ≤ 0.30% IMPURITY G ≤ 0.15% UNSPECIFIED IMPURITY ≤ 0.10% TOTAL ≤ 1.0%	IMPURITY A: 0.21% IMPURITY B: <0.05% IMPURITY C: 0.10% IMPURITY D: <0.05% IMPURITY E: 0.09% IMPURITY G: 0.07% UNSPECIFIED IMPURITY: RRT(0.66)0.08% RRT(2.64)0.06% TOTAL: 0.61%	
LOSS ON DRYING	≤ 0.5%	0.1%	
ASSAY	97.0% ~ 102.0% (ON DRIED SUBSTANCE)	99.6%	
CONCLUSION: CONFORMS TO EP8.0			
MICRONIZED			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 张秋慧 2015.6.23

QC DIRECTOR

张秋慧 2015.6.23

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