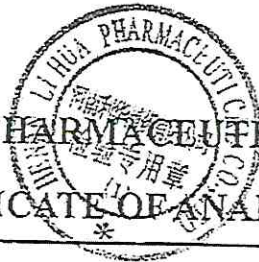


Lot: 0230321



HENANLIHUAPHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.: 20200589EP10

PRODUCT	HYDROCORTISONE	DATE OF SAMPLING	NOV.26,2020
BATCH NUMBER	K05M20201111	DATE OF REPORT	NOV.30,2020
BATCH SIZE	80.50Kg	MANUFACTURING DATE:	NOV.24.2020
		RETEST DATE:	OCT.2025
CRITERIA:	EP10		
NAME OF THE TEST (METHOD)	SPECIFICATION	RESULTS	
APPEARANCE	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION A:IR	CONFORM	CONFORM	
B:HPLC	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION	+162° ~ +168°	+167°	
RELATED SUBSTANCES	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: 0.14% IMPURITY B: <0.05% IMPURITY G: 0.08% IMPURITY H: <0.05 % IMPURITY N: <0.05% UNSPECIFIED IMPURITY: RRT(1.99):0.05% TOTAL: 0.34%	
LOSS ON DRYING	≤0.5%	0.1%	
ASSAY	97.0~103.0% (ON DRIED SUBSTANCE)	100.4%	
CONCLUSION: CONFORMS TO EP10			
RESIDUAL SOLVENTS	METHANOL ≤1500PPM ACETONE ≤3000PPM DICHLOROMETHANE ≤100PPM	39 PPM 1562 PPM NOT DETECTED	
MICRONIZED			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 王磊 2020.11.30

QC DIRECTOR 王小花 2020.11.30

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