

1510000169

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS



PRODUCT	PREDNISONE	DATE OF SAMPLING	AUG 7, 2015
BATCH NUMBER	K03B20150802	DATE OF RELEASE	SEP. 12, 2015
BATCH SIZE	107.78Kg	MANUFACTURING DATE: AUG 7, 2015 RETEST DATE: JUL. 2020	
CRITERIA:	USP37		
NAME OF THE TEST	SPECIFICATION	RESULTS	
APPEARANCE	WHITE TO PRACTICALLY WHITE, CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A.B	MEETS TEST	
SPECIFIC ROTATION	+167° ~ +175°	+170°	
WATER	≤ 1.0%	0.1%	
RESIDUE ON IGNITION	NEGLIGIBLE	NEGLIGIBLE	
CHROMATOGRAPHIC PURITY	INDIVIDUAL IMPURITY ≤ 1.5% TOTAL ≤ 2.0%	THE MAX: 0.25% TOTAL: 1.2%	
ASSAY	97.0 ~ 102.0% (ON ANHYDROUS BASIS)	98.1%	
CONCLUSION: CONFORMS TO USP37			
RESIDUAL SOLVENTS	METHANOL ≤ 3000PPM ACETONE ≤ 5000PPM CHLOROFORM ≤ 60PPM	17PPM 979PPM NOT DETECTED	
MELTING POINT	ABOUT 230°C	232°C	
THE TOTAL VISIBLE BACTERIA	< 100CFU/g	< 10CFU/g	
FUNGUS	< 10CFU/g	< 10CFU/g	
E. COLI	NOT DETECTABLE	QUALIFIED	
SOLUBILITY: VERY SLIGHTLY SOLUBLE IN WATER, SLIGHTLY SOLUBLE IN ALCOHOL, IN CHLOROFORM, IN DIOXANE AND IN METHANOL.			
MICRONIZED: 90% < 10µm, 100% < 30µm			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 张秋慧 2015.9.12

QC DIRECTOR

2015.9.12

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