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HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT		PREDNISONE	DATE OF SAMPLING	FEB.22.2016
BATCH NUMBER		K03B20160203	DATE OF RELEASE	MAY.10.2016
BATCH SIZE		108.12Kg	MANUFACTURING DATE :FEB.22.2016 RETEST DATE:JAN.2021	
CRITERIA: USP38				
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULT	
APPEARANCE		WHITE TO PRACTICALLY WHITE, CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:IR<197K>	CONFORM	CONFORM	
	B: CHEMISTRY REACTION	CONFORM	CONFORM	
ASSAY<621>		97.0%~102.0% (ON ANHYDROUS BASIS)	98.1%	
RESIDUE ON IGNITION<281>		NEGLECTIBLE	NEGLECTIBLE	
ORGANIC IMPURITIES <621>		ANY INDIVIDUAL IMPURITY ≤ 1.5% TOTAL ≤ 2.0%	THE MAX: 0.52% TOTAL: 1.7%	
OPTICAL ROTATION<781S>		+167° ~ +173°	+170°	
WATER<921>		≤ 1.0%	0.1%	
CONCLUSION: CONFORMS TO USP38				
RESIDUAL SOLVENTS		METHANOL ≤ 3000PPM ACETONE ≤ 5000PPM CHLOROFORM ≤ 60PPM	NOT DETECTED 1717PPM 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.	QUALIFIED	
MICRONIZED: 90% < 10μm, 100% < 30μm				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER

QC DIRECTOR

Note: 1. Tested three batches for same product with same process.

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2016.5.10