

HENAN LIHUA PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

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| PRODUCT | | PREDNISOLONE | DATE OF SAMPLING | MAR.13.2020 |
| BATCH NUMBER | | K04I20200304 | DATE OF REPORT | MAR.23.2020 |
| BATCH SIZE | | 241.92 Kg | MANUFACTURING DATE: MAR.5.2020 RETEST DATE: FEB.2025 | |
| CRITERIA: | | USP42 | | |
| NAME OF THE TEST (METHOD) | | SPECIFICATION | RESULTS | |
| APPEARANCE | | WHITE TO PRACTICALLY WHITE ,CRYSTALLINE POWDER | WHITE CRYSTALLINE POWDER | |
| IDENTIFICATION | A: IR <197K> | CONFORM | CONFORM | |
| | B:UV<197U> | CONFORM | CONFORM | |
| SPECIFIC ROTATION<781S> | | +97° ~+103° | +98° | |
| LOSS ON DRYING<731> | | ≤1.0% | 0.1% | |
| RESIDUE ON IGNITION<281> | | NEGLIGIBLE | NEGLIGIBLE | |
| SELENIUM<291> | | ≤0.003% | <0.003% | |
| CHROMATOGRAM PURITY <621> | | ANY PEAK ≤1.0% ONLY ONE PEAK >0.50% TOTAL ≤2.0% | HYDROCORTISONE: 0.58% THE MAX OF OTHER IMPURITY: 0.06% TOTAL: 0.64% | |
| ASSAY<621> | | 97.0~102.0% (ON DRIED SUBSTANCE) | 98.1% | |
| CONCLUSION: CONFORMS TO USP42 | | | | |
| RESIDUAL SOLVENTS | | METHANOL ≤700PPM METHYLENE CHLORIDE ≤600PPM | 24 PPM 35 PPM | |
| MICRONIZED | | | | |
| STORAGE: STORE IN AN AIRTIGHT CONTAINER PROTECTED FROM LIGHT | | | | |

CHECKER

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QC DIRECTOR

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