

# HENANLIHUAPHARMACEUTICAL CO., LTD.

## CERTIFICATE OF ANALYSIS

|                                                               |                |                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                 |             |
|---------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| PRODUCT                                                       |                | HYDROCORTISONE                                                                                                                                                                                                                                                  | DATE OF SAMPLING                                                                                                                                                                                                                                                                                                | MAR.20.2020 |
| BATCH NUMBER                                                  |                | 05M20200301                                                                                                                                                                                                                                                     | DATE OF REPORT                                                                                                                                                                                                                                                                                                  | MAR.28.2020 |
| BATCH SIZE                                                    |                | 318.48 Kg                                                                                                                                                                                                                                                       | MANUFACTURING DATE: MAR.19.2020<br>RETEST DATE: FEB.2025                                                                                                                                                                                                                                                        |             |
| CRITERIA: EP9                                                 |                |                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                 |             |
| NAME OF THE TEST<br>(METHOD)                                  |                | SPECIFICATION                                                                                                                                                                                                                                                   | RESULTS                                                                                                                                                                                                                                                                                                         |             |
| APPEARANCE                                                    |                | WHITE OR ALMOST WHITE CRYSTALLINE<br>POWDER                                                                                                                                                                                                                     | WHITE CRYSTALLINE POWDER                                                                                                                                                                                                                                                                                        |             |
| IDENTIFICATION                                                | A:IR(2.2.24)   | CONFORM                                                                                                                                                                                                                                                         | CONFORM                                                                                                                                                                                                                                                                                                         |             |
|                                                               | B:HPLC(2.2.29) | CONFORM                                                                                                                                                                                                                                                         | CONFORM                                                                                                                                                                                                                                                                                                         |             |
| SPECIFIC OPTICAL<br>ROTATION(2.2.7)                           |                | +162° ~ +168°                                                                                                                                                                                                                                                   | +166°                                                                                                                                                                                                                                                                                                           |             |
| RELATED SUBSTANCES(2.2.29)                                    |                | IMPURITY C: ≤0.5%<br>IMPURITY D: ≤0.5%<br>IMPURITY E: ≤0.5%<br>IMPURITY I: ≤0.5%<br>IMPURITY F: ≤0.3%<br>IMPURITY A: ≤0.2%<br>IMPURITY B: ≤0.2%<br>IMPURITY G: ≤0.4%<br>IMPURITY H: ≤0.15%<br>IMPURITY N: ≤0.15%<br>UNSPECIFIED IMPURITY ≤0.10%<br>TOTAL: ≤2.0% | IMPURITY C: <0.05%<br>IMPURITY D: 0.06%<br>IMPURITY E: <0.05%<br>IMPURITY I: <0.05%<br>IMPURITY F: <0.05%<br>IMPURITY A: 0.09%<br>IMPURITY B: <0.05%<br>IMPURITY G: 0.13%<br>IMPURITY H: <0.05%<br>IMPURITY N: <0.05%<br>UNSPECIFIED IMPURITY: RRT(1.72)0.05%<br>RRT(1.75)0.06%, RRT(1.97)0.05%<br>TOTAL: 0.44% |             |
| LOSS ON DRYING(2.2.32)                                        |                | ≤0.5%                                                                                                                                                                                                                                                           | 0.1%                                                                                                                                                                                                                                                                                                            |             |
| ASSAY(2.2.25)                                                 |                | 97.0~103.0%<br>(ON DRIED SUBSTANCE)                                                                                                                                                                                                                             | 100.9%                                                                                                                                                                                                                                                                                                          |             |
| CONCLUSION: CONFORMS TO EP9                                   |                |                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                 |             |
| RESIDUAL SOLVENTS                                             |                | METHANOL ≤1500PPM<br>ACETONE ≤3000PPM<br>DICHLOROMETHANE ≤100PPM                                                                                                                                                                                                | 30 PPM<br>790 PPM<br>NOT DETECTED                                                                                                                                                                                                                                                                               |             |
| MICRONIZED                                                    |                |                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                 |             |
| STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT |                |                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                 |             |

CHECKER

QC DIRECTOR

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