

**HENAN LIHUA PHARMACEUTICAL CO., LTD.**

**CERTIFICATE OF ANALYSIS**

|                                                               |              |                                                                                                                                                                         |                                                                                                                                                                                             |             |
|---------------------------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| PRODUCT                                                       |              | HYDROCORTISONE ACETATE                                                                                                                                                  | DATE OF SAMPLING                                                                                                                                                                            | MAR.10.2020 |
| BATCH NUMBER                                                  |              | K06M20200303                                                                                                                                                            | DATE OF REPORT                                                                                                                                                                              | MAY.18.2020 |
| BATCH SIZE                                                    |              | 102.36 Kg                                                                                                                                                               | MANUFACTURING DATE: FEB.26.2020<br>RETEST DATE: JAN.2025                                                                                                                                    |             |
| CRITERIA : EP10                                               |              |                                                                                                                                                                         |                                                                                                                                                                                             |             |
| 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       | CONFORM                                                                                                                                                                 | CONFORM                                                                                                                                                                                     |             |
| SPECIFIC OPTICAL ROTATION<br>(2.2.7)                          |              | +158° ~+167°                                                                                                                                                            | +165°                                                                                                                                                                                       |             |
| RELATED SUBSTANCES(2.2.29)                                    |              | IMPURITY A≤ 0.5%<br>IMPURITY B≤ 0.3%<br>IMPURITY C≤ 0.6%<br>IMPURITY D≤ 0.3%<br>IMPURITY E≤ 0.3%<br>IMPURITY G≤ 0.15%<br>UNSPECIFIED IMPURITY≤ 0.10%<br><br>TOTAL≤ 1.5% | IMPURITY A: <0.05%<br>IMPURITY B: <0.05%<br>IMPURITY C: 0.35%<br>IMPURITY D: <0.05%<br>IMPURITY E: <0.05%<br>IMPURITY G: <0.05%<br>UNSPECIFIED IMPURITY: RRT(1.47)0.08%<br><br>TOTAL: 0.43% |             |
| LOSS ON DRYING(2.2.32)                                        |              | ≤0.5%                                                                                                                                                                   | 0.1%                                                                                                                                                                                        |             |
| ASSAY(2.2.29)                                                 |              | 97.0%~102.0%<br>(ON DRIED SUBSTANCE)                                                                                                                                    | 100.1%                                                                                                                                                                                      |             |
| CONCLUSION: CONFORMS TO EP10                                  |              |                                                                                                                                                                         |                                                                                                                                                                                             |             |
| RESIDUAL SOLVENTS                                             |              | METHANOL≤3000PPM<br>ACETONE≤5000PPM<br>METHYLENE CHLORIDE≤600PPM                                                                                                        | 12 PPM<br>529 PPM<br>NOT DETECTED                                                                                                                                                           |             |
| MICRONIZED: 85%≤30µm                                          |              |                                                                                                                                                                         |                                                                                                                                                                                             |             |
| STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT |              |                                                                                                                                                                         |                                                                                                                                                                                             |             |

CHECKER *[Signature]* 2020.5.18

QC DIRECTOR *[Signature]* 2020.5.18

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