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# HENAN LIHUA PHARMACEUTICAL CO., LTD.

## CERTIFICATE OF ANALYSIS

|                                                               |                        |                                                                                                                                                                                 |                                                                                                                                                                                          |             |
|---------------------------------------------------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| PRODUCT                                                       | HYDROCORTISONE ACETATE |                                                                                                                                                                                 | DATE OF SAMPLING                                                                                                                                                                         | MAY.13.2017 |
| BATCH NUMBER                                                  | K06M20170505M          |                                                                                                                                                                                 | DATE OF REPORT                                                                                                                                                                           | MAY.17.2017 |
| BATCH SIZE                                                    | 214.84Kg               |                                                                                                                                                                                 | MANUFACTURING DATE: APR.27.2017<br>RETEST DATE: MAR.2022                                                                                                                                 |             |
| CRITERIA : EP9                                                |                        |                                                                                                                                                                                 |                                                                                                                                                                                          |             |
| NAME OF THE TEST (METHOD)                                     |                        | SPECIFICATION                                                                                                                                                                   | RESULTS                                                                                                                                                                                  |             |
| APPEARANCE                                                    |                        | WHITE OR ALMOST WHITE CRYSTALLINE POWDER                                                                                                                                        | WHITE CRYSTALLINE POWDER                                                                                                                                                                 |             |
| IDENTIFICATION                                                | A:IR(2.2.24)           | CONFORM                                                                                                                                                                         | CONFORM                                                                                                                                                                                  |             |
|                                                               | B:HPLC                 | CONFORM                                                                                                                                                                         | CONFORM                                                                                                                                                                                  |             |
| SPECIFIC OPTICAL ROTATION (2.2.7)                             |                        | +158° ~ +167°                                                                                                                                                                   | +164°                                                                                                                                                                                    |             |
| 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: 0.06%<br>IMPURITY B: 0.09%<br>IMPURITY C: 0.19%<br>IMPURITY D: <0.05%<br>IMPURITY E: 0.12%<br>IMPURITY G: <0.05%<br>UNSPECIFIED IMPURITY: RRT(1.43)0.08%<br><br>TOTAL: 0.54% |             |
| LOSS ON DRYING(2.2.32)                                        |                        | ≤0.5%                                                                                                                                                                           | 0.1%                                                                                                                                                                                     |             |
| ASSAY(2.2.29)                                                 |                        | 97.0%~102.0%<br>(ON DRIED SUBSTANCE)                                                                                                                                            | 99.0%                                                                                                                                                                                    |             |
| CONCLUSION: CONFORMS TO EP9                                   |                        |                                                                                                                                                                                 |                                                                                                                                                                                          |             |
| RESIDUAL SOLVENTS                                             |                        | METHANOL ≤ 3000PPM<br>ACETONE ≤ 5000PPM<br>METHYLENE CHLORIDE ≤ 600PPM<br>DMF ≤ 880PPM                                                                                          | 49PPM<br>683PPM<br>NOT DETECTED<br>326PPM                                                                                                                                                |             |
| MICRONIZED: 90% < 20 μ m                                      |                        |                                                                                                                                                                                 |                                                                                                                                                                                          |             |
| STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT |                        |                                                                                                                                                                                 |                                                                                                                                                                                          |             |

CHECKER 张秋慧 2017.5.17

QC DIRECTOR 王花 2017.5.17

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