



山东新华制药股份有限公司

Shandong Xinhua Pharmaceutical Co., Ltd

14 Dongyi Road, Zibo, 255005 China

Tel: 86-533-2196807

Commodity: Hydrocortisone Base Micro EP8.0

This is to certify that we, the undersigned, have inspected the quality of the above mentioned goods and found the result of the inspection as below:

| Items                                       | Specification                            | Results                  |
|---------------------------------------------|------------------------------------------|--------------------------|
| Batch No.                                   |                                          | 14033                    |
| Batch Quantity                              |                                          | 10 KG                    |
| Appearance                                  | White or almost white crystalline powder | White crystalline powder |
| Identification:                             |                                          |                          |
| A: Infrared absorption                      | Complies                                 | Complies                 |
| B: HPLC                                     | Complies                                 | Complies                 |
| Specific Rotation (on the dried basis) (+°) | 162-168                                  | 163.1                    |
| Related Substances: Impurity A (%)          | ≤0.2                                     | 0.06                     |
| Impurity B (%)                              | ≤0.2                                     | 0.07                     |
| Impurity C (%)                              | ≤0.5                                     | Disregard                |
| Impurity D (%)                              | ≤0.5                                     | 0.4                      |
| Impurity E (%)                              | ≤0.5                                     | Disregard                |
| Impurity F (%)                              | ≤0.3                                     | 0.06                     |
| Impurity G (%)                              | ≤0.4                                     | 0.1                      |
| Impurity H (%)                              | ≤0.15                                    | Disregard                |
| Impurity I (%)                              | ≤0.5                                     | 0.1                      |
| Impurity N (%)                              | ≤0.15                                    | Disregard                |
| Any Individual Impurity (%)                 | ≤0.10                                    | 0.066                    |
| Total Impurities (%)                        | ≤2.0                                     | 0.99                     |
| Loss on drying (%)                          | ≤1.0                                     | 0.22                     |
| Assay (on the dried basis) (%)              | 97.0~103.0                               | 99.5                     |
| Residual Solvents:                          |                                          |                          |
| 1,2-Dichloroethane (%)                      | ≤5                                       | Not detected             |
| Methanol (ppm)                              | ≤1000                                    | 638                      |
| Chloroform (ppm)                            | ≤60                                      | Not detected             |
| Microbial Limits:                           |                                          |                          |
| Total aerobic microbial count (cfu/g)       | ≤800                                     | <10                      |
| Fungi (cfu/g)                               | ≤80                                      | <10                      |
| E.Coli (cfu/g)                              | Not found                                | Not found                |
| Particle Size                               |                                          |                          |
| < 5um (%)                                   | ≥90                                      | 95                       |
| Manuf. Date                                 |                                          | NOV. 2014                |
| Expiry Date                                 |                                          | NOV. 2018                |

**Conclusion:** The product is tested in accordance with Ph. Eur.8.0. The above items meet the requirements.