



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

FAGRON IBERICA, S.A.U  
Corresponde al lote de FAGRON:

13C14-B01

Director Técnico

CERTIFICATE OF ANALYSIS

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|                           |                                            |                    |                          |
|---------------------------|--------------------------------------------|--------------------|--------------------------|
| Product                   | Prednisone                                 | Manufacturing date | 2012.11.08               |
| Batch No.                 | NUPD 121101                                | Report date        | 2012.11.20               |
| Test criteria             | EP7.2                                      | Retest date        | 2014.11.08               |
|                           | Specifications                             |                    | Result                   |
| Appearance                | A white to almost white crystalline powder |                    | White crystalline powder |
| Identification            | A, B                                       |                    | Positive                 |
| Specific optical rotation | +167° ~ +175°                              |                    | +170°                    |
| Related substances        | Cortisone ≤ 0.25%                          |                    | 0.12%                    |
|                           | Dimmer 1 ≤ 0.25%                           |                    | 0.06%                    |
|                           | Dimmer 2 ≤ 0.25%                           |                    | 0.07%                    |
|                           | Each single unknown ≤ 0.10%                |                    | Conforms                 |
|                           | Total impurities ≤ 0.75%                   |                    | 0.35%                    |
| Loss on drying            | ≤ 1.0%                                     |                    | 0.24%                    |
| Assay*                    | 97.0% ~ 103.0%                             |                    | 98.3%                    |
| Residual solvents         | Acetone ≤ 2000ppm                          |                    | 182 ppm                  |
| Particle size             | 99% < 20 μm                                |                    | Conforms                 |
| Batch size                | 103.24 kg                                  |                    |                          |
| Quantity                  | 100 kg                                     |                    |                          |
| Conclusion                | The above product conforms to EP7.2.       |                    |                          |

\*Storage conditions: Preserve in well-closed containers, protected from light, T ≤ 25°C.

\*Calculated on the dried basis

Checked by: 张莹 2012.11.29

Approved by: 贾晓萍 2012.11.29



天津市经济技术开发区西区新业九街19号 邮编: 300462  
No. 19, XINYE 9th Street, West Area of Tianjin Economic-Technological Development Area, Tianjin, 300462, China  
电话 (Telephone): 86 22 66321554 传真 (FAX): 86 22 66321556