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# 秦皇岛紫竹药业有限公司外贸报告书

**QINHUANGDAO ZIZHU PHARMACEUTICAL CO., LTD.**

## Certificate of analysis

报告编号: 25002014002

COA Code: 25002014002

|                                             |                                                                                                                                                                              |                                     |                                 |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---------------------------------|
| Product name<br>品 名                         | Estrone<br>雌酚酮                                                                                                                                                               | Batch No.<br>批号                     | 25001403001                     |
| Batch quantity<br>批 量                       | 33.80kg                                                                                                                                                                      | Package Size<br>包装规格                | 1kg/bag<br>1kg/袋                |
| Mfg. Date<br>生产日期                           | Mar.03,2014<br>2014 年 03 月 03 日                                                                                                                                              | Retest date<br>复验期                  | Mar.02,2016<br>2016 年 03 月 02 日 |
| Report date<br>报告日期                         | May. 04,2014<br>2014 年 05 月 04 日                                                                                                                                             | Basis of standards<br>标准依据          | USP32<br>美国药典 32 版              |
| Items<br>项 目                                | Specifications<br>标准规定                                                                                                                                                       | Results<br>检验结果                     |                                 |
| Description<br>性状                           | White or almost white crystalline powder<br>本品为白色或类白色结晶性粉末                                                                                                                   | White crystalline powder<br>白色结晶性粉末 |                                 |
| Specific rotation<br>比旋度                    | +158° — +165°                                                                                                                                                                | +161°                               |                                 |
| Identification<br>鉴别                        | A : The infrared Spectrum of the test preparation should be consistent with reference standard.<br>A: 本品的红外光吸收图谱应与对照品的图谱 致                                                   | Conforms<br>符合                      |                                 |
|                                             | B: The max ultraviolet absorption wavelength and minimum absorption wavelength of test preparation should be consistent with reference standard.<br>B: 本品的紫外光最大和最小吸收波长与对照品一致 | Conforms<br>符合                      |                                 |
| Clarity of solution<br>溶液澄清度                | The solution should be clear.<br>应澄清                                                                                                                                         | Conforms<br>符合                      |                                 |
| Residue on ignition<br>炽灼残渣                 | ≤0.5%                                                                                                                                                                        | 0.09%                               |                                 |
| Loss on drying<br>干燥失重                      | ≤0.5%                                                                                                                                                                        | 0.05%                               |                                 |
| Limit of equilenin and equilin<br>马烯雌酮和马烯雌酮 | The color of test solution should not be redder than reference standard solution.<br>供试液不得红于对照液溶液                                                                            | No Detectable<br>未检出                |                                 |



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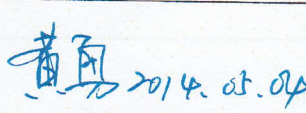
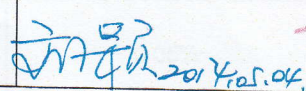
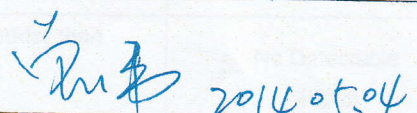
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| Items<br>项 目                                                  | Specifications<br>标准规定                                                                                                                             |                                                                                                    | Results<br>检验结果                                                                                     |
| Ordinary impurities<br>有关物质                                   | Conforms<br>应符合规定                                                                                                                                  |                                                                                                    | Conforms<br>符合                                                                                      |
| Purity by HPLC<br>含量                                          | 97.0%~103.0%, calculated on the dried basis.<br>按干燥品计, 含雌酚酮应为 97.0%~103.0%                                                                         |                                                                                                    | 98.5%                                                                                               |
| Conclusion<br>结 论                                             | The product conforms to USP32 standard.<br>本产品符合美国药典 32 版规定                                                                                        |                                                                                                    |                                                                                                     |
| Storage Condition<br>储存条件                                     | Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15°C and 30°C.<br>遮光、密封保存, 储存温度 25°C, 允许偏差 15°C 至 30°C。 |                                                                                                    |                                                                                                     |
| Address:<br>生产地址:                                             | No.10, Longhai Road, Economic & Technological Development Zone, Qinhuangdao, Hebei<br>P.R.China<br>河北省秦皇岛市经济技术开发区龙海道 10 号                          |                                                                                                    |                                                                                                     |
| Report person/ Date<br>报告人/日期                                 | <br>2014.05.04                                                  | QA director/ Date<br>QA 主管/日期                                                                      | <br>2014.05.04 |
| Technology and Quality Department Manager/ Date<br>技术质量部经理/日期 |                                                                                                                                                    | <br>2014.05.04 |                                                                                                     |

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