

**杭州东瑞医药科技有限公司**  
**HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.**

**CERTIFICATE OF ANALYSIS**

**Exemestane**

<b>Batch No.:</b> DR20120604	<b>Quantity:</b> 1.0kg
<b>Manufacture Date:</b> 2012.06.04	<b>Expiry Date:</b> 2016.06.03

**TESTS:**

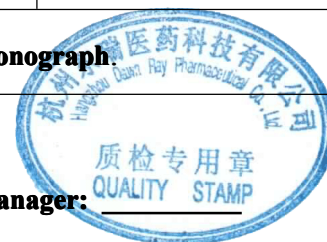
<b>Items</b>	<b>Specification</b>	<b>Results</b>
Appearance	White crystalline powder	White crystalline powder
Identification	A:IR B:RT(HPLC)	Conforms
Residue on ignition	≤0.1%	0.04%
Heavy Metals	≤ 10ppm	Conforms
Loss on drying	≤0.50%	0.03%
Water	≤0.5%	0.02%
Specific rotation	+290 <sup>o</sup> ~ +300 <sup>o</sup>	+290.86 <sup>o</sup>
Spirooxiran 1	≤0.15%	Not Detected
Spirooxiran 2	≤0.15%	Not Detected
Exemestane related compound A	≤0.15%	Not Detected
Exemestane related compound C	≤0.15%	Not Detected
Any unspecified impurity	≤0.10%	0.05%
Total impurity	≤0.50%	0.25%
Micron		100%≤ 20μm
Assay (HPLC)	98.0~102.0% (on dry basis)	100.02%

Conclusion: The results conform with **USP Pending Monograph**.

**Analyst:** \_\_\_\_\_

**Checker:** \_\_\_\_\_

**QA.Manager:** \_\_\_\_\_



**Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China**

**Tel:+86-571- 85335020**

**E-mail: agnes@dawnraypharmal.com**

**Fax: +86-571- 85335020**

**Website: http://www.dawnraypharma.com/**