

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

CERTIFICATE OF ANALYSIS

Estradiol hemihydrate (CAS 35380-71-3)

<b>Batch No.:</b> DR20120109	<b>Piece:</b> 5kg
<b>Package Size:</b> 1kg/drum	<b>Specification:</b> EP6.0
<b>Manufacture Date:</b> 2012.01.09	<b>Expiry Date:</b> 2015.01.08

**TESTS:**

Items	Specification	Results
Appearance	White or almost white, crystalline powder or colourless crystals	white crystalline powder
Solubility	Practically insoluble in water, soluble in acetone, sparingly soluble in alcohol, slightly soluble in ether and in methylene chloride	Conforms
Identification	A: IR B: TLC C: Positive	Conforms
Specific optical rotation	+76.0° ~ +83.0°	+78.6°
Melting range	175~180°C	175.5~179.5°C
Water	2.9%~3.5%	3.25%
Related Substance	Impurity A ≤ 0.3%	Undetected
	Impurity B ≤ 0.3%	0.17%
	Impurity C ≤ 0.3%	0.13%
	Impurity D ≤ 0.3%	Undetected
	Total impurities ≤ 0.5%	0.33%
	Any other impurity ≤ 0.1%	0.02%
Residual Solvents	Alcohol ≤ 0.5%	0.06%
Assay	97.0~103.0% (on the dried basis)	99.21%

Conclusion: The results conform with EP6.0.



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

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

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

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

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

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

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

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