



Certificate of analysis

Productname: Estradiol Hemihydrate

Cas number: 35380-71-3

Molecular Formula: $2(C_{18}H_{24}O_2) \cdot H_2O$

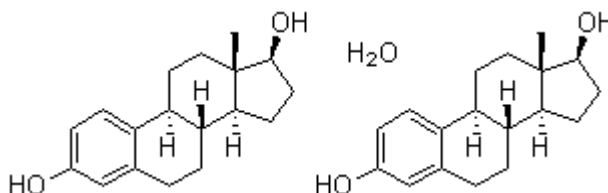
Molecular Weight: 562.79

Date of production: Oct. 29, 2014

Batch NO: 20141029

Exp Date: Oct. 28, 2016

Chemical structure



| Items | Specifications | Test results |
|----------------------------------|--|--------------------------|
| Appearance | White or almost white, crystalline powder or colourless crystals | White crystalline powder |
| Identification | A: IR B: TLC C: Positive | Conforms |
| Specific optical rotation | +76.0° ~ +83.0° | +80.7° |
| Melting range | 175~180°C | 175.5~179.5°C |
| Water | 2.9%~3.5% | 3.4% |
| Related Substance | Impurity A ≤ 0.3% | No Detectable |
| | Impurity B ≤ 0.3% | 0.11% |
| | Impurity C ≤ 0.3% | No Detectable |
| | Impurity D ≤ 0.3% | 0.19% |
| | Total impurities ≤ 0.5% | 0.30% |
| | Any other impurity ≤ 0.1% | 0.02% |
| Residual Solvents | Methanol ≤ 3000ppm | No Detectable |
| | Ethanol ≤ 5000ppm | 1171ppm |
| | Acetone ≤ 5000ppm | No Detectable |
| | Acetic ≤ 5000ppm | No Detectable |
| Assay | 97.0~103.0% (on the dried basis) | 99.1% |

Conclusion: It complies with the EP7.0 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F