

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

CERTIFICATE OF ANALYSIS

Norethisterone

| | |
|-------------------------------------|--------------------------------|
| Batch No.: DR20131008 | Piece: 50kg |
| Manufacture Date: 2013.10.08 | Expiry Date: 2017.10.07 |

TESTS:

| Items | Specification | Results |
|------------------------|---|-------------|
| Characters | White or almost white crystalline powder | Conforms |
| Identification | TLC UV spectrum IR spectrum | Positive |
| Melting point | 202 ~ 208°C | 202.5~207°C |
| Loss on drying | ≤0.5% | 0.16% |
| Specific rotation | - 30~ - 38° | -34.3° |
| Limit of ethinyl group | 8.18%~8.43% | 8.24% |
| Related substances | total impurities≤1.5% only one impurity≤0.5% | Conforms |
| Solution appearance | clear,and free from undissolved solid | Conforms |
| Assay | 97.0 ~ 102.0% | 98.84% |

Conclusion: The results conform with USP34.



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