

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

CERTIFICATE OF ANALYSIS

Ketoconazol

| | |
|-------------------------------------|--------------------------------|
| Batch No.: DR20130625 | Quantity : 500kg |
| Packing : 25kgs /drum | Specification : USP34 |
| Manufacture Date: 2013.06.25 | Expiry Date: 2016.06.24 |

TESTS:

| Items | Specification | Results |
|---------------------------------|--|-----------------|
| Appearance | white or almost white crystalline powder | Conforms |
| Packaging and storage | Preserve in well-closed containers | Conforms |
| Identification | IR test | Conforms |
| Specific rotation | -1° ~ +1° | 0° |
| Melting range | 148°C~152°C | 148.5°C~150.0°C |
| Loss on drying | ≤0.5% | 0.15% |
| Residue on ignition | ≤0.1% | 0.04% |
| Heavy metals | ≤0.002% | <0.001% |
| Chromatographic purity | Meets the requirements | Conforms |
| Residual Solvents Ethyl acetate | ≤0.5% | 0.42% |
| Assay | 98.0%~102.0% | 99.4% |

Conclusion: The results conform with the USP34.

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