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

## CERTIFICATE OF ANALYSIS

## Ivermectin

| | |
|---|---|
| **Batch No.:** DR20140114 | **Piece:**150kg |
| **Manufacture Date:** 2014.01.14 | **Expiry Date:** 2016.12 |

***TESTS:***

| Items | Specification | Results |
|---|---|---|
| Characteristics | White crystalline powder | White crystalline powder |
| Specific Rotation | -17° ~ -20° | -19° |
| Identification | 1)IR:Infra-red spectrum of the sample should correspond to that of the reference standard<br>2)HPLC:The chromatogram of the assay preparation exhibits major peaks for component H2Bm，the retention times and sizes of which correspond to those exhibited in the chromatogram of the standard preparation | Conforms<br><br>Conforms |
| Appearance of solution | The solution is clear and not more intensely coloured than reference solution BY7 | Conforms |
| Water | ≤ 1.0% | 0.1% |
| Sulfate Ash | ≤ 0.1% | 0.06% |
| Heavy Metals | ≤ 20PPM | <20PPM |
| Limit of Alcohol | ≤ 5.0% | 3.7% |
| Limit of Formamide | ≤ 3.0% | 2.5% |
| Limit of Metbanol | ≤ 3000PPM | 314.7PPM |
| Limit of Toluene | ≤ 890PPM | Conforms |
| Related substance RRT1.3-1.5<br>Impurities atRRT1.3-1.5<br>Individual of all other impurities<br>Total | ≤2.5%<br>≤1%<br>≤ 5% | 2.1%<br>0.52%<br>3.9% |
| Assay | H2B1a+H2B1b：95.0%~102.0%<br>H2B1a/H2B1a+H2B1b：≥90.0% | 97.1%<br>97.2% |
| Conclusion: The results conform with EP8.0 | | |

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