

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

**CERTIFICATE OF ANALYSIS**

**D-Biotin**

|                                     |                                |
|-------------------------------------|--------------------------------|
| <b>Batch No.:</b> DR20131227        | <b>Piece:</b> 90kg             |
| <b>Manufacture Date:</b> 2013.12.27 | <b>Expiry Date:</b> 2016.12.26 |

**TESTS:**

| <b>Items</b>      | <b>Specification</b>                                                                                                                                                                                                                   | <b>Results</b>                         |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Appearance        | White or almost white crystalline Powder                                                                                                                                                                                               | White crystalline Powder               |
| Identification    | IR:match with the reference IR spectrum<br>2)Specific rotation: +89°~ +93°<br>3)Retention time: should be similar to that of the reference solution                                                                                    | Conforms<br>+91°<br>Conforms           |
| Loss on drying    | ≤0.4%                                                                                                                                                                                                                                  | 0.3%                                   |
| Residual solvents | Benzene:≤2PPM<br>Toluene:≤100PPM<br>DMSO:≤5000PPM                                                                                                                                                                                      | <0.2PPM<br><10PPM<br><500PPM           |
| Assay             | 97.5%~100.5%                                                                                                                                                                                                                           | 99.0%                                  |
| Related substance | Any impurity:≤1.0%<br>Total impurities:≤2.0%                                                                                                                                                                                           | 0.27%<br>0.48%                         |
| Microbial test    | Total viable aerobic count:≤1000cfu/g<br>Total yeasts and moulds count:≤100cfu/g<br>Escherichia coli: N,d/1g<br>Staphylococcus aureus: N,d/1g<br>Pseudomonas aeruginosa N,d/1g<br>Enterobacteria: N,d/1g<br>Salmonella species: N,d/1g | N,D<br>N,D<br>N,D<br>N,D<br>N,D<br>N,D |

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Conclusion: The results conform with USP35

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