

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

CERTIFICATE OF ANALYSIS

Reboxetine mesylate (CAS:71620-89-8)

| | |
|-------------------------------------|-----------------------------|
| Batch No.: DR20150129 | Quantity: 1kg |
| Manufacture Date: 2015.01.29 | Expiry Date: 2016.12 |

TESTS:

| Items | Specification | Results |
|-------------------------------|--|-------------|
| Appearances | White or almost white crystalline powder | Conforms |
| Melting range | 146~150°C | 147°C~148°C |
| Identification | 1) Chemical reaction: Positive reaction | Conforms |
| | 2) IR spectrum: should conform to the reference standard | Conforms |
| | 3) UV spectrum: max absorption at wave length of 274nm, min absorption at wave length of 247nm | Conforms |
| Clarity and color of solution | Should Conforms | Conforms |
| Related substance | Individual impurity: ≤0.3% | 0.016% |
| | Total impurities: ≤1.0% | 0.029% |
| Loss on drying | ≤0.5% | 0.06% |
| Residue on ignition | ≤0.3% | 0.04% |
| Heavy metals | ≤10ppm | Conforms |
| Assay | ≥98.5% | 99.3% |

Conclusion: The results conform with CFDA(YBH02392008) standard.



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