# Hangzhou Huarong Pharm Co.,Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.
TEL: 0086-571-86758373 FAX: 0086-571-81131109


## CERTIFICATE OF ANALYSIS

| Product name | Voriconazole | | |
|---|---|---|---|
| Batch No. | 5691-22-010 | Batch Size | 69.34kg |
| Batch Type | Commercial | Report Date | 2022-04-14 |
| Retest Date | 2027-03-07 | Storage Condition | Preserve in an airtight container |
| Manufacture Date | 2022-03-08 | Reference | USP |

| Test | Specification | Results |
|---|---|---|
| Appearance | White to almost white powder | White powder |
| *Solubility | Freely soluble in acetone and methylene chloride, practically insoluble in water. | ------ |
| Identification | 1)The infrared absorption spectrum is concordant with that obtained with Voriconazole reference standard. | Conforms |
| | 2)The retention time of the major peak of the Sample solution corresponds to that of Reference solution (b), as obtained in the test of Enantiomeric purity. | Conforms |
| | * The X-ray diffraction spectrum of the substance corresponds to that of the reference standard. | ---- |
| Water | ≤0.4% | <0.1% |
| Residue on ignition | ≤0.1% | <0.1% |
| Enantiomeric purity (HPLC) | Voriconazole related compound B ≤0.2% | <LOQ |
| Related substances 1(IC) | Voriconazole related compound F ≤0.1% | N.D |
| Related substances 2 (HPLC) | Voriconazole related compound C ≤0.2% | 0.01% |
| | Voriconazole related compound D ≤0.1% | N.D |
| | Any unidentified impurity ≤0.10% | <LOQ |
| | Total impurities(Include related compound B and F) ≤0.5% | 0.01% |
| Assay(HPLC) | 97.5～102.0%(on anhydrous and solvent-free basis) | 100.2% |
| Residual solvents | Methanol≤3000ppm | N.D |
| | Methylene chloride≤600ppm | <LOD |
| | Isopropanol ≤5000ppm | 343ppm |
| | Acetone≤5000ppm | N.D |
| | Tetrahydrofuran≤720ppm | N.D |
| Elemental impurity | Palladium ≤10ppm | <LOD |
| Conclusion | Complies with USP | |

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* X-ray:skip test,perform testing for the validation batches,and then test every ten batches.

*Solubility:The solobility test is skip test which is conducted periodically on first three batches every year and validation batches.