



Certificate of Analysis-Oxytocin

CAS:50-56-6

Batch Number: FTF231211 Batch Quantity: 100g

Manufacture Date: Dec.11th,2023

Analysis Date:Dec.11th,2023

Certificate Date: Dec.11th,2023

Storage 2-8°C, Sealed, sterile, Dry, matte, No radiation, NO harmful substances, Cannot be stored together with food
Shelf life 2 years when properly stored.

| Item | Standard | Test Results | | |
|---|---|---|----------|------|
| Appearance | White or almost white , hygroscopic powder | conforms | | |
| Sequence | Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH ₂ (Cys1&Cys6 bridge) | conforms | | |
| Solubility | Very soluble in water. It dissolves in dilute solutions of acetic acid and of ethanol (96 per cent). | conforms | | |
| HPLC | The principal peak in the chromatogram obtained with the test solution is similar in retention time to principal peak in the chromatogram obtained with the reference solution. | conforms | | |
| Amino acid analysis | Asp | 0.90-1.10 | Asp | 0.95 |
| | Glu | 0.90-1.10 | Glu | 0.98 |
| | Pro | 0.90-1.10 | Pro | 1.02 |
| | Gly | 0.90-1.10 | Gly | 1.03 |
| | Leu | 0.90-1.10 | Leu | 0.97 |
| | Ile | 0.90-1.10 | Ile | 1.01 |
| | Tyr | 0.7-1.05 | Tyr | 0.85 |
| | Half-Cys | 1.40-2.10 | Half-Cys | 1.55 |
| | No more than the traces of the other amino acids are present. | No more than the traces of the other amino acids are present. | | |
| PH | 3.0-6.0 (200mg OT in 10ml Of CO ₂ free water) | 4.6 | | |
| Related Substances | Unspecified impurity for each impurity: NMT1.0% | 0.26%(single largest impurity) | | |
| MS | 1007.2±1.0 | conforms | | |
| Acetic acid | 6.0~10.0% | 8.2% | | |
| Water Content(Karl Fischer) | NMT 5.0% | 4.1% | | |
| Assay(By HPLC) | 93.0~102.0% | 98.7% | | |
| Biological activity (calculated on the basis of 1mg of Oxytocin peptide being equivalent to 600IU of biological activity) | With reference to anhydrous and acetic acid free substance | 519IU/mg | | |
| | As is reference | 522IU/mg | | |
| Specific Optical Rotation | -19.5 to -23.5 (C=0.5%; 1% acetic acid) | -20.12° | | |
| Residual solvent | Methanol NMT 3000ppm ;Acetonitrile NMT 410 ppm;Triethylamine NMT 320 ppm | conforms | | |

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 INSPECTOR: 黄子烨

