

CERTIFICATE OF ANALYSIS

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|--|---|-----------------------|-------------------|
| Product Name: | Oxytocin Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH₂ | | |
| Batch No. | 2309006 | Analyzed on | November 17, 2023 |
| Manufacturing Date | October 26, 2023 | Expiry Date TO | October 25, 2025 |
| Quantity | 312g | CAS No | 50-56-6 |
| Analytical results | | | |
| Items | Specifications | | Results |
| Characteristic | White or almost white powder. | | White powder |
| Identification | A. HPLC :Retention time conforms to that of the reference standard | | Conforms |
| | B.Amino acids : Asp: 0.90-1.10; Glu: 0.90-1.10 Pro: 0.90-1.10; Gly: 0.90-1.10 Leu: 0.90-1.10; Tyr: 0.7-1.05 Half-Cys: 1.4-2.1; Ile: 0.90-1.10 | | Conforms |
| pH | 3.0-6.0 | | 5 |
| Related substances (HPLC) | Impurity A≤1.0% | | 0.19% |
| | Impurity B≤1.0% | | 0.08% |
| | Impurity C≤1.5% | | Less than 0.1% |
| | Other single impurity≤0.5% | | 0.05% |
| | Total impurities≤5.0% | | 0.40% |
| Acetic acid (HPLC) | 6.0%-10.0% | | 7.00% |
| Water(KF) | NMT 5.0% | | 1.30% |
| Bacterial endotoxins | Less than 300 IU/mg | | Conforms |
| AcN(GC) | Not more than 0.041% | | Conforms |
| MeOH(GC) | Not more than 0.3% | | Conforms |
| Triethylamine(GC) | Not more than 0.032% | | Conforms |
| Assay Calculated with reference to anhydrous,acetic acid free substance | 95.0%-102.0% | | 100.80% |
| | On powder | NLT 80.0 % | 92.50% |
| | | NLT 480 IU/mg | 555IU/mg |
| Conclusion | Meets Ph. Eur. 10.0 | | |

Inspector: Carlifor Wu

Verifier: Jack He