**Singapore Hengtai Industrial Co.,Ltd**

**Room 1508, 15/F, Grand Central Office Tower 2, 625 Nathan Road, Mongkok, Hong Kong**

COA No.:25061801

# Certificate of Analysis

| | | | |
|---|---|---|---|
| **Product Name** | HGH 191AA(Somatropin) | **Batch No.** | MKC-250617 |
| **Molecular Formular** | C990H1528N262O300S7 | **Molecular Weight** | 22124.7Da |
| **Mfgt.Date** | 2025-05-29 | **Retest Date** | 2027-05-29 |

| **Tests** | **Acceptance Criteria** | | **Results** |
|---|---|---|---|
| Appearance | White or off-white powder | | White powder |
| Solubility | Can be dissolved to 10mg/mlin pure water | | Conforms |
| Molecular Ion Mass | 22124.7±1 | | Conforms |
| pH | 6.0~9.0(C=10mg/ml) | | 7.6 |
| Purity(HPLC) | >98.0% | | 99.43% |
| Related substances(HPLC) | The largest individual impurity test NMT 1.0% | | 0.55% |
| | The total impurities test NMT 2.0% | | 0.26% |
| Residual solvent(GC) | Methylene chloride | NMT 600ppm | N.D |
| | Acetonitrile | NMT 400ppm | 300ppm |
| | Methanol | NMT 3000ppm | N.D |
| | NN-Dimethylformamide | NMT 890ppm | N.D |
| | Isopropyl ether | NMT 5000ppm | N.D |
| Assay | 80.0%~120.0% | | 92.92% |
| TFA Content | ≤0.500% | | Conforms |
| Bacterial Endotoxins | NMT10 EU/mg | | Conforms |
| Microbial Limits | TAMC | NMT 1000 cfu/g | Conforms |
| | TYMC | NMT100 cfu/g | Conforms |
| | Escherichia Coil presence | Negative | Conforms |
| | Salmonella | Negative | Conforms |
| | P.Aeruginosa | Negative | Conforms |
| | S.Aureus | Negative | Conforms |
| Sodium ion | NMT 3 .0% | | 1.69% |
| Peptide Content(Mass Balance) | NLT 80.0% | | 98.67% |
| Conclusion:conformed with the product standards. | | | |

Storage Conditions: Keep in tight container,protect from light,store at a temperature of 20±5℃.

For and on behalf of
Singapore Hengtai Industrial Co., Limited
新加坡恆泰實業有限公司
Authorized Signature(s)

***For research and expott only***

**INITIATOR:** 王磊 2025-6-12

**REVIEWER:** 石鑫 2025-6-1

For and on behalf of
Singapore Hengtai Industrial Co., Limited
新加坡恆泰實業有限公司
Authorized Signature(s)