

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Somatropin (Recombinant Human Growth Hormone)
- **English Name:** Somatropin
- **CAS Number:** 12629-01-5
- **Formula:** 191 Amino Acid Polypeptide (Native Human GH Sequence)
- **Molecular Weight:** 22125.8 Da
- **Product Characteristics:** High-purity recombinant human growth hormone, white lyophilized powder, odorless, soluble in PBS/saline buffer. Ultra-high biological activity (≥ 3.0 IU/mg) and HPLC purity ($\geq 99.0\%$), ultra-low endotoxin/heavy metal/aggregation content. Exceptional stability at 2-8°C for 36 months, degrades at high temperature/freeze-thaw cycles. Non-combustible, fully biodegradable, non-toxic to the environment. May cause allergic reactions in sensitive individuals; strict GMP-compliant handling required. Suitable for biopharmaceutical R&D and human growth hormone drug development.

2. Technical Specifications (Biopharmaceutical Grade)

Item	Specification
Appearance	White to off-white lyophilized powder
Purity (HPLC)	$\geq 99.0\%$
Biological Activity	≥ 3.0 IU/mg
pH Value (1mg/mL in PBS, 25°C)	6.5-8.5
Moisture Content	$\leq 5.0\%$
Bacterial Endotoxin	≤ 0.5 EU/mg
Sterility	Negative
Heavy Metals (Pb)	≤ 5 ppm
Protein Content	$\geq 95.0\%$
Aggregation (SEC-HPLC)	$\leq 1.0\%$
Amino Acid Sequence	Conforms to native human GH sequence
Identity (ELISA)	Positive
Solubility	Soluble in PBS/0.9% saline buffer
Storage Stability	36 months (2-8°C, sealed, protected from light)
Reconstituted Stability	48 hours (2-8°C, 1mg/mL PBS solution)

3. Product Advantages

1. **Native Sequence & High Activity:** Exact 191 amino acid sequence of native human growth hormone; ≥ 3.0 IU/mg biological activity ensures consistent physiological function as endogenous GH.
2. **Ultra-High Purity & Low Impurities:** $\geq 99\%$ HPLC purity, ≤ 0.5 EU/mg endotoxin, trace heavy metals and aggregation; meets USP/EP/ICH standards for human biopharmaceutical development.
3. **Long-Term Stability:** 36-month shelf life at 2-8°C (the longest among similar products); sucrose as lyoprotectant prevents protein denaturation and aggregation.
4. **Sterile & Apyrogenic:** Sterile (negative) and apyrogenic; no additional sterilization required for in vitro experiments/cell culture and pre-clinical research.
5. **Biodegradable & Eco-Friendly:** Fully biodegradable via protein hydrolysis; non-toxic to aquatic/soil organisms; no environmental pollution risk.
6. **GMP-Compliant Production:** Manufactured under GMP management systems; full traceability of all production steps; consistent batch-to-batch quality.

4. Application Fields

- **Biopharmaceutical R&D:** Human growth hormone drug development, formulation research, potency testing and quality control of somatropin products.
- **In Vitro Diagnostics:** Raw material for GH immunoassay kits (ELISA, chemiluminescence); clinical diagnostic reagent for growth hormone deficiency and acromegaly detection.



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- **Endocrinology Research:** Growth hormone function study, somatotrophic axis research, cell proliferation and differentiation experiment with GH-responsive cells.
 - **Pre-Clinical Research:** Animal model research for growth hormone deficiency; efficacy and safety evaluation of somatotropin formulations.
 - **Academic Research:** Peptide hormone structure-activity relationship study, recombinant protein expression and purification research, hormone receptor signaling pathway study.
- ## 5. Usage Methods
- **Reconstitution:** Add sterile PBS/0.9% physiological saline buffer to the lyophilized powder to prepare 1mg/mL stock solution; gently swirl (do not vortex) to dissolve completely (avoid foam/protein denaturation).
 - **Stock Solution Storage:** 1mg/mL stock solution stored at 2-8°C for ≤48h; aliquot and freeze at -20°C for long-term use (avoid repeated freeze-thaw cycles).
 - **Working Concentration:** Dilute stock solution with appropriate buffer (PBS, HEPES) to working concentration (0.001-1 µg/mL, adjust according to experiment/cell model).
 - **Optimal Conditions:** Use sterile GMP-compliant technique for all operations; perform experiments at 37°C for cell culture/25°C for in vitro assays; use neutral buffer (pH6.5-8.5) to maintain protein stability; discard unused reconstituted solution after 48h.
- ## 6. Packaging & Storage
- **Packaging Specifications:** 1mg/vial, 5mg/vial, 10mg/vial, 50mg/vial (sterile GMP-compliant glass vials with rubber stoppers and aluminum crimp seals); customized packaging (100mg-1g) available upon request.
 - **Storage Conditions: 2-8°C (refrigerated),** dark, sealed, protected from light and moisture; avoid freeze-thaw cycles, high temperature (>37°C) and room temperature storage; store in a dedicated GMP-compliant biological reagent refrigerator.
 - **Shelf Life:** 36 months (unopened, 2-8°C); 48 hours (reconstituted 1mg/mL PBS solution, 2-8°C); 12 months (aliquoted stock solution, -20°C, avoid repeated freeze-thaw).
 - **Transportation:** UN 3373 (Biological Substance, Category B); **refrigerated transport (2-8°C)** with insulated GMP-compliant packaging and ice packs; use cold chain express delivery with temperature monitoring; avoid freeze-thaw and direct sunlight during transport.
- ## 7. Safety & Protection
- **Mandatory PPE:** Wear nitrile gloves, N95 dust mask, chemical splash goggles and GMP-compliant lab coat for all handling; use face shield and sterile gloves for powder weighing/reconstitution.
 - **Handling Precautions:** Operate in a clean, GMP-compliant, well-ventilated lab/dust-free workbench; avoid dust generation/inhalation/skin/eye contact; use sterile technique for reconstitution; no eating/drinking/smoking in work area.
 - **Allergy Prevention:** Sensitive individuals (to recombinant proteins/polypeptides) should avoid contact; keep antihistamine/bronchodilator available in the lab for emergency use.
 - **Emergency Measures:** Rinse eyes with plenty of water for 15-20 minutes and consult a doctor if contact occurs; wash skin with soap and water for 10 minutes if irritation/rash occurs; seek medical attention immediately for respiratory allergy symptoms.
- ## 8. Quality Assurance
- Manufactured under ISO 9001, GMP and ICH Q7 management systems; strict raw material inspection, recombinant expression control and purification process validation.
 - Each batch is tested for purity, biological activity, endotoxin, sterility, amino acid sequence and identity; accompanied by a Certificate of Analysis (COA) complying with USP/EP/ICH standards.
 - All raw materials are sourced from GMP/ISO-certified suppliers; full traceability of production, testing, packaging and shipping records for all batches.
 - Provide professional technical support: reconstitution guidance, buffer selection, cell culture protocol optimization and pre-clinical research design; custom expression/purification service for modified somatotropin variants available.
 - Comply with international regulations (REACH, TSCA, IATA, FDA); complete product certification and testing reports (including mass spectrometry/amino acid sequence analysis) available upon request; GMP audit support provided for drug development projects.