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Technical Data Sheet (TDS)

1. Product Overview

- **Product Name**: Recombinant Human Growth Hormone (重组人类生长激素，rHGH)
- **CAS Number**: 9002-72-6
- **Formula**: $C_{990}H_{1528}N_{262}O_{300}S_7$
- **Formula Weight**: 22124.77 g/mol
- **Molecular Form**: Recombinant polypeptide hormone (191 amino acid residues, identical to native human growth hormone)
- **Product Characteristics**: High-purity pharmaceutical GMP grade Recombinant Human Growth Hormone is produced via genetic engineering (E. coli/CHO cell expression), with identical amino acid sequence and biological activity to native human growth hormone. Odorless white lyophilized powder, soluble in neutral aqueous solutions, very highly hygroscopic and stable only under ultra-low temperature dry storage. Potent anabolic and growth-promoting effects by regulating protein/carbohydrate/lipid metabolism, FDA/EMA approved for pediatric/adult growth hormone deficiency, short stature and growth disorder treatment. Core raw material for injectable recombinant growth hormone pharmaceutical formulations, with high bioavailability and no immunogenicity (identical to native HGH).

2. Technical Specifications (CP/USP/EP/FDA Compliant, GMP Grade)

Item	Specification (Pharmaceutical Grade)
Appearance	White to off-white odorless lyophilized powder
Assay (Potency, dry basis)	≥ 3.0 IU/mg (Biological Assay)
Peptide Purity (Main Peak)	≥ 99.0% (RP-HPLC)
Loss on Drying (60℃, vacuum)	≤ 1.0%
Residue on Ignition	≤ 0.1% (600℃±50℃)
Heavy Metals (Pb)	≤ 2 ppm (AAS)
Heavy Metals (As)	≤ 0.5 ppm (AFS)
Related Peptides	≤ 1.0% (RP-HPLC)
Water Content	≤ 1.0% (Karl Fischer Titration)
Bacterial Endotoxins	≤ 0.05 EU/μg (LAL Test)
Protein Homogeneity	≥ 99.0% (SEC)
Host Cell Protein Residue	≤ 10 ppm (ELISA)
Plasmid DNA Residue	≤ 10 pg/mg (Real-Time PCR)
Residual Solvents	Meets USP <467> Class 1/2/3 limits (GC)
Total Aerobic Count	≤ 5 CFU/g
Pathogens (E. coli/Staph. aureus/Salmonella)	Negative
Solubility	Soluble in water (pH 5.5-7.5), dilute phosphate buffer
Particle Size	200-300 mesh (lyophilized powder)
pH Value (1mg/mL aqueous)	6.0-7.0 (25℃)

Item	Specification (Pharmaceutical Grade)
Hygroscopy	Very high (stable at RH ≤30%)
Cold Chain Stability	48 months at -80℃ (vacuum); 3 days at 2-8℃ (after opening)

3. Product Advantages

1. **Recombinant Native Sequence**: Identical amino acid sequence to native human growth hormone; no immunogenicity, high bioavailability and biological potency.
2. **High Purity GMP Grade**: ≥99.0% RP-HPLC purity, ≥3.0 IU/mg biological potency, ultra-low host cell protein/DNA residue; meets global pharmacopoeia (CP/USP/EP/FDA) and recombinant biological product standards; GMP compliant.
3. **Potent Anabolic/Growth-Promoting Effect**: Regulates protein synthesis, carbohydrate/lipid metabolism and cell proliferation; effective for growth hormone deficiency, short stature and growth disorder treatment in pediatric/adult patients.
4. **Excellent Physiochemical Properties**: Soluble in neutral aqueous solutions (easy formulation); lyophilized powder for ultra-long-term ultra-low temperature storage; stable under recommended conditions.
5. **Low Toxicity Profile**: No skin irritation; minimal systemic toxicity at therapeutic dosages; only rare allergic reaction risk in hypersensitive individuals.
6. **Biodegradable**: Hydrolyzes to non-toxic amino acids in vivo/environment; no toxic metabolites; environmentally friendly.

4. Application Fields

- **Pharmaceutical Industry**: Production of subcutaneous/intramuscular injectable rHGH formulations (vials/cartridges/pen) for pediatric/adult growth hormone deficiency, idiopathic short stature, Turner syndrome and Prader-Willi syndrome treatment; FDA/EMA approved clinical recombinant biological product raw material.
- **Biomedical Research**: Research reagent for growth hormone pharmacology, somatotrope research, growth disorder drug development; cell culture supplement for growth hormone-dependent cell lines (e.g., chondrocytes, myoblasts).
- **Biotechnology**: Core material for growth hormone analog modification research; hormone assay standard reference material; growth disorder animal model research; recombinant protein expression technology development.

5. Usage Methods

- **Pharmaceutical Formulation (GMP Grade)**: Used as active pharmaceutical ingredient (API); formulate into injectable solution (4 IU/10 IU/16 IU per vial) with excipients (mannitol, glycine, phosphate buffer, water for injection); adjust pH to 6.0-7.0 for solubility; lyophilized for ultra-long-term storage.
- **Research Use (Lab Grade)**: 0.001-1 μM concentration for in vitro cell experiments; 0.1-1 IU/kg body weight for in vivo animal experiments; dissolve in sterile phosphate-buffered saline (PBS,