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

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: Insulin (Recombinant Human Insulin)
- English Name: Insulin
- CAS Number: 11061-68-0
- Formula: Recombinant Human Insulin (51 Amino Acids, native human pancreatic hormone sequence)
- Molecular Weight: 5807.6 Da
- Product Characteristics: High-purity recombinant human insulin, white lyophilized powder, odorless, soluble in PBS/neutral buffer. High biological activity (≥27.0 IU/mg) and HPLC purity (≥98.5%), ultra-low endotoxin/heavy metal/aggregation content. Excellent stability at 2-8℃ 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 diabetes drug development.

2. Technical Specifications (Biopharmaceutical Grade)

Item	Specification
Appearance	White to off-white lyophilized powder
Purity (HPLC)	≥ 98.5%
Biological Activity	≥ 27.0 IU/mg
pH Value (1mg/mL in PBS, 25℃)	6.5-7.5
Moisture Content	≤ 3.0%
Bacterial Endotoxin	≤ 0.5 EU/mg
Sterility	Negative
Heavy Metals (Pb)	≤ 5 ppm
Protein Content	≥ 97.0%
Amino Acid Sequence	Conforms to native human insulin sequence
Aggregation (SEC-HPLC)	≤ 0.8%
Solubility	Soluble in PBS/neutral buffer (pH6.5-7.5)
Storage Stability	36 months (2-8℃, sealed, protected from light)
Reconstituted Stability	72 hours (2-8℃, 1mg/mL PBS solution)

3. Product Advantages

1. Native Human Sequence & Physiological Activity: Exact 51 amino acid sequence of native human pancreatic insulin; ≥27.0 IU/mg biological activity ensures consistent physiological blood glucose regulation function, matching endogenous insulin action.
2. High Purity & Low Impurities: ≥98.5% HPLC purity, ≤0.5 EU/mg endotoxin, trace heavy metals and low aggregation (<0.8%); meets USP/EP/ICH biopharmaceutical standards for human drug development and clinical research.
3. Long-Term GMP Stability: 36-month shelf life at 2-8℃; glycine as lyoprotectant/stabilizer effectively prevents protein denaturation and aggregation, maintaining high activity during long-term storage.
4. Sterile & Apyrogenic: Sterile (negative) and apyrogenic; no additional sterilization required for in vitro experiments/cell culture, pre-clinical research and formulation development.
5. Biodegradable & Eco-Friendly: Fully biodegradable via protein hydrolysis by natural enzymes; non-toxic to aquatic/soil organisms; no environmental pollution, complying with global environmental protection requirements.
6. GMP-Compliant & Traceable: Manufactured under GMP and ISO 9001 management systems; full traceability of all production and testing steps; consistent batch-to-batch quality for reliable experimental and development results.

4. Application Fields

- Biopharmaceutical R&D: Human insulin drug development, formulation research, potency testing and quality control of insulin products for diabetes treatment.
- In Vitro Diagnostics: Raw material for insulin immunoassay kits (ELISA, chemiluminescence); clinical diagnostic reagent for diabetes, insulin deficiency and insulin resistance detection.
- Diabetes Research: Physiological blood glucose regulation study, pancreatic islet cell function research, animal model experiment for type 1/2 diabetes fundamental research.
- Pharmaceutical Formulation: Pre-formulation research for injectable human insulin preparations; excipient compatibility, stability testing and formulation optimization for diabetes treatment drugs.
- Academic Research: Peptide hormone structure-activity relationship study, recombinant human insulin expression/purification technology research, insulin receptor signaling pathway and diabetes pathogenesis study.

5. Usage Methods

- Reconstitution: Add sterile PBS/0.9% physiological saline buffer (pH6.5-7.5) to the lyophilized powder to prepare 1mg/mL stock solution; gently swirl along the vial wall (do not vortex) to dissolve completely (avoid foam and protein denaturation).
- Stock Solution Storage: 1mg/mL stock solution stored at 2-8℃ for ≤72h; aliquot into sterile centrifuge tubes and freeze at -20℃ for long-term use (avoid repeated freeze-thaw cycles to prevent activity loss and aggregation).
- Working Concentration: Dilute the stock solution with appropriate biological buffer (PBS, HEPES, MES) to the required working concentration (0.001-5 μg/mL) according to experimental purposes, cell models and research designs.

6. Packaging & Storage

- Packaging Specifications: 1mg/vial, 5mg/vial, 10mg/vial, 50mg/vial (sterile GMP-compliant neutral glass vials with medical rubber stoppers and aluminum crimp seals); customized packaging specifications (100mg-1g) available upon request for large-scale R&D and pre-clinical projects.
- Storage Conditions: **2-8℃ refrigerated storage**, dark, sealed, protected from light and moisture; avoid freeze-thaw cycles, high temperature (>37℃) and long-term room temperature storage; store in a dedicated GMP-compliant biological reagent refrigerator with constant temperature control and temperature recording.

7. Safety & Protection

- Mandatory PPE: Wear sterile nitrile gloves, N95 dust mask, chemical splash goggles and GMP-compliant lab coat for all product handling; use a face shield and sterile disposable gloves for powder weighing and reconstitution operations to prevent direct contact and cross-contamination.
- Handling Precautions: Operate in a clean, GMP-compliant, well-ventilated lab or dust-free clean bench; avoid dust generation, inhalation and direct skin/eye contact; strictly follow sterile operation norms for reconstitution; no eating, drinking or smoking in the working area to prevent product contamination.

8. Quality Assurance

- The product is manufactured in strict accordance with ISO 9001 quality management system, GMP pharmaceutical production specifications and ICH Q7 guidelines; strict raw material inspection, recombinant expression process control and multi-step high-purity purification process validation are implemented to ensure product quality.
- Each batch of products undergoes comprehensive quality testing including purity, biological activity, endotoxin, sterility, amino acid sequence and aggregation content; each batch is accompanied by a Certificate of Analysis (COA) that complies with USP/EP/ICH international biopharmaceutical standards.
- All raw materials and auxiliary materials are sourced from qualified suppliers with GMP/ISO certification; the whole process of production, testing, packaging and shipping has complete traceability records to realize full life cycle quality tracking.