

## Technical Data Sheet (TDS)

### 1. Product Overview

- **Product Name:** Insulin Glargine
- **English Name:** Insulin Glargine
- **CAS Number:** 113102-64-0
- **Formula:** Long-Acting Recombinant Insulin Analogue (51 Amino Acids, Lys<sup>6</sup>, Arg<sup>6</sup> human insulin variant)
- **Molecular Weight:** 6063.9 Da
- **Product Characteristics:** High-purity long-acting recombinant insulin analogue, white lyophilized powder, odorless, soluble in PBS/neutral buffer. Ultra-high biological activity ( $\geq 27.5$  IU/mg) and HPLC purity ( $\geq 99\%$ ), 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 long-acting diabetes drug development.

### 2. Technical Specifications (Biopharmaceutical Grade)

Item	Specification
Appearance	White to off-white lyophilized powder
Purity (HPLC)	$\geq 99.0\%$
Biological Activity	$\geq 27.5$ IU/mg
pH Value (1mg/mL in PBS, 25°C)	7.0-8.0
Moisture Content	$\leq 3.0\%$
Bacterial Endotoxin	$\leq 0.5$ EU/mg
Sterility	Negative
Heavy Metals (Pb)	$\leq 5$ ppm
Protein Content	$\geq 98.0\%$
Amino Acid Sequence	Conforms to insulin glargine sequence
Aggregation (SEC-HPLC)	$\leq 0.5\%$
Solubility	Soluble in PBS/neutral buffer (pH7.0-8.0)
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 Analogue & High Activity:** Exact standard insulin glargine amino acid sequence;  $\geq 27.5$  IU/mg biological activity ensures consistent long-acting blood glucose regulation function.
2. **Ultra-High Purity & Ultra-Low Impurities:**  $\geq 99\%$  HPLC purity,  $\leq 0.5$  EU/mg endotoxin, trace heavy metals and aggregation ( $< 0.5\%$ ); meets USP/EP/ICH standards for human biopharmaceutical development.

- 3. Long-Term GMP Stability:** 36-month shelf life at 2-8°C; glycine as dual lyoprotectant/stabilizer prevents protein denaturation, aggregation and activity loss.
- 4. Sterile & Apyrogenic:** Sterile (negative) and apyrogenic; no additional sterilization required for in vitro experiments/cell culture and pre-clinical diabetes 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 and ISO 9001 management systems; full traceability of all production steps; consistent batch-to-batch quality for drug development.

#### 4. Application Fields

- **Biopharmaceutical R&D:** Long-acting insulin drug development, formulation research, potency testing and quality control of insulin glargine products.
- **In Vitro Diagnostics:** Raw material for insulin immunoassay kits (ELISA, chemiluminescence); clinical diagnostic reagent for diabetes and insulin resistance detection.
- **Diabetes Research:** Long-acting blood glucose regulation study, insulin receptor interaction research, animal model experiment for type 1/2 diabetes.
- **Pharmaceutical Formulation:** Pre-formulation research for injectable insulin glargine preparations; excipient compatibility and stability testing for long-acting formulations.
- **Academic Research:** Peptide hormone analogue structure-activity relationship study, recombinant insulin expression/purification research, diabetes treatment mechanism study.

#### 5. Usage Methods

- **Reconstitution:** Add sterile PBS/0.9% saline buffer (pH7.0-8.0) 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 (0.001-2 µg/mL, adjust according to experiment/cell model).
- **Optimal Conditions:** Use sterile GMP-compliant technique for all operations; perform cell culture experiments at 37°C/5% CO<sub>2</sub>; use neutral buffer (pH7.0-8.0) 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.



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- **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 sterile nitrile gloves, N95 dust mask, chemical splash goggles and GMP lab coat for all handling; use face shield and sterile latex 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 GMP work area.
- **Allergy Prevention:** Sensitive individuals (to recombinant insulin/proteins) 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, diabetes model protocol optimization and data analysis; custom expression/purification service for modified insulin analogues 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 diabetes drug development projects.