

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Porcine Insulin (猪胰岛素)
- **CAS Number:** 12584-58-6
- **Formula:** C₂₅₇ H₃₈₃ N₆₅ O₇₇ S₆
- **Formula Weight:** 5778.69 g/mol
- **Molecular Form:** Natural polypeptide pancreatic hormone (51 amino acid residues)
- **Product Characteristics:** High-purity pharmaceutical GMP grade Porcine Insulin is a natural pancreatic hormone extracted and purified from porcine pancreas, with identical biological activity to human insulin (single amino acid difference). Odorless white lyophilized powder, soluble in acidic aqueous solutions, highly hygroscopic and stable under ultra-low temperature dry storage. Potent hypoglycemic effect by regulating glucose metabolism, FDA/EMA approved for type 1/2 diabetes treatment. Core raw material for injectable insulin pharmaceutical formulations, with high bioavailability and low immunogenicity.

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)	≥ 26.0 IU/mg (Biological Assay)
Peptide Purity (Main Peak)	≥ 99.0% (RP-HPLC)
Loss on Drying (60°C, vacuum)	≤ 1.0%
Residue on Ignition	≤ 0.1% (600°C±50°C)
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	≤ 0.1 EU/μg (LAL Test)
Insulin Monomer/Dimer	≤ 5.0% (SEC)
Residual Solvents	Meets USP <467> Class 1/2/3 limits (GC)
Total Aerobic Count	≤ 10 CFU/g
Pathogens (E. coli/Staph. aureus)	Negative
Solubility	Soluble in acidic water (pH 2.5-3.5), dilute HCl
Particle Size	200-300 mesh (lyophilized powder)
pH Value (1mg/mL suspension)	5.0-7.0 (25°C)
Hygroscopy	High (stable at RH ≤40%)
Cold Chain Stability	36 months at -20°C (vacuum); 7 days at 4°C (after opening)

3. Product Advantages

1. **High Purity GMP Grade:** ≥99.0% RP-HPLC purity, ≥26.0 IU/mg biological potency, meets global pharmacopoeia (CP/USP/EP/FDA) standards; GMP compliant for pharmaceutical formulation.
2. **Natural Polypeptide Hormone:** Extracted and purified from porcine pancreas, identical biological activity to human insulin; low immunogenicity and high bioavailability.
3. **Potent Hypoglycemic Effect:** Regulates glucose uptake and metabolism in liver/muscle/adipose tissue; rapid and sustained hypoglycemic effect for diabetes treatment.
4. **Excellent Physicochemical Properties:** Soluble in acidic aqueous solutions (easy formulation); lyophilized powder for long-term cold chain storage; stable under recommended conditions.
5. **Low Toxicity Profile:** No skin irritation; minimal systemic toxicity at therapeutic dosages; only mild allergic reaction risk in insulin-sensitive individuals.
6. **Biodegradable:** Hydrolyzes to non-toxic amino acids in vivo/environment; no toxic metabolites; environmentally friendly.

4. Application Fields



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- **Pharmaceutical Industry:** Production of subcutaneous/intramuscular injectable insulin formulations (vials/cartridges/pen) for type 1/2 diabetes mellitus treatment; FDA/EMA approved clinical drug raw material.
- **Biomedical Research:** Research reagent for insulin pharmacology, glucose metabolism research, diabetes drug development; cell culture supplement for insulin-dependent cell lines.
- **Biotechnology:** Core material for insulin analog modification research; hormone assay standard reference material; diabetes animal model research.

5. Usage Methods

- **Pharmaceutical Formulation (GMP Grade):** Used as active pharmaceutical ingredient (API); formulate into injectable solution (100 IU/mL) with excipients (zinc chloride, sodium chloride, hydrochloric acid, water for injection); adjust pH to 2.5-3.5 for solubility; lyophilized for long-term storage.
- **Research Use (Lab Grade):** 0.01-10 μM concentration for in vitro cell experiments; 1-10 IU/kg body weight for in vivo animal experiments; dissolve in 0.01 M HCl to prepare stock solution (store at -20°C , avoid repeated freeze-thaw).
- **Critical Notes:**
 1. Raw powder **for pharmaceutical use only under GMP conditions**; no direct human use (unformulated).
 2. Strict cold chain storage/transport ($-20^{\circ}\text{C}\pm 5^{\circ}\text{C}$); avoid moisture (RH >40%) and repeated freeze-thaw.
 3. Formulated products for subcutaneous/intramuscular injection only; monitor blood glucose for dosage adjustment; avoid use in insulin-allergic individuals.

6. Packaging & Storage

Packaging Specifications (Moisture-Proof/Vacuum/Cold Chain)

- 100 IU/vial (pharmaceutical GMP grade, vacuum-sealed glass vial, anhydrous desiccant, aluminum crimp seal)
- 1000 IU/vial (research grade, vacuum-sealed glass vial)
- 10,000 IU/vial (bulk pharmaceutical grade, vacuum-sealed glass vial)
- Custom packaging (10 IU/50 IU) for research/small-batch orders (sterile vacuum vials)
- All packaging with **cold chain label** and moisture-proof seal; secondary packaging with styrofoam cooler (dry ice for transport).

Storage Conditions (Strict Cold Chain)

- **Long-term Storage:** $-20^{\circ}\text{C}\pm 5^{\circ}\text{C}$, dry, dark, **vacuum-sealed**; RH $\leq 40\%$; store in dedicated polypeptide ultra-low temperature freezer.
- **Short-term Storage:** $4^{\circ}\text{C}\pm 2^{\circ}\text{C}$ (refrigerated), up to 7 days after opening; keep sealed with anhydrous desiccant.
- **Avoid:** Room temperature storage ($>25^{\circ}\text{C}$), moisture (RH >40%), repeated freeze-thaw, direct sunlight, contact with water/enzymes/strong acids/bases/heavy metals.

7. Safety & Protection

- The product is **harmful if swallowed**, causes serious eye irritation and may trigger allergic skin reactions in insulin-sensitive individuals; hypoglycemia risk if systemic exposure.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, powder-free nitrile gloves ($\geq 0.18\text{mm}$), disposable clean lab coat.
- Operate in a **low-humidity clean room (RH $\leq 40\%$)**; use dry sterile equipment; avoid dust generation/inhalation and eye contact; identify insulin-allergic personnel before operation.
- Do not eat/drink/smoke in the work area; wash hands with water after handling; avoid parenteral contact (injection) to prevent hypoglycemia.

8. Quality Assurance

- Manufactured in accordance with **GMP (Good Manufacturing Practice)**, **ISO 9001 (Quality)** and **ISO 14001 (Environment)** standards.
- Each batch is tested by an independent third-party laboratory and accompanied by a **Certificate of Analysis (COA)** with full potency/purity test data.