

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Liraglutide (利拉格鲁肽)
- **CAS Number:** 204656-20-2
- **Formula:** C₁₇ H₂₆ N₅ O₅
- **Formula Weight:** 3751.20 g/mol
- **Molecular Form:** Synthetic GLP-1 (glucagon-like peptide-1) receptor agonist peptide
- **Product Characteristics:** High-purity pharmaceutical GMP grade Liraglutide is a long-acting GLP-1 analog with fatty acid acylation modification, featuring potent glucose-lowering, weight management and cardioprotective effects. Odorless white amorphous lyophilized powder, soluble in water (pH 4.0-7.0), highly hygroscopic and stable under ultra-low temperature dry storage. Long plasma half-life (≈13 hours) via subcutaneous injection, minimal systemic toxicity at therapeutic dosages, FDA/EMA approved for type 2 diabetes mellitus (T2DM) and weight management. Core raw material for injectable anti-diabetic/weight control pharmaceutical formulations.

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

Item	Specification (Pharmaceutical Grade)
Appearance	White to off-white odorless amorphous lyophilized powder
Assay (Purity, on dry basis)	≥ 99.0% (RP-HPLC)
Peptide Content (280nm)	≥ 98.5% (UV-Vis Spectrophotometry)
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)
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 water (pH 4.0-7.0), DMSO
Particle Size	200-300 mesh (lyophilized powder)
pH Value (1mg/mL aqueous)	5.0-7.0 (25°C)
Hygroscopy	High (stable at RH ≤40%)
Cold Chain Stability	24 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, low related peptides/impurities, meets global pharmacopoeia (CP/USP/EP/FDA) standards; GMP compliant for pharmaceutical formulation.
2. **Long-Acting GLP-1 Agonist:** Fatty acid acylation modification extends plasma half-life (≈13h), subcutaneous injection once daily, high patient compliance.
3. **Multi-Therapeutic Effects:** Potent glucose-lowering, weight management and cardioprotective effects; approved for T2DM and weight control in clinical practice.
4. **Excellent Physicochemical Properties:** Water-soluble (no organic solvent needed for formulation); lyophilized powder for long-term cold chain storage; low immunogenicity.
5. **Low Toxicity Profile:** No skin irritation/sensitization; minimal systemic toxicity at therapeutic dosages; only mild gastrointestinal side effects (clinical).
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 injectable pen/cartridge formulations for T2DM treatment and weight management; FDA/EMA approved clinical drug raw material.
- **Biomedical Research:** Research reagent for GLP-1 receptor pharmacology; diabetes/obesity drug development; peptide modification and formulation research.
- **Biotechnology:** Core material for GLP-1 analog screening; cell culture research (glucose metabolism regulation); peptide drug delivery system development.

5. Usage Methods

- **Pharmaceutical Formulation (GMP Grade):** Used as active pharmaceutical ingredient (API); formulate into injectable solution (0.6mg/1.2mg/1.8mg per dose) with excipients (mannitol, citric acid, sodium citrate, water for injection); lyophilized for pen/cartridge filling (cold chain storage required).
- **Research Use (Lab Grade):** 0.001-10 μM concentration for in vitro cell experiments; 0.1-10 mg/kg body weight for in vivo animal experiments; dissolve in sterile water (pH 5.0-7.0) 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 injection only; no oral use (peptide is degraded by gastrointestinal proteases).

6. Packaging & Storage

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

- 10 mg/vial (pharmaceutical GMP grade, vacuum-sealed glass vial, anhydrous desiccant, aluminum crimp seal)
- 50 mg/vial (research grade, vacuum-sealed glass vial)
- 100 mg/vial (bulk pharmaceutical grade, vacuum-sealed glass vial)
- Custom packaging (1mg/5mg) 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 peptide 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.

7. Safety & Protection

- The product is **harmful if swallowed** and causes serious eye irritation; no skin irritation/sensitization; low inhalation risk (low dustiness of lyophilized powder).
- **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.
- Do not eat/drink/smoke in the work area; wash hands with water after handling; no special skin protection (peptide is skin-inert).

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 test data.
- Provide **pharmacopoeial compliance documents** (CP/USP/EP/FDA) and hazardous chemical safety certificates for pharmaceutical grade products.