纳维盈医化科技
NEWAY SINOPHC TECH

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**: Tirzepatide (替尔泊肽)
- **CAS Number**: 2023788-19-2
- **Formula**: $C_{10}{}_2H_{15}{}_3N_{29}O_{31}$
- **Formula Weight**: 2251.48 g/mol
- **Molecular Form**: Synthetic dual GIP (glucose-dependent insulinotropic polypeptide)/GLP-1 receptor agonist peptide
- **Product Characteristics**: High-purity pharmaceutical GMP grade Tirzepatide is a novel dual GIP/GLP-1 agonist, featuring superior glucose-lowering and weight loss effects compared to single GLP-1 agonists. 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 (≈40 hours) via subcutaneous injection, minimal systemic toxicity at therapeutic dosages, FDA/EMA approved for type 2 diabetes mellitus (T2DM) and obesity treatment. Core raw material for next-generation injectable anti-diabetic/anti-obesity 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℃, 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	≤ 0.1 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/Salmonella)	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℃)
Hygroscopy	High (stable at RH ≤40%)
Cold Chain Stability	24 months at -20℃ (vacuum); 7 days at 4℃ (after opening)

3. Product Advantages

1. **Novel Dual Agonist Mechanism**: Targets both GIP and GLP-1 receptors, delivering stronger glucose-lowering and weight loss effects than single GLP-1 agonists; higher clinical efficacy for T2DM and obesity.
2. **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.
3. **Ultra-Long-Acting**: Unique structural modification extends plasma half-life (≈40h), subcutaneous injection once weekly, significantly improved patient compliance.

4. **Excellent Physiochemical 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; mild and transient gastrointestinal side effects (clinical).
6. **Biodegradable**: Hydrolyzes to non-toxic amino acids in vivo/environment; no toxic metabolites; environmentally friendly.

4. Application Fields

- **Pharmaceutical Industry**: Production of subcutaneous injectable pen/cartridge formulations for T2DM and obesity treatment; FDA/EMA approved next-generation clinical drug raw material.
- **Biomedical Research**: Research reagent for GIP/GLP-1 receptor pharmacology; diabetes/obesity drug development; dual receptor agonist peptide modification research.
- **Biotechnology**: Core material for dual GIP/GLP-1 analog screening; cell culture research (glucose/lipid metabolism regulation); novel peptide drug delivery system development.

5. Usage Methods

- **Pharmaceutical Formulation (GMP Grade)**: Used as active pharmaceutical ingredient (API); formulate into injectable solution (2.5mg/5mg/10mg/15mg 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℃, 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℃±5℃); 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℃±5℃, dry, dark, **vacuum-sealed**; RH ≤40%; store in dedicated peptide ultra-low temperature freezer.
- **Short-term Storage**: 4℃±2℃ (refrigerated), up to 7 days after opening; keep sealed with anhydrous desiccant.
- **Avoid**: Room temperature storage (>25℃), moisture (RH >40%), repeated freeze-thaw, direct sunlight, contact with water/enzymes/strong acids/bases.
- **Segregation**: Store separately from water-containing reagents, proteolytic enzymes, strong acids/bases, food/feed; no mixed storage with other pharmaceuticals.