纳维盈医化科技
NEWAY SINOPHC TECH

NEWAY SINOPHC TECH. LIMITED

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Technical Data Sheet (TDS)

1. Product Overview

- **Product Name**: Semaglutide (司美格鲁肽)
- **CAS Number**: 910463-68-2
- **Formula**: $C_{187}H_{279}N_{47}O_{53}$
- **Formula Weight**: 4113.57 g/mol
- **Product Characteristics**: High-purity synthetic glucagon-like peptide-1 (GLP-1) receptor agonist peptide, a long-acting anti-diabetic/anti-obesity pharmaceutical raw material (FDA/EMA approved). White odorless amorphous lyophilized powder, soluble in water (pH 4.0-7.0), highly hygroscopic, stable under ultra-low temperature dry storage. Pharmaceutical grade (GMP) meets CP/USP/EP/FDA standards, with potent glucose-lowering, weight-loss and cardioprotective effects; long half-life (≈7 days) via subcutaneous injection, minimal systemic toxicity at therapeutic dosages. Core raw material for injectable anti-diabetic/anti-obesity drugs (pen/injection formulation).

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)
HPLC Main Peak Purity	≥ 99.0% (RP-HPLC)
Related Peptides	≤ 1.0% (RP-HPLC)
Water Content (Karl Fischer)	≤ 1.0%
Bacterial Endotoxins	≤ 0.1 EU/μg (LAL Test)
Residual Solvents	Meets USP <467> Class 1/2/3 limits (GC)
Microbial Limit	Total Aerobic Count ≤10 CFU/g; Yeast/Mold ≤1 CFU/g
Pathogens	E. coli/Staphylococcus aureus/Salmonella: Negative
Solubility	Soluble in water (1mg/mL, pH 5.0-7.0); soluble in 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. **High Purity GMP Grade**: ≥99.0% 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**: Unique fatty acid acylation modification, long plasma half-life (≈7 days), subcutaneous injection once weekly, high patient compliance.
3. **Multi-Therapeutic Effects**: Potent glucose-lowering, weight-loss and cardioprotective effects; approved for type 2 diabetes and obesity treatment (human clinical).
4. **Excellent Physiochemical Properties**: Soluble in water (no organic solvent needed for formulation); lyophilized powder for long-term cold chain storage.
5. **Low Toxicity Profile**: No skin irritation, non-sensitizing; 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

- **Pharmaceutical Industry**: Production of subcutaneous injectable pen/cartridge formulations for type 2 diabetes mellitus (T2DM) and obesity treatment; 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 (0.25mg/0.5mg/1mg per dose) with excipients (mannitol, citric acid, sodium citrate, water for injection); lyophilized for pen/cartridge filling (cold chain storage).
- **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 repeated freeze-thaw and moisture (RH >40%).
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.
- **Segregation**: Store separately from water-containing reagents, proteolytic enzymes, strong acids/bases, food/feed; no mixed storage with other pharmaceuticals.

7. Safety & Protection

- The product is **harmful if swallowed** and causes serious eye irritation; no skin irritation/sensitization; low inhalation risk (low dustiness).
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, powder-free nitrile gloves (≥0.18mm), disposable clean lab coat.
- Operate in a **low-humidity clean room (RH ≤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).