Technical Data Sheet (TDS) - Denosumab

Revision Date: 22 FEB 2026**Product Name**: Denosumab 得诺单抗**CAS Number**: 821213-18-7**Formula**: $C_{6\ 40\ 8}H_{9\ 9\ 12}N_{17\ 20}O_{20\ 0\ 4}S_{48}$ **Molecular Weight**: ~146.0 kDa (Fully human monoclonal antibody)

1. Product Overview

Denosumab is a high-purity pharmaceutical-grade **fully human monoclonal antibody (mAb)** targeting receptor activator of nuclear factor kappa-B ligand (RANKL), a core biopharmaceutical raw material for clinical bone metabolism regulation and anti-bone tumor preparations. It exerts therapeutic effects by specifically binding to RANKL, blocking the RANKL-RANK signaling pathway, inhibiting osteoclast formation, activation and survival, and thereby reducing bone resorption and increasing bone mineral density. As a lyophilized biologic powder, it has stable physical and chemical properties under recommended cold storage conditions, and is widely used in the production of subcutaneous injection preparations for the treatment of osteoporosis, giant cell tumor of bone, bone metastases of solid tumors and hypercalcemia of malignancy.

2. Technical Specifications (Complies with USP 45 & ChP 2025)

Item	Specification
Appearance	White to off-white loose lyophilized powder, no caking
Protein Content (after reconstitution)	60.0 ± 5.0 mg/mL
Biological Potency	≥ 90.0% of reference standard
Purity (SEC-HPLC, monomer)	≥ 98.0%
Related Protein (total impurities)	≤ 2.0%
Host Cell Protein (HCP)	≤ 10.0 ng/mg protein
Endotoxin Content	≤ 0.5 EU/mg protein
pH Value (1:10 reconstitution,25℃)	5.5 ~ 6.5
Osmolality (after reconstitution)	280 ~ 320 mOsmol/kg
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Sterility	Negative
Mycoplasma	Negative
Temperature Stability	Stable at 2~8℃ (potency retention ≥ 95% for 24 months)
Reconstitution Stability	Stable for 8h at 25℃ after reconstitution (potency ≥ 90%)

3. Product Advantages

1. **Fully Human Monoclonal Antibody**: Low immunogenicity, no human anti-murine antibody (HAMA) response, suitable for long-term clinical administration.
2. **Specific Targeting**: High affinity for RANKL, precise blocking of bone resorption signaling pathway, potent and durable therapeutic effect.
3. **Broad Clinical Efficacy**: Effective for osteoporosis, bone giant cell tumor, solid tumor bone metastasis and malignant hypercalcemia, with multiple clinical indications.
4. **High Biochemical Purity**: Ultra-low host cell protein and impurity content, meeting strict biopharmaceutical quality standards.
5. **Stable Lyophilized Form**: Lyophilized powder with good stability under cold storage, convenient for transportation and storage; rapid reconstitution with no insoluble particles.
6. **Convenient Administration**: Subcutaneous injection, no intravenous infusion required, high patient compliance.

4. Application Fields

- **Osteoporosis Treatment**: Postmenopausal female osteoporosis, male osteoporosis, glucocorticoid-induced osteoporosis.
- **Bone Tumor Therapy**: Giant cell tumor of bone (unresectable or recurrent), bone metastases of solid tumors (breast cancer, prostate cancer, lung cancer, etc.).

- **Metabolic Bone Disease**: Malignant hypercalcemia caused by tumor, prevention of skeletal-related events (SREs) in tumor patients.
- **Biopharmaceutical R&D**: RANKL signaling pathway research, in vitro osteoclast inhibition experiment, preclinical animal model research.

5. Usage Methods

Reconstitution & Dosage (Adjust according to clinical indication)

- **Reconstitution**: Reconstitute the lyophilized powder with sterile water for injection (1.0 mL for 60 mg specification), gently swirl (do not shake) to dissolve completely, no insoluble particles allowed.
- **Clinical Dosage**:
  - Postmenopausal osteoporosis: 60 mg subcutaneously every 6 months.
  - Giant cell tumor of bone: 120 mg subcutaneously every 4 weeks (with 120 mg on days 8 and 15 of the first month).
  - Tumor bone metastasis: 120 mg subcutaneously every 4 weeks (prevent skeletal-related events).
- **R&D Usage**: 1-10 μg/mL for in vitro cell experiment, 1-5 mg/kg for in vivo animal experiment (adjust according to model).

Processing Requirements

- Operate in a **Class 100 clean bench** under GMP sterile conditions; wear sterile PPE during reconstitution and preparation.
- Avoid violent shaking during reconstitution to prevent protein denaturation and aggregation.
- Use the reconstituted solution within 8h at room temperature (25℃) or within 24h if stored at 2~8℃; discard unused solution.

6. Packaging & Storage

Packaging Specifications

- 60 mg / glass vial (lyophilized powder, single dose, R&D/clinical use)
- 120 mg / glass vial (lyophilized powder, single dose, clinical use)
- 1 g / glass vial (bulk lyophilized powder, biopharmaceutical production use)
- Custom bulk packaging available for biopharmaceutical manufacturers (GMP-compliant).

Storage Conditions

- **Core Requirement**: Store in a **refrigerator at 2~8℃**, avoid freezing (-20℃ or below) and repeated freeze-thaw cycles.
- Keep the vial tightly sealed, protected from light and moisture; store in the original packaging to avoid direct sunlight.
- Store separately from strong acids, strong bases, oxidizing agents and organic solvents to prevent protein contamination.
- **Shelf Life**: 24 months (unopened, under 2~8℃ specified storage conditions); 8h at 25℃ / 24h at 2~8℃ after reconstitution.

Transportation

- Classified as **cold chain biopharmaceutical raw material**; transport in a refrigerated vehicle with constant temperature 2~8℃.
- Use shockproof, light-proof and sealed packaging; avoid package collision, temperature fluctuation and direct sunlight during transport.
- Accompany with temperature monitoring recorder during transportation to ensure temperature compliance.

7. Safety & Protection

- The product is a biopharmaceutical raw material, for professional medical/R&D use only; not for unauthorized use or direct administration without formulation.
- Wear **sterile nitrile rubber gloves, goggles and sterile mask** during handling, reconstitution and preparation to avoid direct contact with skin and mucous membranes.
- In case of skin contact: Rinse the affected area with plenty of sterile water for 10 minutes; no special treatment for mild contact.
- In case of eye contact: Rinse eyes thoroughly with sterile water for injection for 15 minutes; consult a physician if irritation persists.