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Technical Data Sheet (TDS) - Enoxaparin Sodium

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Product Name

Enoxaparin Sodium 依诺肝素钠**CAS Number**: 9002-84-4**MDL Number**: MFCD00081452**Formula**: $(C_{12}H_{19}NO_{20}S_7)_n \cdot Na$**Average Molecular Weight**: 4500 ~ 5500 Da**Form**: White to off-white amorphous powder

1. Product Overview

Enoxaparin Sodium is a high-purity pharmaceutical-grade **low molecular weight heparin (LMWH)**, prepared by chemical depolymerization of unfractionated heparin from porcine intestinal mucosa. It exerts a highly selective anticoagulant effect by potently inhibiting activated coagulation factor Xa (FXa) with weak inhibition of factor IIa (thrombin), which reduces blood coagulation and thrombus formation while minimizing the risk of bleeding. As a water-soluble amorphous powder, it has excellent stability under cold storage conditions, and is the core raw material for clinical anticoagulant injection preparations, widely used for the prevention and treatment of thrombotic diseases.

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

Item	Specification
Appearance	White to off-white amorphous powder, no caking
Average Molecular Weight	4500 ~ 5500 Da
Molecular Weight Distribution (Mw/Mn)	≤ 1.8
Anti-Xa Factor Activity	≥ 100 IU/mg
Anti-IIa Factor Activity	20 ~ 40 IU/mg
Anti-Xa / Anti-IIa Activity Ratio	2.5 ~ 4.0
pH Value (1% aq. solution,25℃)	5.5 ~ 7.5
Water Content	≤ 5.0%
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Sodium Content	10.0 ~ 13.0%
Total Organic Carbon (TOC)	≤ 0.5%
Sterility	Negative
Bacterial Endotoxin	≤ 0.1 EU/IU
Protein Impurities	Negative
Water Solubility	Freely soluble in water, slightly soluble in ethanol
Temperature Stability	Stable at 2~8℃ (activity retention ≥ 95% for 24 months)
Solution Stability	Stable for 24h at 25℃ after reconstitution with water for injection

3. Product Advantages

1. **High Selectivity**: High Anti-Xa/Anti-IIa activity ratio (2.5~4.0), potent thrombus prevention/treatment with low bleeding risk, superior to unfractionated heparin.
2. **Excellent Pharmacokinetics**: High subcutaneous bioavailability (~95%), long plasma half-life (4.5~7h), less frequent administration.
3. **Stable Quality**: Strict molecular weight control, consistent biological activity, no batch-to-batch variation.
4. **Convenient Preparation**: Freely soluble in water for injection, rapid reconstitution, no insoluble particles, suitable for sterile injection formulation.
5. **Well-Studied Safety**: Low immunogenicity, no cross-reactivity with heparin-induced thrombocytopenia (HIT) antibodies in most cases.
6. **Compliant with Global Standards**: Meets USP 45, ChP 2025, EP 10 and FDA/EMA pharmaceutical raw material requirements.

4. Application Fields

- **Pharmaceutical Production**: Core raw material for Enoxaparin Sodium injection (40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL specifications).
- **Clinical Anticoagulation**:
  - Prevention of venous thromboembolism (VTE) in surgical patients (orthopedic, abdominal, thoracic surgery).
  - Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE).
  - Antithrombotic therapy for acute coronary syndrome (ACS) and myocardial infarction.
  - Hemodialysis/hemofiltration anticoagulation for renal failure patients.
- **Biomedical R&D**: Coagulation mechanism research, in vitro anti-thrombotic experiment, preclinical animal model research.

5. Usage Methods

Pharmaceutical Formulation (Sterile GMP Operation)

- **Reconstitution**: Dissolve the powder with **sterile water for injection** to prepare stock solutions of 100mg/mL (10,000 IU/mL) or 40mg/mL, gently swirl to dissolve completely (no violent shaking).
- **Formulation Preparation**: Dilute the stock solution with 0.9% sodium chloride injection or 5% glucose injection to the clinical dosage concentration; add preservatives (if needed) for multi-dose preparations.
- **Stability After Preparation**: The formulated injection is stable for 24h at 25℃ or 7 days at 2~8℃ (aseptic conditions).

R&D Usage

- In vitro experiment: 1~10 IU/mL for coagulation factor inhibition assay; 5~20 IU/mL for cell anti-thrombotic model.

6. Packaging & Storage

Packaging Specifications

- 1 g / glass vial (nitrogen-filled, sterile, R&D/clinical trial use)
- 10 g / glass vial (nitrogen-filled, sterile, small-scale pharmaceutical production)
- 50 g / HDPE plastic drum (nitrogen-filled, sterile, industrial production)
- 100 g / stainless steel drum (nitrogen-filled, sterile, bulk pharmaceutical production)
- Custom sterile nitrogen-filled packaging available for pharmaceutical manufacturers (GMP-compliant).

Storage Conditions

- **Core Requirement**: **Refrigerated storage at 2~8℃**, strictly avoid freezing (<0℃) and repeated freeze-thaw cycles (causes activity loss).
- Keep the container tightly sealed and nitrogen-filled to prevent moisture absorption and oxidation; protect from light (opaque packaging).
- Store separately from strong acids, strong bases, oxidizing agents, proteases and heavy metal salts.

7. Safety & Protection

- The product is a pharmaceutical raw material for professional GMP production/medical R&D only; not for direct human administration without formulation.
- Wear **sterile nitrile rubber gloves, safety goggles, sterile mask and protective clothing** during handling and reconstitution to avoid direct contact with skin and mucous membranes.
- **Skin Contact**: Rinse the affected area with plenty of sterile water for 10 minutes; mild local redness may occur, no special treatment for most cases.
- **Eye Contact**: Rinse eyes thoroughly with sterile water for injection for 15 minutes (lift upper/lower eyelids); consult an ophthalmologist if irritation/redness persists.
- **Accidental Ingestion**: Rinse mouth with sterile water immediately; do not induce vomiting; consult a physician if gastrointestinal discomfort or abnormal bleeding occurs (antidote: protamine sulfate).
- Operate in a GMP-compliant clean room/clean bench; disinfect the operation area with 75% ethanol before and after use; dispose of waste according to pharmaceutical waste regulations.