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Technical Data Sheet (TDS) - Etomidate

Revision Date: 10 FEB 2026**CAS Number**: 33125-97-2**Molecular Formula**: C_{16} H_{16} N_2O_2**Molecular Weight**: 268.31 g/mol

1. Product Overview

Etomidate is a short-acting non-barbiturate intravenous anesthetic raw material with a unique imidazole carboxylate structure. It exerts rapid sedative and anesthetic effects by enhancing the activity of the γ-aminobutyric acid (GABA) receptor complex in the central nervous system. Characterized by rapid onset, short duration of action, minimal cardiovascular and respiratory depression, it is a high-purity pharmacopoeial-grade raw material for clinical anesthesia induction, suitable for patients with cardiovascular diseases or high-risk surgical anesthesia.

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

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Melting Point	66 ~ 70℃
Specific Rotation (25℃, c=1 in $CHCl_3$)	+67° ~ +73°
Solubility	Soluble in ethanol, chloroform, propylene glycol; slightly soluble in water
pH Value (0.5% propylene glycol solution, 25℃)	4.0 ~ 6.0
Optical Purity	≥ 99.5% (enantiomeric excess)

3. Product Advantages

1. **Pharmacological Superiority**: Rapid onset (30~60s after IV injection), short duration (3~5min), rapid postoperative recovery with no residual sedation.
2. **Cardiovascular Safety**: No significant hypotension, bradycardia or myocardial depression; ideal for elderly and cardiovascular disease patients.
3. **Minimal Respiratory Depression**: Far less respiratory inhibition than barbiturates and propofol at clinical doses.
4. **High Purity**: Pharmacopoeial grade (≥99.0%) with ultra-low impurity content, ensuring clinical safety and efficacy.
5. **Stable Quality**: Compliant with international pharmacopoeial standards, consistent batch-to-batch performance, easy to formulate into injections.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anesthesia:

- Induction of general anesthesia for elective and emergency surgeries (especially for high-risk patients with cardiovascular/respiratory diseases).

- Sedation for short invasive medical procedures (endoscopy, interventional radiology, dental surgery).
- Anesthesia induction for pediatric and geriatric surgical patients.
- Production of etomidate injection (propylene glycol formulation) for hospital clinical use.

5. Usage Methods (for Pharmaceutical Formulation)

- **Formulation Type**: Sterile intravenous injection (propylene glycol-based aqueous solution).
- **Solvent System**: Propylene glycol + water for injection (1:1 v/v, optimal solubility).
- **Clinical Formulation Concentration**: 2 mg/mL (standard clinical concentration).
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; avoid high temperature (>40℃) and strong light during formulation.
- **Compatibility**: Compatible with normal saline, 5% glucose injection for clinical dilution.

6. Packaging & Storage

Packaging Specifications

- 5 g / HDPE sealed bottle (R&D/laboratory use)
- 25 g / aluminum foil vacuum-sealed bottle (pilot production)
- 100 g / stainless steel sealed drum (industrial GMP production)
- Custom GMP-compliant packaging for bulk orders available.

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **Sealing Requirement**: Tightly sealed to prevent moisture absorption and oxidation; protect from direct light.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents and reducing agents.
- **Shelf Life**: 24 months (unopened, 2~8℃ refrigeration); 6 months after opening (sealed, refrigerated).

Transportation

- Classified as pharmaceutical raw material (non-narcotic anesthetic); transport in compliance with pharmaceutical transportation regulations.
- Refrigerated transport (2~8℃) with temperature monitoring; avoid collision, package damage and direct sunlight.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, dust mask) during handling to avoid skin/mucosa contact and dust inhalation.
- In case of skin contact: Rinse with plenty of running water for 10 minutes; for eye contact: Rinse with sterile water for injection for 15 minutes and consult a physician if irritation persists.
- Do not ingest; accidental oral intake may cause central nervous system depression—seek emergency medical treatment immediately.
- Operate in a well-ventilated GMP workshop with local exhaust ventilation for powder handling.

8. Quality Assurance

- Produced in accordance with **GMP** and **ICH Q7** guidelines for pharmaceutical raw materials.
- Each batch is accompanied by a detailed Certificate of Analysis (COA) with full test data.
- Complies with USP 45, ChP 2025 and EP 10.0 pharmacopoeial standards.
- Provide technical support for formulation development, including solubility testing and compatibility data.