

Technical Data Sheet (TDS) - Midazolam Maleate

Revision Date: 20 FEB 2026 **CAS Number:** 81826-61-1 **Molecular Formula:**

$C_{18}H_{13}ClFN_3 \cdot C_4H_4O_4$ **Molecular Weight:** 441.82 g/mol

1. Product Overview

Midazolam Maleate is a short-acting benzodiazepine pharmaceutical raw material, the maleate salt of midazolam with high water solubility and bioavailability. It exerts sedative, anxiolytic, hypnotic and anticonvulsant effects by binding to the γ -aminobutyric acid (GABA) receptor complex in the central nervous system. Characterized by rapid onset, short duration of action, and mild respiratory/cardiovascular depression, it is a high-purity pharmacopoeial-grade raw material for clinical sedation, anesthesia induction and adjuvant therapy, suitable for preoperative sedation, procedural sedation and critical care sedation.

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

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	$\geq 99.0\%$
Related Substances	Total $\leq 0.5\%$; Single Impurity $\leq 0.1\%$
Loss on Drying	$\leq 0.5\%$
Residue on Ignition	$\leq 0.1\%$
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/ μ g
Sterility	Sterile
Melting Point	120 ~ 124°C
Specific Rotation (25°C, c=1 in CH ₃ OH)	+108° ~ +118°
Solubility	Freely soluble in water and methanol; soluble in ethanol; slightly soluble in ether
pH Value (1% aqueous solution, 25°C)	3.0 ~ 4.5
Optical Purity	$\geq 99.5\%$ (enantiomeric excess)

3. Product Advantages

- Pharmacological Superiority:** Rapid onset (1-3min after IV injection, 15-30min after oral administration), short duration of action (2-4h), rapid postoperative recovery with no obvious residual sedation.
- High Water Solubility:** The maleate salt form has significantly improved water solubility compared with midazolam base, easy to prepare into injections and oral liquid preparations.
- Mild Side Effects:** Far less respiratory and cardiovascular depression than barbiturates; low risk of hypotension and bradycardia at clinical doses.
- Multi-Effect Integration:** Integrates sedation, anxiolysis, hypnosis and anticonvulsion, suitable for multiple clinical scenarios with one drug.
- High Purity & Stability:** Pharmacopoeial grade purity ($\geq 99.0\%$) with ultra-low impurity content; stable under recommended storage conditions, easy to formulate and store.

4. Application Fields

Pharmaceutical Raw Material for Clinical Sedation & Anesthesia:

- Preoperative sedation: Relieve preoperative anxiety and tension in surgical patients, improve anesthesia induction smoothness.
- Procedural sedation: Sedation for endoscopic, interventional radiology, dental and other short invasive procedures.
- Anesthesia induction/adjuvant: Induction of general anesthesia for short surgeries; adjuvant sedation for local/epidural anesthesia.
- Critical care sedation: Sedation for patients in intensive care unit (ICU) with mechanical ventilation.



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- Anticonvulsion: Emergency treatment of acute seizures (e.g., status epilepticus).
- Production of dosage forms: Injection, oral tablet, oral liquid, nasal spray.

5. Usage Methods (for Pharmaceutical Formulation)

- **Injection Formulation:** 1 mg/mL aqueous injection, prepared with water for injection, compatible with normal saline and 5% glucose injection for clinical dilution.
- **Oral Formulation:** 2-5 mg tablet/capsule or 0.5 mg/mL oral liquid, mixed with appropriate excipients (lactose, starch).
- **Nasal Spray:** 0.2% nasal spray formulation, prepared with propylene glycol as cosolvent to improve mucosal absorption.
- **Processing Requirements:** Aseptic operation in GMP-certified workshop; avoid high temperature (>50°C) and strong light during formulation; control pH at 3.0-4.5 to ensure stability.

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°C (refrigerated, dark place); avoid freezing and high temperature (>25°C).
- **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 heavy metal salts.
- **Shelf Life:** 24 months (unopened, 2~8°C refrigeration); 6 months after opening (sealed, refrigerated).

Transportation

- Classified as a psychotropic pharmaceutical raw material (Category IV); transport in compliance with national psychotropic drug transportation regulations.
- Refrigerated transport (2~8°C) with real-time temperature monitoring; use shockproof, moisture-proof, light-proof packaging.

7. Safety & Protection

- The product is a **Category IV psychotropic controlled drug**; production, sale and use must comply with national drug regulatory laws and regulations (special license required).
- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, protective clothing) 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 and dust collection system.

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 complete test data.
- Comply with USP 45, ChP 2025 and EP 10.0 pharmacopoeial standards; complete quality control system from raw material sourcing to finished product delivery.
- Provide full technical support for formulation development, including solubility test, compatibility data and dosage form design guidance.