Technical Data Sheet (TDS) - Mivacurium Chloride

Revision Date: 22 FEB 2026**CAS Number**: 94246-42-9**Molecular Formula**: $C_{58}H_{80}Cl_2N_4O_{10}$ **Molecular Weight**: 1062.17 g/mol

1. Product Overview

Mivacurium Chloride is a short-acting non-depolarizing muscle relaxant pharmaceutical raw material, a bisquaternary ammonium benzylisoquinolinium compound. It exerts muscle relaxant effects by competitively blocking acetylcholine receptors at the neuromuscular junction, featuring **ultra-short duration of action, rapid onset, and spontaneous rapid recovery without cumulative effect**. As a high-purity pharmacopoeial-grade raw material, it is widely used for adjuvant muscle relaxation in clinical general anesthesia, suitable for tracheal intubation and intraoperative muscle relaxation maintenance in short and medium surgical procedures, with good cardiovascular safety and no obvious side effects.

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

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 98.5%
Related Substances	Total ≤ 1.0%; Single Impurity ≤ 0.5%
Loss on Drying	≤ 1.0%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Specific Rotation (25℃, c=1 in H_2O)	+14° ~ +20°
Chloride Content	5.1 ~ 5.7%
Solubility	Freely soluble in water and methanol; soluble in ethanol; slightly soluble in chloroform
pH Value (1% aqueous solution, 25℃)	4.0 ~ 6.0
Optical Purity	≥ 99.0% (enantiomeric excess)

3. Product Advantages

1. **Ultra-Short Acting & Rapid Recovery**: Onset in 1.5-2 min after IV injection, duration of action 15-20 min, spontaneous recovery without needing a specific antagonist (neostigmine), reducing postoperative recovery time.
2. **No Cumulative Effect**: Repeated administration does not cause drug accumulation, suitable for prolonged surgical procedures with intermittent dosing.
3. **Cardiovascular Safety**: No obvious effect on heart rate, blood pressure and cardiac output at clinical doses; low risk of hypotension and bradycardia, suitable for patients with cardiovascular diseases.
4. **High Purity & Stability**: Pharmacopoeial grade purity (≥98.5%), ultra-low impurity content; stable under recommended storage conditions, easy to formulate into injections.
5. **Good Water Solubility**: Freely soluble in water, can be prepared into aqueous injection directly, compatible with common clinical infusion solutions (normal saline, 5% glucose).

4. Application Fields

Pharmaceutical Raw Material for Clinical Anesthesia Muscle Relaxation:

- Tracheal intubation during general anesthesia induction (short and medium surgical procedures).
- Intraoperative muscle relaxation maintenance for orthopedics, general surgery, gynecology and obstetrics, ophthalmology and other surgeries.
- Muscle relaxation for invasive medical procedures requiring artificial ventilation.
- Production of clinical injection dosage forms (mivacurium chloride injection) for hospital operating rooms and ICUs.

5. Usage Methods (for Pharmaceutical Formulation)

- **Formulation Type**: Sterile intravenous injection (aqueous solution).
- **Standard Concentration**: 2 mg/mL aqueous injection, prepared with water for injection, no need for cosolvents.
- **Compatibility**: Can be mixed with normal saline, 5% glucose injection and lactated Ringer's solution for clinical dilution and administration.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; avoid high temperature (>40℃) and strong light during formulation and storage; control pH at 4.0-6.0 to ensure drug 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℃ (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, reducing agents and muscle relaxant antagonists.
- **Shelf Life**: 24 months (unopened, 2~8℃ refrigeration); 6 months after opening (sealed, refrigerated).

Transportation

- Classified as a pharmaceutical raw material for clinical use; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8℃) with real-time temperature monitoring; use shockproof, moisture-proof, light-proof packaging; avoid collision and package damage.

7. Safety & Protection

- 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 muscle weakness and respiratory muscle paralysis—seek emergency medical treatment and artificial ventilation immediately.
- Operate in a well-ventilated GMP workshop with local exhaust ventilation and dust collection system; prepare emergency respiratory support equipment in the operation area.

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; establish a 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 clinical formulation guidance.