Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Midazolam Hydrochloride
- **CAS Number**: 78214-87-0
- **Molecular Formula**: $C_{18}H_{13}ClFN_3 \cdot HCl$
- **Molecular Weight**: 362.23 g/mol
- **Chemical Source**: Synthetic fine chemical (chiral synthesis from 2-fluoroaniline via cyclization, imidazole modification, chlorination and hydrochlorination; purified by recrystallization to ensure ultra-high purity and low impurity content; optimized process for excellent water solubility and formulation compatibility for injectable preparations).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; **freely soluble in water** (200 g/L at 25℃), freely soluble in ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and weakly acidic environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: Classic **short-acting benzodiazepine central nervous system depressant**; high affinity for GABA-A receptors, potentiates GABA inhibitory effects; fast onset (1-3 minutes), short duration of action (2-4 hours); produces sedation, hypnosis, anxiolysis, amnesia and mild muscle relaxation; the gold standard for clinical procedural sedation, anesthesia induction adjuvant and ICU mild sedation.
- **Main Application**: Pharmaceutical intermediate for human injectable sedative/hypnotic formulations (anesthesia induction, procedural sedation, ICU sedation); pharmaceutical R&D reference reagent for benzodiazepine receptor pharmacology and neuropharmacology research.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Midazolam Hydrochloride)	≥ 99.5%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.3%	HPLC
Chloride (Cl^-)	19.5-20.5%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
Melting Point	194-198℃	Melting Point Apparatus (light protection)
pH Value (1% aqueous solution,25℃)	3.0-4.5	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method (light protection)
Water Solubility (25℃)	≥ 190 g/L	Solubility Test
Bulk Density	1.35-1.39 g/cm³	Pycnometer Method

Item	Specification	Test Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25℃, 60% RH, light protection)	HPLC

3. Product Advantages

1. **Ultra-High Water Solubility**: Freely soluble in water (200 g/L at 25℃), suitable for preparing high-concentration injectable formulations (5 mg/mL); no organic solvent required for basic formulations, reduces vascular/tissue irritation and formulation complexity.
2. **Rapid Onset & Short Duration**: Onset in 1-3 minutes after intravenous injection, peak effect at 5-10 minutes, duration of action 2-4 hours; short half-life (≈1.5 hours) facilitates clinical dose adjustment, no cumulative toxicity, ideal for short procedural sedation.
3. **High Receptor Selectivity**: High affinity for GABA-A receptors with benzodiazepine binding sites; potent sedative/hypnotic effects with mild muscle relaxation and anticonvulsant activity; minimal off-target effects, high clinical safety.
4. **Pharmaceutical Grade Purity**: Assay ≥99.5%, related substances ≤0.3%, meets the highest USP/EP/CP standards; ultralow heavy metal and microbial limits, suitable for intravenous injection in critically ill ICU patients and pediatric populations.

4. Application Fields

4.1 Pharmaceutical Industry (Anesthesia Induction & Adjuvant)

- **General Anesthesia Induction**: Core raw material for 5 mg/mL injectable formulations; used for intravenous induction of general anesthesia in adults/pediatrics; rapid sedation, smooth induction, low incidence of hypotension/respiratory depression at clinical doses.
- **Intraoperative Anesthesia Adjuvant**: Formulation for intraoperative sedation and analgesia adjuvant; reduces the dosage of general anesthetics, reduces postoperative adverse reactions, shortens recovery time.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Adult Anesthesia Induction**: 5 mg/mL injectable formulation, intravenous bolus 0.15-0.2 mg/kg; slow injection over 30-60 seconds, adjust dosage according to age and physical status.
- **Adult Procedural Sedation**: 1 mg/mL dilute formulation, intravenous bolus 0.5-1 mg; repeat 0.5 mg every 2-3 minutes if necessary, maximum total dose 5 mg.
- **ICU Mild Sedation**: 2 mg/mL formulation, continuous intravenous infusion 0.02-0.1 mg/kg/h; adjust infusion rate according to sedation level (Ramsay score 2-3).
- **Pediatric Use (≥6 months)**: 5 mg/mL formulation, intravenous bolus 0.05-0.1 mg/kg; slow injection, avoid rapid administration to prevent respiratory depression.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, **light protection**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection**).

7. Safety & Protection

- The product is a short-acting benzodiazepine toxic pharmaceutical intermediate with central nervous system depressant effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant full face shield, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **light protection**.
- Monitor neurological and respiratory status for personnel with prolonged operation time (>4 hours); take a rest every 2 hours for continuous operation.