纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

Issue Date: 29 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Flumazenil
- **CAS Number**: 78755-81-4
- **Molecular Formula**: C_{15} $H_{14}FN_3O_2$
- **Molecular Weight**: 287.29 g/mol
- **Chemical Source**: Synthetic fine chemical (chiral synthesis from 2-fluoroaniline via cyclization, imidazole modification, esterification and purification; refined by recrystallization to ensure ultra-high purity and low impurity content; optimized process for improved formulation compatibility for injectable preparations).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; sparingly soluble in water (5 g/L at 25℃), freely soluble in ethanol/methanol/chloroform, soluble in organic solvents (acetone/DMSO); stable in dry, dark and weakly acidic environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Specific competitive benzodiazepine (BZD) receptor antagonist**; no intrinsic agonist activity, only blocks BZD receptor binding; fast onset (1-2 minutes), short duration of action (45-90 minutes); rapid reversal of benzodiazepine-induced sedation, hypnosis and respiratory depression; the gold standard antidote for benzodiazepine overdose and post-anesthesia sedation reversal.
- **Main Application**: Pharmaceutical intermediate for human injectable antidote formulations (benzodiazepine overdose, post-anesthesia sedation reversal); pharmaceutical R&D reference reagent for BZD 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 (Flumazenil)	≥ 99.5%	HPLC
Loss on Drying	≤ 0.3%	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
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
Melting Point	198-202℃	Melting Point Apparatus (light protection)
pH Value (0.5% aqueous solution,25℃)	4.0-6.0	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℃)	≥ 4 g/L	Solubility Test
Bulk Density	1.32-1.36 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.2% related substances after 7 days (25℃, 60% RH, light protection)	HPLC

3. Product Advantages

1. **Absolute Receptor Specificity**: Only competitively blocks benzodiazepine receptors, no intrinsic agonist activity and no effect on other neurotransmitter receptors (GABA, glutamate, dopamine); minimal off-target effects, the most specific BZD antagonist for clinical use.
2. **Rapid Onset & Short Duration**: Onset in 1-2 minutes after intravenous injection, peak effect at 5 minutes, duration of action 45-90 minutes; short half-life (≈1 hour) facilitates clinical dose adjustment, no cumulative effect, safe for repeated administration.
3. **Ultra-High Purity**: Assay ≥99.5%, related substances ≤0.3%, meets the highest pharmaceutical grade requirements of USP/EP/CP; no harmful impurities, high patient tolerance, suitable for intravenous injection in critically ill patients (overdose, post-anesthesia).
4. **Effective Reversal of BZD Effects**: Rapidly reverses all benzodiazepine-induced effects (sedation, hypnosis, amnesia, respiratory depression); restores spontaneous breathing and consciousness in overdose patients, shortens post-anesthesia recovery time.
5. **Mild Systemic Toxicity**: Low acute toxicity (oral LD_{50} = 380 mg/kg in rats), no significant cardiovascular/respiratory side effects at clinical therapeutic doses; safe for use in patients with mild cardiovascular disease.

4. Application Fields

4.1 Pharmaceutical Industry (Benzodiazepine Overdose Antidote)

- **Acute BZD Overdose**: Core raw material for 0.1 mg/mL injectable formulations; used for the emergency treatment of acute benzodiazepine overdose (diazepam, lorazepam, alprazolam); rapid reversal of coma and respiratory depression, reduces mortality.
- **Combined Sedative Overdose**: Formulation adjuvant for the treatment of mixed sedative-hypnotic overdose (BZD + barbiturate); reverses BZD-induced respiratory depression, improves oxygenation for further treatment.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Adult BZD Overdose**: 0.1 mg/mL injectable formulation, intravenous bolus 0.2 mg (2 mL) over 15 seconds; repeat 0.1 mg every 60 seconds if necessary, maximum total dose 1 mg; continuous infusion 0.1-0.4 mg/h for recurrent sedation.
- **Adult Post-Anesthesia Reversal**: 0.05 mg/mL dilute formulation, intravenous bolus 0.1-0.2 mg; repeat 0.1 mg every 2-3 minutes if necessary, maximum total dose 0.5 mg.
- **Pediatric Use (≥1 year old)**: 0.1 mg/mL formulation, intravenous bolus 0.01 mg/kg; repeat 0.01 mg/kg every 60 seconds if necessary, maximum total dose 0.1 mg/kg (or 1 mg, whichever is less).

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 specific BZD receptor antagonist toxic pharmaceutical intermediate with mild neurological 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 status for personnel with prolonged operation time (>4 hours); take a rest every 2 hours for continuous operation.