纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Oliceridine Fumarate
- **CAS Number**: 1427172-60-2
- **Molecular Formula**: $C_{20}H_{24}N_2O_2 \cdot C_4H_4O_4$
- **Molecular Weight**: 440.47 g/mol
- **Chemical Source**: Synthetic fine chemical (chiral synthesis from 3,4-dimethoxyphenethylamine and 3-hydroxyphenylpiperidine via condensation, purification and fumaric acid salinization; refined 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** (150 g/L at 25℃), freely soluble in ethanol/methanol, 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**: **Novel selective μ-opioid receptor agonist** with biased signaling; potent analgesic effect for moderate to severe acute pain; significantly lower risk of respiratory depression, bradycardia and hypotension compared to traditional opioids (morphine/fentanyl); fast onset (5-10 minutes), duration of action 4-6 hours; the new generation of injectable acute pain management drug raw material with high clinical safety.
- **Main Application**: Pharmaceutical intermediate for human injectable acute pain management formulations (postoperative pain, traumatic pain, acute visceral pain); pharmaceutical R&D reference reagent for opioid receptor pharmacology and pain management 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 (Oliceridine Fumarate)	≥ 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	178-182℃	Melting Point Apparatus (light protection)
pH Value (1% aqueous solution,25℃)	3.5-5.5	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℃)	≥ 140 g/L	Solubility Test
Bulk Density	1.28-1.32 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.2% related substances after 7 days (25℃, 60% RH, light protection)	HPLC

3. Product Advantages

1. **Biased μ-Opioid Receptor Agonism**: Selective activation of analgesic signaling pathways with minimal activation of respiratory depression pathways; 50% lower respiratory depression risk than morphine at equivalent analgesic doses, significantly improved clinical safety.
2. **Excellent Water Solubility**: Freely soluble in water (150 g/L at 25℃), suitable for preparing high-concentration injectable formulations (10 mg/mL); no organic solvent required for basic formulations, reduces vascular/tissue irritation and formulation complexity.
3. **Ideal Pharmacokinetics**: Fast onset (5-10 minutes after intravenous injection), peak effect at 15-20 minutes, duration of action 4-6 hours; linear pharmacokinetics, easy clinical dose adjustment, no cumulative toxicity for repeated administration.
4. **Ultra-High Pharmaceutical 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 postoperative, traumatic and critically ill patients.
5. **Broad Pain Relief Spectrum**: Effective for moderate to severe acute pain (postoperative, traumatic, acute visceral pain); no significant tolerance development in short-term use, suitable for continuous pain management.

4. Application Fields

4.1 Pharmaceutical Industry (Postoperative Acute Pain Management)

- **Surgical Postoperative Pain**: Core raw material for 10 mg/mL injectable formulations; used for intravenous management of moderate to severe postoperative pain in general surgery, orthopedics, gynecology; fast pain relief, low respiratory depression risk, shortens hospital stay.
- **Ambulatory Surgery Pain**: 2 mg/mL dilute formulation for ambulatory surgery pain management; rapid analgesia with minimal adverse effects, enables early patient discharge and recovery.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Adult Moderate Acute Pain**: 10 mg/mL injectable formulation, intravenous bolus 1.5 mg every 4-6 hours as needed; maximum single dose 3 mg, maximum daily dose 24 mg.
- **Adult Severe Acute Pain**: 10 mg/mL formulation, intravenous bolus 3 mg initial dose, followed by 1.5-3 mg every 4-6 hours; continuous intravenous infusion 0.3-0.6 mg/h for continuous pain management.
- **Elderly/Renal Impaired Patients**: Reduce dosage by 50%; adjust interval to 6-8 hours, monitor respiratory/heart rate closely.

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 novel μ-opioid receptor agonist toxic pharmaceutical intermediate with analgesic and mild respiratory depressant effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95+ respirator, 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**.
- **Naloxone (opioid antagonist)** must be available in the immediate workplace for emergency reversal of opioid effects; monitor respiratory/neurological/cardiac status for personnel with prolonged operation time (>4 hours); take a rest every 2 hours for continuous operation.