NEWAY SINOPHC TECH. LIMITED
ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 https://www.newayphc.com

Technical Data Sheet (TDS) - Sufentanil

Revision Date: 28 FEB 2026**CAS Number**: 56030-54-7**Molecular Formula**: $C_{22}H_{30}N_2O_2S$**Molecular Weight**: 386.55 g/mol

1. Product Overview

Sufentanil is a high-potency synthetic opioid analgesic pharmaceutical raw material, a thiophene derivative of fentanyl with ultra-strong analgesic activity. It exerts potent and long-lasting analgesic effects by selectively binding to central nervous system μ-opioid receptors, with analgesic potency **5-10 times that of fentanyl** and higher receptor affinity. As a pharmacopoeial-grade raw material with high purity and stable quality, it is widely used in clinical perioperative analgesia, anesthesia induction/maintenance, and severe chronic pain management, featuring rapid onset, strong efficacy, and relatively mild respiratory depression at clinical doses.

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

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Melting Point	96 ~ 100℃
Specific Rotation (25℃, c=1 in $CHCl_3$)	+60° ~ +68°
Solubility	Freely soluble in chloroform, ethanol; soluble in acetone; slightly soluble in water
pH Value (0.1% aqueous suspension, 25℃)	5.0 ~ 7.0
Optical Purity	≥ 99.5% (enantiomeric excess)
Stability	Stable at 2~8℃, dark and sealed conditions; degraded by strong light/heat

3. Product Advantages

1. **Ultra-High Analgesic Potency**: 5-10 times stronger than fentanyl, 500-1000 times stronger than morphine, low dosage achieves super-strong and long-lasting analgesic effect.
2. **Favorable Pharmacokinetics**: Rapid onset (2-3min after IV injection), long duration of action (2-4h), suitable for both short and medium surgical procedures.
3. **Relatively Mild Side Effects**: Respiratory depression is mild and reversible at clinical analgesic doses; little effect on hemodynamics, high tolerance for surgical patients.
4. **High Purity & Stability**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; stable under recommended storage conditions, good compatibility with common pharmaceutical excipients.
5. **Diverse Formulation Potential**: Can be prepared into injections, transdermal patches, and patient-controlled analgesia (PCA) preparations, adapting to multiple clinical administration routes.

4. Application Fields

Pharmaceutical Raw Material for Clinical Analgesia & Anesthesia:

- **Perioperative analgesia**: Anesthesia induction/maintenance for general surgery, cardiothoracic surgery, neurosurgery, and orthopedic surgery; postoperative acute severe pain relief.
- **Chronic pain management**: Cancer pain, intractable neuropathic pain, and palliative care for end-stage patients (long-acting formulations).
- **Obstetric analgesia**: Labor analgesia for parturients (low-dose epidural administration).

- **Critical care analgesia**: Sedation and analgesia for ICU patients with mechanical ventilation and severe trauma.
- **Dosage form production**: Intravenous injection, epidural injection, transdermal patch, PCA pump preparation.

5. Usage Methods (for Pharmaceutical Formulation)

- **Injection Formulation**: 0.05 mg/mL sterile aqueous injection, prepared with water for injection plus cosolvents (propylene glycol/ethanol) to improve solubility; compatible with normal saline/5% glucose injection.
- **Epidural Formulation**: 0.01-0.02 mg/mL dilute solution, prepared with isotonic buffer solution to adjust pH to 5.0-7.0.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; avoid strong light and high temperature (>25℃) during formulation; use brown glass containers for packaging to prevent photodegradation; control moisture to avoid hydrolysis.

6. Packaging & Storage

Packaging Specifications

- 1 g / brown glass sealed bottle (nitrogen-filled, R&D/laboratory use)
- 5 g / aluminum foil vacuum-sealed brown glass bottle (pilot production)
- 25 g / stainless steel sealed drum (nitrogen-filled, industrial GMP production)
- Custom GMP-compliant nitrogen-filled packaging for bulk orders available.

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **Sealing Requirement**: Nitrogen-filled tight sealing, protect from direct light and moisture; prevent contact with air to avoid oxidation.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents, reducing agents, and metal ions.
- **Shelf Life**: 24 months (unopened, nitrogen-filled, 2~8℃ refrigeration); 3 months after opening (sealed, refrigerated, used up as soon as possible).

Transportation

- Classified as **Class I narcotic controlled pharmaceutical raw material**; transport in compliance with national narcotic drug transportation regulations.
- Refrigerated transport (2~8℃) with real-time temperature monitoring; use shockproof, light-proof, moisture-proof packaging; avoid package collision and light exposure during transport.

7. Safety & Protection

- The product is a **Class I narcotic controlled drug**; production, sale and use must comply with national drug regulatory laws and regulations (special operation license required).
- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable protective clothing) during handling to avoid skin/mucosa contact and dust inhalation.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; in case of eye contact: Rinse with sterile water for injection for 15 minutes and consult a physician immediately.
- No oral intake; accidental ingestion may cause severe respiratory depression and coma—seek emergency medical treatment at once and administer opioid antagonist (naloxone) under medical supervision.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection system; set up a dedicated operation area and complete account management for narcotic drugs.

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, including raw material inspection, in-process control and finished product release testing.