Technical Data Sheet (TDS) - Fentanyl Citrate

Revision Date: 15 FEB 2026**CAS Number**: 297-19-8**Molecular Formula**: $C_{22}H_{28}N_2O_4 \cdot C_6H_8O_7$ **Molecular Weight**: 528.55 g/mol

1. Product Overview

Fentanyl Citrate is a high-potency synthetic opioid analgesic pharmaceutical raw material, a citrate salt of fentanyl with high water solubility and bioavailability. It exerts strong and rapid analgesic effects by binding to central nervous system μ-opioid receptors, with analgesic potency 50-100 times that of morphine. As a pharmacopoeial-grade raw material, it is widely used in clinical acute/chronic pain relief and anesthesia adjuvant therapy, featuring rapid onset, strong efficacy and short duration of action.

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	148 ~ 151℃
Specific Rotation (25℃, c=1 in H_2O)	+21° ~ +26°
Solubility	Freely soluble in water; soluble in ethanol; slightly soluble in ether
pH Value (1% aqueous solution, 25℃)	4.0 ~ 6.0
Optical Purity	≥ 99.5% (enantiomeric excess)

3. Product Advantages

1. **Ultra-High Analgesic Potency**: 50-100 times stronger than morphine, low dosage achieves significant analgesic effect, reducing side effects caused by high dosage.
2. **Excellent Solubility**: High water solubility, easy to prepare into injection, transdermal patch and other dosage forms, suitable for various clinical administration routes.
3. **High Purity**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content, ensuring clinical safety and stable efficacy.
4. **Rapid Onset & Short Duration**: Rapid analgesic effect (3-5min after injection), short action time, convenient for clinical dosage adjustment.
5. **Stable Quality**: Compliant with international pharmacopoeial standards, consistent batch-to-batch performance, good storage stability under recommended conditions.

4. Application Fields

Pharmaceutical Raw Material for Clinical Analgesia & Anesthesia:

- Perioperative analgesia: Induction and maintenance of general anesthesia, postoperative acute pain relief.
- Chronic pain management: Cancer pain, intractable neuropathic pain (transdermal patch formulation).
- Acute pain relief: Severe trauma, postoperative pain, obstetric analgesia.
- Anesthesia adjuvant: Local anesthesia, epidural anesthesia adjuvant analgesia.

- Production of various dosage forms: Injection, transdermal patch, sublingual tablet, buccal spray.

5. Usage Methods (for Pharmaceutical Formulation)

- **Injection Formulation**: 0.05-0.1 mg/mL aqueous injection, prepared with water for injection, compatible with normal saline/5% glucose injection.
- **Transdermal Patch**: Combined with pressure-sensitive adhesive, plasticizer and other excipients, prepared into controlled-release transdermal patch (25-100 μg/h release rate).
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; avoid contact with strong acids/alkalis/oxidizing agents during formulation; control pH at 4.0-6.0 to ensure 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 other opioid raw materials.
- **Shelf Life**: 24 months (unopened, 2~8℃ refrigeration); 6 months after opening (sealed, refrigerated).

Transportation

- Classified as **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, moisture-proof, light-proof packaging.

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 license required).
- 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 10-15 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—seek emergency medical treatment and administer opioid antagonist (naloxone) at once.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection system; set up dedicated operation area and account management.

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).
- Comply with USP 45, ChP 2025 and EP 10.0 pharmacopoeial standards; 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 dosage form design guidance.