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Technical Data Sheet (TDS) - Alfentanil

Revision Date: 08 FEB 2026**CAS Number**: 71195-58-9**Molecular Formula**: $C_{21}H_{32}N_6$ O**Molecular Weight**: 384.52 g/mol

1. Product Overview

Alfentanil is a high-potency, short-acting synthetic opioid analgesic and anesthetic raw material. It exerts pharmacological effects by binding to opioid μ-receptors in the central nervous system, producing rapid and intense analgesia and sedation with a short duration of action and rapid recovery. It is a key pharmaceutical raw material for clinical intravenous anesthesia, suitable for anesthesia induction, maintenance, and intraoperative analgesia in surgical procedures, with strict compliance to pharmacopoeial quality standards and high purity.

2. Technical Specifications (Complies with ChP 2025 & EP 10.0)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 98.5%
Related Substances (Total)	≤ 1.0%; Single Impurity ≤ 0.5%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Specific Rotation (25℃, c=1 in CH_3OH)	-30° ~ -38°
Solubility	Freely soluble in methanol; soluble in water/ethanol; slightly soluble in ether
Melting Point	142 ~ 146℃
pH Value (1% aqueous solution, 25℃)	5.0 ~ 7.0

3. Product Advantages

1. **Pharmacological Superiority**: Rapid onset (1~2 min after intravenous injection), short duration of action (10~15 min), rapid postoperative recovery with no obvious residual effect.
2. **High Purity**: Pharmacopoeial grade purity (≥98.5%), low impurity content, ensuring clinical safety and efficacy.
3. **Stable Quality**: Consistent physicochemical properties, compliant with international pharmacopoeial standards (ChP/EP/USP).
4. **Controlled Safety**: Low bacterial endotoxin and heavy metal content, sterile grade, meeting pharmaceutical raw material production requirements.
5. **Well-Characterized**: Clear molecular structure and pharmacological mechanism, easy to formulate into injection preparations.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anesthesia:

- Induction and maintenance of general anesthesia for short surgical procedures (e.g., ophthalmology, dentistry, plastic surgery).
- Intraoperative analgesia for medium and long surgeries (adjuvant to other anesthetics).
- Sedation and analgesia for invasive medical operations (e.g., interventional radiology, endoscopic procedures).
- Preparation of injectable dosage forms (alfentanil hydrochloride injection) for hospital clinical use.

5. Usage Methods (for Pharmaceutical Formulation)

- **Formulation Type**: Mainly prepared as sterile aqueous injection (alfentanil hydrochloride).
- **Solvent**: Water for injection (compatible with normal saline, 5% glucose injection).
- **Formulation Concentration**: Common clinical concentration 0.5 mg/mL ~ 1 mg/mL (adjustable according to preparation requirements).

- **Processing Requirement**: Aseptic operation in GMP-certified workshop; avoid contact with strong acids/alkalis during formulation.

6. Packaging & Storage

Packaging Specifications

- 10 g / HDPE sealed bottle (laboratory/R&D use)
- 50 g / aluminum foil sealed bottle (pilot production)
- 100 g / stainless steel sealed drum (industrial production)
- Custom packaging available for bulk orders (GMP-compliant)

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **Sealing Requirement**: Keep container tightly sealed to prevent moisture absorption and oxidation.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents, and other opioid raw materials.
- **Shelf Life**: 24 months (unopened, under specified refrigerated storage conditions; 6 months after opening if properly sealed).

Transportation

- Classified as **narcotic pharmaceutical raw material**; transport in compliance with national narcotic drug transportation regulations.
- Use refrigerated transport vehicles (2 ~ 8℃); avoid direct sunlight, collision, and package damage.

7. Safety & Protection

- The product is a **controlled narcotic drug**; production, sale, and use must comply with national drug regulatory laws and regulations (special license required).
- Wear professional PPE (nitrile gloves, safety goggles, dust mask) during handling to avoid direct contact with skin/mucosa and inhalation of dust.
- 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 respiratory depression—seek emergency medical treatment at once.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection system.

8. Quality Assurance

- Produced in accordance with **GMP** and **ICH** guidelines; each batch is accompanied by a Certificate of Analysis (COA) with complete test data.
- Comply with Chinese Pharmacopoeia (2025), European Pharmacopoeia (10.0), and United States Pharmacopoeia (45) standards.
- Provide full technical support for formulation development, including solubility test and compatibility data.
- Batch-to-batch quality consistency is guaranteed with strict raw material sourcing and production process control.