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# Technical Data Sheet (TDS)

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## 1. Product Overview

- **Product Name**: Fosufloxacin Hydrochloride
- **CAS Number**: 112811-71-9
- **Molecular Formula**: $C_{19}H_{20}FN_3O_6S \cdot HCl$
- **Molecular Weight**: 457.90 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via cephalosporin ring expansion, amination and salification; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral/injectable antibacterial preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in water, soluble in methanol/ethanol, slightly soluble in acetonitrile; stable in dry, dark and weakly acidic environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Third-generation cephalosporin antibacterial agent** with potent broad-spectrum bactericidal activity against gram-positive and gram-negative bacteria (Staphylococcus aureus, Streptococcus pneumoniae, E. coli, Pseudomonas aeruginosa, Klebsiella pneumoniae); inhibits bacterial cell wall synthesis to block proliferation; good water solubility, high bioavailability, low toxicity; the classic antibacterial raw material for treating respiratory tract, urinary tract, abdominal and systemic bacterial infections.
- **Main Application**: Pharmaceutical intermediate for human oral/injectable antibacterial formulations (tablets, capsules, injections); pharmaceutical R&D reference reagent for antibacterial pharmacology and cephalosporin drug research; analytical reference material for pharmaceutical quality inspection of cephalosporin antibacterial products.

## 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 (Fosufloxacin Hydrochloride) | ≥ 99.0% | HPLC |
| Loss on Drying | ≤ 0.5% | 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 | ≤ 0.5% | HPLC |
| Sulfate ($SO_4^{2-}$) | ≤ 0.02% | Turbidimetric Method |
| pH Value (1% aqueous suspension,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) |
| Solubility in Water | Freely soluble | Solubility Test |
| Bulk Density | 1.55-1.60 g/cm³ | Pycnometer Method |
| Photostability | ≤ 0.3% related substances after 7 days (25℃, light exposure) | HPLC |

| Item | Specification | Test Method |
|---|---|---|
| Melting Point | 225-231℃ | Melting Point Apparatus (light protection) |

**3. Product Advantages**

1. **Broad-Spectrum Antibacterial Activity**: Third-generation cephalosporin with potent activity against gram-positive/negative bacteria; effective against drug-resistant strains of penicillins and first/second-generation cephalosporins; no cross-resistance with most antibacterial agents.
2. **Excellent Solubility**: Freely soluble in water, suitable for both oral and injectable formulation development; no need for organic solubilizers, reducing formulation complexity and toxic side effects.
3. **Optimal Pharmacokinetics**: High oral bioavailability (≈90%), good tissue penetration (lung, kidney, prostate, abdominal cavity); long half-life (≈7-9 hours), low dosing frequency, high patient compliance.
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical injectable and oral use for adults and pediatric patients.

**4. Application Fields**

**4.1 Pharmaceutical Industry (Oral Antibacterial Formulations)**

- **Respiratory Tract Infections**: Core raw material for 100mg/200mg oral tablets/capsules; used for treating acute bronchitis, pneumonia, sinusitis, pharyngitis caused by susceptible bacteria; high lung tissue concentration.
- **Urinary Tract Infections**: Formulation for treating acute cystitis, pyelonephritis, urethritis; high urinary excretion rate (≈85% of oral dose excreted in urine unchanged).
- **Abdominal Infections**: Used for treating bacterial peritonitis, enteritis, cholecystitis caused by gram-negative bacteria; good abdominal tissue penetration.

**5. Usage & Formulation Guidelines**

**5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)**

- **Oral Tablets/Capsules**: 100 mg/200 mg per unit; adult clinical dose 200 mg twice daily, 5-7 days as a course of treatment.
- **Injectable Formulation**: 200 mg/400 mg per vial; adult clinical dose 400 mg once daily by intravenous drip, 3-7 days as a course of treatment.
- **Pediatric Formulation**: 5 mg/kg body weight per dose, twice daily (oral/injectable), adjusted according to age and weight.

**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** for injectable use).

**7. Safety & Protection**

- The product is a cephalosporin antibacterial pharmaceutical intermediate with irritant and mild toxic effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, 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** for large-scale handling.
- Avoid direct sunlight for 24 hours after skin contact with the powder to prevent photosensitivity reaction (redness, sunburn-like rash).