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Technical Data Sheet (TDS) - Ofloxacin

Revision Date: 25 FEB 2026**CAS Number**: 82419-36-1**Molecular Formula**: $C_{18}H_{20}FN_3O_4$**Molecular Weight**: 361.37 g/mol

1. Product Overview

Ofloxacin is a high-purity pharmacopoeial-grade fluoroquinolone broad-spectrum antibacterial pharmaceutical raw material, with potent inhibitory effects on both gram-negative and gram-positive bacteria, as well as mycoplasma, chlamydia and other pathogenic microorganisms. It exerts its antibacterial effect by inhibiting bacterial DNA gyrase (topoisomerase II) and topoisomerase IV, blocking bacterial DNA replication and transcription, and leading to bacterial death. As a classic second-generation fluoroquinolone antibacterial agent, it features broad antibacterial spectrum, strong potency, good tissue penetration and diverse formulation potential, and is widely used in the production of clinical oral, injectable and topical pharmaceutical preparations for treating various bacterial infections.

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	250 ~ 255℃
Optical Rotation (25℃, c=1 in 0.1mol/L HCl)	-0.05° ~ +0.05°
pH Value (0.1% aqueous suspension, 25℃)	6.0 ~ 8.0
Solubility	Sparingly soluble in water; freely soluble in glacial acetic acid, dimethyl sulfoxide (DMSO); soluble in methanol/ethanol
Stability	Stable at 2~8℃, dark and sealed conditions; degraded by strong light/heat/alkali
Microbial Limit	Total bacterial count ≤ 100 CFU/g; E. coli negative; Mold & yeast ≤ 10 CFU/g

3. Product Advantages

1. **Broad-Spectrum Antibacterial Activity**: Potent against most gram-negative bacteria (E. coli, Pseudomonas aeruginosa, Klebsiella) and gram-positive bacteria (Staphylococcus, Streptococcus); effective against mycoplasma and chlamydia, no cross-resistance with β-lactam antibiotics.
2. **Excellent Pharmacokinetic Properties**: Rapid absorption after oral administration, high bioavailability (≈98%), good tissue penetration (can reach respiratory tract, urinary tract, bone, eye and ear tissues).
3. **High Purity & Stable Quality**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; stable under recommended storage conditions, good compatibility with common pharmaceutical excipients.
4. **Diverse Formulation Potential**: Can be prepared into oral tablets/capsules, sterile injections, eye drops, ear drops and topical gels, adapting to multiple clinical administration routes.
5. **Long-Lasting Antibacterial Effect**: Long half-life (≈6-7h), once or twice daily administration, improving patient compliance.

4. Application Fields

Pharmaceutical Raw Material for Clinical Antibacterial Therapy:

- **Respiratory tract infections**: Acute bronchitis, pneumonia, sinusitis, pharyngitis (caused by sensitive bacteria).
- **Urinary tract infections**: Cystitis, pyelonephritis, urethritis, prostatitis.
- **Skin and soft tissue infections**: Folliculitis, furuncle, cellulitis, traumatic bacterial infections.
- **Ocular/otic infections**: Conjunctivitis, keratitis, otitis externa, otitis media (acute/chronic).
- **Other infections**: Bone and joint infections, abdominal infections, gynecological infections, mycoplasma/chlamydia urethritis.
- **Dosage form production**: 0.1g/0.2g oral tablets, 0.2g/100mL injection, 0.3% eye drops, 0.5% ear drops.

5. Usage Methods (for Pharmaceutical Formulation)

Oral Formulation (Tablets/Capsules)

- **0.2g Oral Tablet**: Mix ofloxacin with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant) and magnesium stearate (lubricant), dry granulate at low temperature (<60℃), compress and coat to prepare oral tablets.
- **Processing Requirements**: Avoid strong light during granulation and compression; control tablet disintegration time within 15 minutes (water).

Injectable Formulation (Sterile Injection)

- **0.2g/100mL Injection**: Dissolve ofloxacin with water for injection plus lactic acid (solubilizer), adjust pH to 6.5-7.5 with sodium hydroxide, add edetate disodium (chelating agent), sterile filter and fill in brown glass vials/ampoules.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; use brown glass containers to avoid photodegradation.

Topical Formulation (Eye/Ear Drops)

- **0.3% Eye Drops**: Dissolve ofloxacin with sterile water for injection plus boric acid buffer (pH adjuster), add sodium chloride (isotonic regulator) and benzalkonium chloride (preservative), sterile filter and fill in brown glass eye drop bottles.
- **0.5% Ear Drops**: Add glycerol (humectant) and propylene glycol (penetration enhancer) on the basis of eye drop formula to improve local tissue adhesion.

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)
- 100 g / HDPE sealed drum (for topical formulation raw material)
- 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, heavy metal ions and photosensitizers.
- **Shelf Life**: 24 months (unopened, nitrogen-filled, under specified storage conditions); 6 months after opening (sealed, refrigerated).

7. Safety & Protection

- 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.