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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Ozoxacin
- **CAS Number**: 165590-75-8
- **Molecular Formula**: $C_{19}H_{20}FN_3O_3$
- **Molecular Weight**: 357.38 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via cyclization, fluorination and amination of pyridobenzoxazine intermediates; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for topical/oral antibacterial preparations).
- **Product Trait**: White to pale yellow crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; slightly soluble in water, freely soluble in dimethylformamide and acetic acid; stable in dry, dark and neutral environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Quinolone broad-spectrum antibacterial agent** with potent bactericidal activity against gram-positive and gram-negative bacteria (Staphylococcus aureus, Streptococcus, E. coli, Pseudomonas aeruginosa, Haemophilus influenzae); inhibits bacterial DNA gyrase and topoisomerase IV to block DNA replication and transcription; high tissue penetration, especially in ocular and skin tissues; low toxicity, suitable for topical ocular/skin and oral antibacterial formulations.
- **Main Application**: Pharmaceutical intermediate for human topical/oral antibacterial formulations (eye drops, ointments, tablets, capsules); pharmaceutical R&D reference reagent for antibacterial pharmacology and quinolone drug research.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to pale yellow crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Ozoxacin)	≥ 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℃)	6.5-8.5	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 Dimethylformamide	Freely soluble	Solubility Test
Bulk Density	1.38-1.42 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC

3. Product Advantages

1. **Broad-Spectrum Bactericidal Activity**: Effective against both gram-positive (Staphylococcus aureus, Streptococcus pneumoniae) and gram-negative bacteria (E. coli, Pseudomonas aeruginosa, H. influenzae); covers most common pathogenic bacteria for ocular, skin, respiratory and urinary tract infections.
2. **High Tissue Penetration**: Excellent penetration into ocular, skin and mucosal tissues; high drug concentration at infection sites, fast antibacterial effect and high clinical efficacy.
3. **Dual Target Inhibition**: Inhibits both bacterial DNA gyrase and topoisomerase IV; low drug resistance rate, effective against quinolone-sensitive and partially resistant strains.
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 topical and oral use for adults and children.
5. **Good Formulation Compatibility**: Freely soluble in organic solvents and acids; compatible with common pharmaceutical excipients for topical (eye drops, ointments) and oral (tablets, capsules) formulations; easy to prepare various dosage forms.
6. **Stable Storage Property**: 36-month shelf life under sealed, dark and dry conditions; slightly hygroscopic with no significant impact on quality; light protection only required for long-term storage.

4. Application Fields

4.1 Pharmaceutical Industry (Topical Antibacterial Formulations)

- **Ocular Infections**: Core raw material for 0.3% eye drop/ointment formulations; used for treating bacterial conjunctivitis, keratitis, blepharitis and dacryocystitis; high ocular tissue concentration, fast antibacterial effect and low irritation.
- **Skin & Mucosal Infections**: 1% ointment/gel formulations for treating impetigo, folliculitis, cellulitis and wound infection caused by susceptible bacteria; local application with low systemic absorption and high safety.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Topical Eye Drops**: 0.3% (w/v) aqueous formulation; instill 1-2 drops per eye, 3-5 times daily for bacterial ocular infections.
- **Topical Ointment**: 1% (w/w) oleaginous formulation; apply a thin layer to the affected area, 2-3 times daily for skin bacterial infections.
- **Oral Tablets/Capsules**: 100 mg/200 mg per unit; adult clinical dose 200 mg twice daily, 5-7 days as a course of treatment.

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 ocular use).

7. Safety & Protection

- The product is a quinolone 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).