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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Norfloxacin
- **CAS Number**: 70458-96-7
- **Molecular Formula**: $C_{16}H_{18}FN_3O_3$
- **Molecular Weight**: 319.33 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 3-chloro-4-fluoroaniline via cyclization, condensation and piperazine substitution; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral/topical antibacterial preparations).
- **Product Trait**: White to pale yellow crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; practically insoluble in water, freely soluble in acetic acid/DMSO, soluble in ethanol/methanol; stable in dry, dark and neutral environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Broad-spectrum fluoroquinolone antibacterial agent** with potent bactericidal activity against gram-negative bacteria (E. coli, Salmonella, Shigella, Pseudomonas aeruginosa); inhibits bacterial DNA gyrase to block DNA replication and transcription; low toxicity, good oral bioavailability; the classic antibacterial raw material for treating urinary tract, gastrointestinal and respiratory tract infections.
- **Main Application**: Pharmaceutical intermediate for human oral/topical antibacterial formulations (tablets, capsules, eye drops, ointments); 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 (Norfloxacin)	≥ 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
Melting Point	218-224℃	Melting Point Apparatus (light protection)
pH Value (1% aqueous suspension,25℃)	6.0-8.0	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 Acetic Acid	Freely soluble	Solubility Test
Bulk Density	1.41-1.45 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC

3. Product Advantages

1. **Broad-Spectrum Bactericidal Activity**: Potent inhibitory effect on most gram-negative bacteria (E. coli, Pseudomonas aeruginosa, Shigella); moderate activity against gram-positive bacteria (Staphylococcus aureus); suitable for treating multiple bacterial infections.
2. **Unique Antibacterial Mechanism**: Inhibits bacterial DNA gyrase (topoisomerase II), blocks bacterial DNA replication and transcription; no cross-resistance with penicillins, cephalosporins and aminoglycosides.
3. **Good Formulation Compatibility**: Freely soluble in organic acids and polar solvents; compatible with common pharmaceutical excipients for oral (tablets/capsules) and topical (eye drops/ointments) formulations; easy to prepare various dosage forms.
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 oral and topical use.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Antibacterial Formulations)

- **Urinary Tract Infections**: Core raw material for 100mg/200mg oral tablets/capsules; used for treating acute cystitis, pyelonephritis caused by gram-negative bacteria; high oral bioavailability and urinary concentration.
- **Gastrointestinal Infections**: Formulation for treating bacterial dysentery, enteritis caused by Shigella, Salmonella; fast onset of action, short treatment course (3-5 days).
- **Respiratory Tract Infections**: Mild to moderate bronchitis, pneumonia caused by susceptible gram -negative bacteria; suitable for outpatient treatment with oral administration.

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.
- **Ophthalmic 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.

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 ophthalmic use).

7. Safety & Protection

- The product is a fluoroquinolone 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).