纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Levofloxacin
- **CAS Number**: 100986-85-4
- **Molecular Formula**: C_{18} H_{20} FN_3O_4
- **Molecular Weight**: 361.37 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from ofloxacin via chiral resolution, or direct asymmetric synthesis; purified by recrystallization to ensure high optical purity and low impurity content; optimized process for good formulation compatibility for oral/injectable/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 (S-isomer of ofloxacin)** with potent bactericidal activity against gram-positive and gram-negative bacteria (Staphylococcus aureus, Streptococcus pneumoniae, E. coli, Pseudomonas aeruginosa, Haemophilus influenzae); inhibits bacterial DNA gyrase and topoisomerase IV to block DNA replication and transcription; 2x antibacterial activity of ofloxacin, high tissue penetration, low toxicity; the classic antibacterial raw material for treating respiratory tract, urinary tract, abdominal and systemic infections.
- **Main Application**: Pharmaceutical intermediate for human oral/injectable/topical antibacterial formulations (tablets, capsules, injections, 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 (Levofloxacin)	≥ 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	214-220℃	Melting Point Apparatus (light protection)
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 Acetic Acid	Freely soluble	Solubility Test
Bulk Density	1.48-1.52 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC

Item	Specification	Test Method
Optical Purity (ee)	≥ 99.5%	Chiral HPLC

3. Product Advantages

1. **High Antibacterial Activity**: S-isomer of ofloxacin with 2x the bactericidal activity; broad-spectrum coverage of gram-positive/negative bacteria and atypical pathogens (Mycoplasma, Chlamydia); effective against drug-resistant strains of other antibiotics.
2. **Excellent Pharmacokinetics**: High oral bioavailability (≈99%), good tissue penetration (lung, kidney, prostate, ocular tissue); long half-life (≈6-8 hours), low dosing frequency.
3. **Multiple Dosage Forms**: Compatible with oral, injectable and topical formulation processes; easy to prepare tablets, capsules, injections, eye drops and ointments for different clinical needs.
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, optical purity ≥99.5%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical injectable and oral use.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Antibacterial Formulations)

- **Respiratory Tract Infections**: Core raw material for 250mg/500mg 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, prostatitis; high urinary excretion rate (≈80% of oral dose excreted in urine unchanged).
- **Abdominal Infections**: Used for treating bacterial peritonitis, enteritis caused by gram-negative bacteria; good abdominal tissue penetration.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets/Capsules**: 250 mg/500 mg per unit; adult clinical dose 500 mg once daily or 250 mg twice daily, 5-7 days as a course of treatment.
- **Injectable Formulation**: 500 mg/100 mL injection; adult clinical dose 500 mg once daily by intravenous drip, 3-7 days as a course of treatment.
- **Ophthalmic Eye Drops**: 0.5% (w/v) aqueous formulation; instill 1-2 drops per eye, 3-6 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 injectable/ocular 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).