NEWAY SINOPHC TECH. LIMITED
ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com； Phone:+86-021-50350029 https://www.newayphc.com

# Technical Data Sheet (TDS)

**Issue Date: 25 FEB 2026Version: V1.0**

## 1. Product Overview

- **Product Name**: Cefdinir
- **CAS Number**: 91832-40-5
- **Molecular Formula**: $C_{14}H_{13}N_5O_5S_2$
- **Molecular Weight**: 395.41 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 7-ACA via acylation, cyclization and vinylation; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral cephalosporin antibacterial preparations).
- **Product Trait**: White to pale yellow crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; practically insoluble in water, freely soluble in DMSO, slightly soluble in methanol; 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 oral cephalosporin broad-spectrum antibacterial agent** with potent bactericidal activity against gram-positive and gram-negative bacteria (Streptococcus, Staphylococcus aureus, E. coli, Klebsiella pneumoniae, Haemophilus influenzae); inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins (PBPs); oral bioavailability ~25-30%, long half-life (≈1.7 hours); resistant to most β-lactamases; the classic oral cephalosporin raw material for treating respiratory tract, urinary tract and skin soft tissue infections.
- **Main Application**: Pharmaceutical intermediate for human oral antibacterial formulations (tablets, hard capsules, for oral suspension); pharmaceutical R&D reference reagent for cephalosporin pharmacology and antibacterial drug research; analytical reference material for pharmaceutical quality inspection of cephalosporin products.

## 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 (Cefdinir) | ≥ 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℃) | 2.5-4.5 | 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 DMSO | Freely soluble | Solubility Test |
| Bulk Density | 1.70-1.75 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 (Streptococcus pyogenes, S. pneumoniae) and gram-negative bacteria (E. coli, K. pneumoniae, H. influenzae); covers most common pathogenic bacteria for respiratory and urinary tract infections.
2. **β-Lactamase Resistance**: Resistant to hydrolysis by most plasmid-mediated and chromosomal β-lactamases; no drug resistance for most clinical pathogenic bacteria, high clinical efficacy.
3. **Oral Bioavailability**: Good oral absorption (bioavailability ~25-30%), no need for injection administration; convenient clinical use, suitable for outpatient treatment and pediatric use (for oral suspension).
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 use for adults and children.
5. **Good Formulation Compatibility**: Compatible with common oral pharmaceutical excipients (lactose, mannitol, microcrystalline cellulose); easy to prepare tablets, capsules and dry suspension formulations; suitable for taste modification for pediatric preparations.
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 (Oral Antibacterial Formulations)**

- **Respiratory Tract Infections**: Core raw material for 100mg/200mg oral tablets/capsules; used for treating acute pharyngitis, tonsillitis, acute bronchitis, community-acquired pneumonia caused by susceptible bacteria; high tissue concentration in respiratory tract.
- **Urinary Tract Infections**: Formulation for treating acute cystitis, pyelonephritis caused by gram-negative bacteria; good urinary excretion rate (≈60% of oral dose excreted in urine unchanged).
- **Skin & Soft Tissue Infections**: Used for treating impetigo, folliculitis, cellulitis caused by Staphylococcus aureus and Streptococcus; local antibacterial effect is significant.
- **Pediatric Infections**: 125mg/5mL dry suspension formulation for treating pediatric respiratory tract and urinary tract infections; easy to adjust dosage according to weight, good taste acceptability.

**5. Usage & Formulation Guidelines**

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

- **Oral Tablets/Capsules (Adult)**: 100 mg/200 mg per unit; clinical dose 200 mg twice daily or 300 mg once daily, 5-7 days as a course of treatment.
- **Oral Dry Suspension (Pediatric)**: 125 mg/5 mL; clinical dose 7 mg/kg twice daily, adjusted according to age and weight, 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 and moisture-proof**).

**7. Safety & Protection**

- The product is a third-generation 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); **cephalosporin/penicillin-allergic personnel are prohibited from operating**.
- 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**.
- Avoid direct sunlight and high humidity in the work area; keep the operation tools clean and dry; do not mix with other pharmaceutical raw materials randomly.