

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 双氯芬酸钠
- English Name: Diclofenac Sodium
- CAS Number: 15307-79-6
- Molecular Formula: $C_{14}H_{10}Cl_2NNaO_2$
- Molecular Weight: 318.13 Da
- **Product Characteristics:** High-purity pharmaceutical grade diclofenac sodium, a potent non-steroidal anti-inflammatory analgesic (NSAID) acting by inhibiting prostaglandin synthesis; white odorless crystalline powder, **freely soluble in water** (key advantage over raw diclofenac), soluble in ethanol/methanol; meets USP/EP/BP and Chinese Pharmacopoeia standards; excellent anti-inflammatory, analgesic and antipyretic activity; stable under recommended storage conditions; compatible with common pharmaceutical excipients; suitable for oral/topical/injectable pharmaceutical formulation development.

2. Technical Specifications (Complies with USP/EP/BP & Chinese Pharmacopoeia Standards)

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	283-285°C (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. solution, 25°C)	7.0-8.5
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl ⁻)	≤ 0.01%
Sulfate (SO ₄ ²⁻)	≤ 0.01%
Related Substances	≤ 0.5% (HPLC)
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Particle Size	≥95% passing 100 mesh
Water Solubility	Freely soluble (50 g/100 mL, 25°C)
Organic Solubility	Soluble in ethanol/methanol, slightly soluble in acetone
Bulk Density	1.40-1.45 g/cm ³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30°C (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)

3. Product Advantages

1. **High Pharmaceutical Purity:** Assay ≥99.0%, low related substances (≤0.5%), batch-to-batch consistency; complies with global pharmacopoeia standards (USP/EP/BP); meets GMP production requirements for pharmaceutical raw materials, suitable for injectable/oral/topical formulations.
2. **Excellent Water Solubility:** Freely soluble in water (50 g/100 mL at 25°C), eliminates the need for organic solvents in aqueous formulations; ideal for injectable preparations, water-based gels and oral liquid formulations, reducing formulation irritation and improving bioavailability.
3. **Potent & Broad Efficacy:** Strong anti-inflammatory, analgesic and antipyretic effects; rapid onset of action (10-15 mins for injectable, 15-30 mins for topical, 1-2 hrs for oral); long-lasting efficacy (4-8 hrs); effective for rheumatoid arthritis, osteoarthritis, acute pain and fever.



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4. **Superior Formulability:** Compatible with most pharmaceutical excipients (carbomer, glycerin, starch, lactose, mannitol); no chemical reaction with excipients; easy to process into various dosage forms with good stability and no precipitation.
5. **Long-Term Stability:** Slightly hygroscopic, no degradation under recommended storage conditions; 36-month long shelf life (unopened); easy to store and transport for industrial pharmaceutical production, reducing inventory loss.
6. **Complete Quality Control:** Full test items cover purity, impurities, heavy metals, microorganisms and physical properties; each batch with detailed COA; complete production traceability system from raw material to finished product.

4. Application Fields

- **Pharmaceutical Preparations:** Injectable formulations (for acute severe pain/fever); oral formulations (tablets, capsules, oral liquids, sustained-release preparations) for rheumatoid arthritis, osteoarthritis and chronic pain; water-based topical formulations (gels, creams, sprays) for muscle soreness, joint pain and sports injuries.
- **Veterinary Pharmaceuticals:** Anti-inflammatory analgesic raw material for animal pharmaceutical formulations (livestock/pet).
- **Fine Chemicals:** Intermediate for the synthesis of diclofenac series derivatives and pharmaceutical formulation research.
- **Scientific Research:** Pharmaceutical research reagent for NSAID drug development, water-based formulation optimization and pharmacological mechanism studies.

5. Usage Methods

5.1 Formulation Compatibility

- **Injectable Formulations:** Directly dissolve in sterile water for injection/0.9% normal saline (1-5% w/v); adjust pH to 7.0-8.0 with dilute acid/base; add appropriate preservative/stabilizer; sterile filtration and aseptic filling (no high-temperature sterilization, $\leq 60^{\circ}\text{C}$).
- **Oral Formulations:** Mix with lactose/microcrystalline cellulose/starch (1:5-1:10 ratio) for tablets/capsules; directly dissolve in deionized water (add sweetener/flavor) for oral liquids; control processing temperature below 60°C .
- **Water-Based Topical Gels/Creams:** Directly dissolve in deionized water to form a stock solution, then mix with carbomer/glycerin/triethanolamine (gel) or emulsifier (Tween 80)/white petrolatum (cream); adjust pH to 7.0-8.5 for maximum stability.
- **Key Note:** Use glass/plastic sterile utensils (avoid metal); do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; sterile operation for injectable/oral liquid formulations.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (pharmaceutical grade brown glass bottle, aluminum foil sealed, light-proof/sterile)
- 1 kg/bag (pharmaceutical grade aluminum foil bag, vacuum sealed, light-proof)
- 5 kg/10 kg/drum (sealed HDPE drum with inner pharmaceutical aluminum foil bag, light-proof)
- 25 kg/drum (pharmaceutical grade fiber drum with inner vacuum-sealed aluminum foil bag, light-proof)
- **Custom Packaging:** 500 g/2 kg sterile packaging available for injectable formulation customers (MOQ applicable).

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical; **only for use by trained professional personnel** (pharmaceutical production/formulation/research staff) with relevant operating qualifications.
- Wear **mandatory full PPE** during all handling/processing operations (chemical-resistant goggles + face shield, nitrile rubber gloves $\geq 0.18\text{mm}$, N95 respirator, impermeable lab coat, protective shoes).
- Avoid direct skin contact, eye exposure and dust inhalation; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention **immediately** (especially for eye contact).