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Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 双氯芬酸
- English Name: Diclofenac
- CAS Number: 15307-86-5
- Molecular Formula: $C_{14}H_{11}Cl_2NO_2$
- Molecular Weight: 296.15 Da
- **Product Characteristics**: High-purity pharmaceutical grade diclofenac, a potent non-steroidal anti-inflammatory analgesic (NSAID) acting by inhibiting prostaglandin synthesis; white odorless crystalline powder, slightly soluble in water, soluble in organic solvents (ethanol/DMSO/acetone); 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 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	156-158℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension,25℃)	6.0-7.5
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	Slightly soluble (0.01 g/100 mL, 25℃)
Organic Solubility	Soluble in ethanol/methanol/acetone/DMSO
Bulk Density	1.30-1.35 g/cm³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30℃ (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)

3. Product Advantages

1. **Pharmaceutical Grade 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.
2. **Potent Pharmacological Activity**: Strong anti-inflammatory, analgesic and antipyretic effects; rapid onset of action (15-30 mins for topical, 1-2 hrs for oral); long-lasting efficacy (4-8 hrs); low systemic side effects for topical use.
3. **Good Formulability**: Soluble in common organic solvents; compatible with most pharmaceutical excipients (carbomer, glycerin, starch, lactose, microcrystalline cellulose); suitable for various dosage forms (tablets, capsules, gels, creams, liniments).

4. **Stable Quality**: Slightly hygroscopic, no degradation under recommended storage conditions; 36-month long shelf life (unopened); easy to store and transport for industrial production.
5. **Complete Quality Control**: Full test items cover purity, impurities, heavy metals, microorganisms; each batch with detailed COA; production traceability system from raw material to finished product.

4. Application Fields

- **Pharmaceutical Preparations**: Oral formulations (tablets, capsules, sustained-release preparations) for rheumatoid arthritis, osteoarthritis, acute pain; topical formulations (gels, creams, liniments) for muscle soreness, joint pain, sports injuries, soft tissue inflammation.
- **Medicinal Cosmetics**: Topical soothing/anti-inflammatory medicinal cosmetic ingredients (post-sun repair, mild muscle soreness relief); only for professional formulated medicinal cosmetics (low dosage).

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Formulations (Tablets/Capsules)**: Mix with lactose/microcrystalline cellulose/starch (1:5-1:10 ratio); add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into tablets or fill into hard capsules; no high-temperature processing (≤60℃).
- **Topical Gels/Creams**: Dissolve in ethanol/propylene glycol/DMSO (1:8-1:10 ratio) first, then mix with carbomer/glycerin/triethanolamine (gel) or stearic acid/white petrolatum/Tween 80 (cream); adjust pH to 6.0-7.5; avoid strong acids/alkalis.
- **Liniments/Sprays**: Dissolve in ethanol/acetone (1:5 ratio) for liniments; dissolve in ethanol/water (3:7) for sprays; add appropriate humectant (glycerin) and preservative; ensure clear solution without precipitation.
- **Key Note**: Use glass/plastic utensils (avoid metal); do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; control processing temperature below 60℃ to prevent degradation.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (pharmaceutical grade brown glass bottle, aluminum foil sealed, light-proof)
- 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 available for pharmaceutical 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).
- Wear **mandatory full PPE** during all handling/processing operations (chemical-resistant goggles + face shield, nitrile rubber gloves ≥0.18mm, 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).

8. Quality Assurance

- **Production Standards**: Manufactured in accordance with **pharmaceutical GMP standards** and ISO 9001 quality management system; production workshop meets GMP Class D clean room requirements; closed, sterile production process to ensure purity and quality.
- **Quality Inspection**: Each batch is tested by an independent third-party pharmaceutical testing institution; a complete **Certificate of Analysis (COA)** with full test results is provided for each batch; all test items comply with USP/EP/BP standards.
- **Raw Material Control**: Strict quality inspection of raw materials; only use pharmaceutical grade raw materials meeting global pharmacopoeia standards; complete raw material traceability system (supplier qualification, inspection report, batch number tracking).