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Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 醋氯芬酸
- English Name: Acemetacin
- CAS Number: 53164-05-9
- Molecular Formula: $C_{19}H_{16}ClNO_6$
- Molecular Weight: 389.79 Da
- **Product Characteristics**: High-purity pharmaceutical grade acemetacin, a potent non-steroidal anti-inflammatory analgesic (NSAID) derived from indomethacin; white odorless free-flowing crystalline powder, slightly soluble in water and soluble in common organic solvents; exerts anti-inflammatory, analgesic and antipyretic effects by inhibiting prostaglandin synthesis and phospholipase A2; stable under recommended storage conditions; compatible with common pharmaceutical excipients; meets USP/EP pharmaceutical grade standards; suitable for the preparation of oral and topical anti-inflammatory analgesic pharmaceutical formulations.

2. Technical Specifications (Complies with USP/EP & Pharmaceutical Industrial Standards)

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	150-153℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension,25℃)	5.5-7.0
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 (0.02 g/100 mL, 25℃)
Organic Solubility	Soluble in ethanol/methanol/acetone/DMSO
Bulk Density	1.32-1.37 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. **High Purity & Pharmaceutical Grade**: Assay ≥99.0%, low related substances (≤0.5%), batch-to-batch consistency; complies with USP/EP global pharmacopoeia standards; meets GMP production requirements for pharmaceutical raw materials, ensuring high product quality and clinical safety.
2. **Potent & Broad Pharmacological Activity**: Strong anti-inflammatory, analgesic and antipyretic effects; effective for rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and various acute pain; faster onset of action and longer duration than some traditional NSAIDs; lower gastrointestinal irritation than indomethacin.
3. **Good Formulability**: Soluble in common organic solvents (ethanol, DMSO, acetone); compatible with most pharmaceutical excipients (starch, lactose, microcrystalline cellulose, carbomer,

glycerin); suitable for various dosage forms (tablets, capsules, sustained-release preparations, gels, creams).

4. **Stable Quality & Long Shelf Life**: Slightly hygroscopic, no degradation under recommended storage conditions (≤25℃, dry, dark); 36-month long shelf life (unopened); easy to store and transport for industrial pharmaceutical production, reducing inventory loss.
5. **Complete Quality Control**: Full test items cover purity, impurities, heavy metals, microorganisms and physical and chemical properties; each batch is accompanied by a detailed Certificate of Analysis (COA); complete production traceability system from raw material to finished product.

4. Application Fields

- **Pharmaceutical Preparations**: Oral formulations (tablets, capsules, sustained-release tablets) for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout and acute musculoskeletal pain; topical formulations (gels, creams, liniments) for muscle soreness, joint pain, sports injuries and soft tissue inflammation.
- **Pharmaceutical Research**: Research reagent for NSAID drug development, formulation optimization and pharmacological mechanism studies of indole derivatives.
- **Fine Chemicals**: Intermediate for the synthesis of acemetacin derivatives and indole-based anti-inflammatory drugs.

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Formulations (Tablets/Capsules)**: Mix with lactose/microcrystalline cellulose/starch (1:6-1:10 ratio); add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into ordinary or sustained-release tablets, or fill into hard capsules; control processing temperature below 60℃ to prevent active ingredient degradation.
- **Topical Gels/Creams**: Dissolve in ethanol/propylene glycol/DMSO (1:7-1:10 ratio) first to form a stock solution, then mix with carbomer/glycerin/triethanolamine (gel) or stearic acid/white petrolatum/Tween 80 (cream); adjust pH to 5.5-7.0 to maximize stability and transdermal absorption; use glass/plastic utensils to avoid metal contact.
- **Liniments/Sprays**: Dissolve in ethanol/acetone (1:5 ratio) for liniments; dissolve in ethanol/water (3:7) mixed solvent for sprays; add appropriate humectant (glycerin) and preservative; filter to obtain clear solution and fill into spray/liniment bottles.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (pharmaceutical grade brown glass bottle, aluminum foil sealed, light-proof and moisture-proof)
- 1 kg/bag (pharmaceutical grade aluminum foil bag, vacuum sealed, light-proof)
- 5 kg/10 kg/drum (sealed HDPE drum with inner pharmaceutical grade 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 packaging is available for pharmaceutical customers (MOQ applicable) according to production needs.

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical; **only for use by trained professional personnel** (pharmaceutical production, formulation and research staff) with relevant operating qualifications.

8. Quality Assurance

- **Production Standards**: Manufactured in accordance with **pharmaceutical GMP production standards** and ISO 9001 quality management system; the production workshop meets GMP Class D clean room requirements; closed and sterile production process to ensure the purity and microbial control of the product.
- **Quality Inspection**: Each batch of product is tested by an independent third-party professional 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 pharmaceutical grade standards.