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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Aceclofenac
- **CAS Number**: 89796-99-6
- **Molecular Formula**: $C_{16}H_{13}Cl_2NO_4$
- **Molecular Weight**: 354.18 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 2,6-dichloroaniline and 4-chlorophenylacetic acid via acylation and cyclization)
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic; slightly soluble in water, freely soluble in ethanol/acetone/DMSO, with good compatibility with most organic pharmaceutical excipients.
- **Core Properties**: Potent non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic and antipyretic biological activity; high selectivity for cyclooxygenase-2 (COX-2), low gastrointestinal side effects compared to traditional NSAIDs.
- **Main Application**: Pharmaceutical intermediate for oral anti-inflammatory and analgesic formulations (tablets, capsules, suspensions); raw material for topical anti-inflammatory gels/creams; R&D reagent for pharmaceutical formulation development.

2. Technical Specifications (Pharmaceutical Grade)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Aceclofenac)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 5 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Chloride (Cl^-)	≤ 0.05%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	150-154℃	Melting Point Apparatus
Total Bacterial Count	≤ 10 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	Plate Count Method
Particle Size	95% passing 80 mesh	Standard Sieve Method
pH Value (1% aqueous suspension, 25℃)	3.5-4.5	Digital pH Meter
Water Solubility (25℃)	≥ 0.35 g/L	Solubility Test

3. Product Advantages

1. **High Purity & Low Impurities**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP pharmaceutical grade requirements, ensuring the safety and efficacy of finished drug formulations.
2. **High Pharmacological Activity**: Potent COX-2 selective inhibitor, strong anti-inflammatory, analgesic and antipyretic effects, equivalent to diclofenac with lower side effects.
3. **Low Gastrointestinal Irritation**: High selectivity for COX-2 reduces the inhibition of gastric mucosal prostaglandin synthesis, significantly lower gastrointestinal side effects than aspirin and ibuprofen.

4. **Good Compatibility**: Freely soluble in ethanol, acetone and DMSO, compatible with most pharmaceutical excipients (lactose, microcrystalline cellulose, carbomer), easy for formulation development.
5. **Stable Quality**: 36-month long shelf life under specified storage conditions; slightly hygroscopic, easy to store and transport; stable under normal pharmaceutical processing temperature (≤60℃).
6. **Controllable Particle Size**: 95% passing 80 mesh, good fluidity and compressibility, suitable for direct compression of oral tablets/capsules, high industrial production efficiency.

4. Application Fields

4.1 Pharmaceutical Industry (Human Oral Formulations)

- Core raw material for **oral anti-inflammatory analgesic preparations**: tablets, hard capsules, soft capsules, oral suspensions; for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute musculoskeletal pain.
- Raw material for sustained-release/extended-release formulations: aceclofenac sustained-release tablets, controlled-release capsules, prolonging drug action time and reducing administration frequency.

4.2 Pharmaceutical Industry (Human Topical Formulations)

- Raw material for anti-inflammatory analgesic gels, creams and ointments; for the treatment of local soft tissue contusions, sports injuries and joint pain (external use).

4.3 Pharmaceutical Industry (Veterinary Medicine)

- Anti-inflammatory analgesic raw material for livestock and poultry; used in the production of veterinary oral powders and premixes for the treatment of animal joint inflammation and postoperative pain.
- Low-toxicity NSAID raw material for pets (dogs/cats), suitable for the preparation of pet-specific anti-inflammatory analgesic formulations.

4.4 Other Fields

- Pharmaceutical formulation R&D reagent; reference substance for analytical testing; raw material for the development of new COX-2 selective anti-inflammatory drugs.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in pharmaceutical formulations)

- **Human Oral Formulations**: 100 mg of aceclofenac per unit (tablet/capsule), 1-2 units per day for adult use.
- **Human Topical Formulations**: 1.0-2.0% of the total formula (gels/creams), adjust according to formulation type and clinical needs.
- **Veterinary Formulations**: 5-10 mg/kg body weight for livestock/poultry; 2-5 mg/kg body weight for pets (dogs/cats), once or twice a day.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade)

- 100 g/bottle: Brown glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D use).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade drum with aluminum foil inner lining + sealed plastic cover (bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs.

7. Safety & Protection

- The product is a pharmaceutical intermediate with mild irritation; wear specified PPE during all handling operations (N95 dust mask, chemical splash goggles, nitrile rubber gloves).
- Avoid direct contact with eyes and skin; in case of eye contact, rinse with plenty of water for 15 minutes and seek immediate medical advice.
- Do not ingest the product; if accidentally swallowed, do not induce vomiting and call a poison center/doctor immediately.