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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Flufenamic Acid
- **CAS Number**: 530-78-9
- **Molecular Formula**: $C_{13}H_9F_3NO_2$
- **Molecular Weight**: 269.21 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 2-trifluoromethylbenzoic acid and aniline 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/chloroform, with good compatibility with most organic pharmaceutical excipients.
- **Core Properties**: Potent non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic, antipyretic and anti-inflammatory effects; inhibits prostaglandin synthesis, has good peripheral analgesic activity.
- **Main Application**: Pharmaceutical intermediate for oral/topical anti-inflammatory analgesic formulations; raw material for veterinary anti-inflammatory drugs; 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 (Flufenamic Acid)	≥ 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	132-136℃	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℃)	3.0-4.0	Digital pH Meter
Water Solubility (25℃)	≥ 0.18 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. **Potent Pharmacological Activity**: Strong anti-inflammatory, analgesic and antipyretic effects; effective for treating various inflammatory and pain symptoms, with good clinical application value.
3. **Good Organic Solubility**: Freely soluble in ethanol, acetone and chloroform, compatible with most organic pharmaceutical excipients, suitable for developing various oral and topical formulations.

4. **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℃).
5. **Controllable Particle Size**: 95% passing 80 mesh, good fluidity and compressibility, suitable for direct compression of oral tablets/capsules, high industrial production efficiency.
6. **Low Industrial Production Cost**: Mature synthetic process, high yield, stable batch-to-batch quality, suitable for large-scale industrial production.

4. Application Fields

4.1 Pharmaceutical Industry (Human Oral Formulations)

- Core raw material for **oral anti-inflammatory analgesic preparations**: tablets, hard capsules, soft capsules; for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute musculoskeletal pain.
- Raw material for symptomatic antipyretic formulations; used for the treatment of fever caused by various inflammatory diseases.

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, joint pain and skin inflammatory 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, postoperative pain and fever.
- 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 non-steroidal anti-inflammatory drugs.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in pharmaceutical formulations)

- **Human Oral Formulations**: 50-100 mg of flufenamic acid per unit (tablet/capsule), 2-3 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**: 5-15 mg/kg body weight for livestock/poultry; 2-8 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.
- Wash hands and face thoroughly with soap and water after handling; change contaminated clothing and wash it before reuse.
- Operate in a well-ventilated dust-free area; avoid dust generation and inhalation during weighing and mixing operations.