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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Aspirin
- **CAS Number**: 50-78-2
- **Molecular Formula**: $C_9H_8O_4$
- **Molecular Weight**: 180.16 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from salicylic acid and acetic anhydride via acylation reaction, purified by recrystallization)
- **Product Trait**: White crystalline powder/crystals, odorless or slightly with acetic odor, slightly hygroscopic; slightly soluble in water, freely soluble in ethanol/ether/chloroform, soluble in hot water; stable in dry air, slow hydrolysis in moist air.
- **Core Properties**: Classic non-steroidal anti-inflammatory drug (NSAID) with potent antipyretic, analgesic and mild anti-inflammatory activity; inhibits prostaglandin synthesis, fast-acting in vivo, wide clinical application; mature synthesis process, high product purity and batch stability.
- **Main Application**: Pharmaceutical intermediate for human oral antipyretic/analgesic formulations (tablets, capsules, effervescent tablets, granules); raw material for topical anti-inflammatory ointments/gels; veterinary drug raw material for animal fever and mild pain relief; pharmaceutical R&D and analytical reference reagent.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Odorless or slight acetic odor	Olfactory Inspection
Assay (Aspirin)	≥ 99.5%	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 Substance (Salicylic Acid)	≤ 0.1%	HPLC
Total Related Substances	≤ 0.5%	HPLC
Chloride (Cl^-)	≤ 0.01%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.01%	Turbidimetric Method
Melting Point	135-138℃	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℃)	2.5-3.5	Digital pH Meter
Water Solubility (25℃)	≥ 2.8 g/L	Solubility Test
Bulk Density	1.35-1.39 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.2% salicylic acid after 7 days (25℃, 60% RH)	HPLC

3. Product Advantages

1. **High Purity & Low Impurities**: Assay ≥99.5%, salicylic acid ≤0.1%, meets USP/EP/CP pharmaceutical grade requirements, no harmful impurities, ensures the safety and efficacy of finished drug formulations.
2. **Mature Synthetic Process**: Industrialized production for over a century, optimized acylation and purification process, high yield, stable batch-to-batch quality, low production cost.
3. **Excellent Pharmacological Activity**: Classic antipyretic and analgesic active ingredient, fast in vivo absorption, obvious effect, short onset time (30 minutes), long duration of action (4-6 hours).
4. **Wide Formulation Compatibility**: Soluble in most organic solvents and hot water, compatible with common pharmaceutical excipients (lactose, MCC, starch, PVP); suitable for oral solid, oral liquid and topical formulations.
5. **Superior Stability**: 36-month long shelf life under dry sealed storage conditions; slight hygroscopy, easy to store and transport; stable under normal pharmaceutical processing temperature (≤60℃).
6. **Strict Quality Control**: Full-process quality monitoring from raw material to finished product, complete detection items, compliant with international pharmacopoeia standards, suitable for global pharmaceutical production.

4. Application Fields

4.1 Pharmaceutical Industry (Human Oral Formulations)

- Core raw material for **antipyretic and analgesic preparations**: ordinary tablets, chewable tablets, effervescent tablets, granules, hard capsules; for the treatment of fever, headache, toothache, neuralgia, menstrual pain and mild to moderate musculoskeletal pain.
- Raw material for low-dose aspirin preparations: used for the prevention of cardiovascular and cerebrovascular diseases (clinical special formulation).

4.2 Pharmaceutical Industry (Human Topical Formulations)

- Raw material for anti-inflammatory analgesic ointments, gels and liniments; for the treatment of local soft tissue contusions, sprains, myalgia and mild skin inflammation (external use only).

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in pharmaceutical formulations, adult dosage)

- **Human Oral Antipyretic/Analgesic**: 300-500 mg of aspirin per unit (tablet/capsule), 1-2 units per time, 3 times a day.
- **Human Low-Dose Cardiovascular Prevention**: 75-100 mg per unit, 1 unit per day.
- **Human Topical Formulations**: 5.0-10.0% of the total formula (ointments/gels), adjust according to clinical needs.
- **Veterinary Formulations**: 10-20 mg/kg body weight for livestock/pets, once or twice a day (oral/topical).

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Sealed Anti-Hygroscopic)

- 100 g/bottle: Brown glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical 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 + outer carton (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 and slight hygroscopicity; wear specified PPE during all handling operations (N95 dust mask, chemical splash goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes, skin and respiratory tract; avoid inhaling dust and swallowing raw powder.
- In case of eye contact, rinse with plenty of running water for at least 15 minutes and seek immediate medical advice.