

## Technical Data Sheet (TDS)

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### 1. Product Overview

- **Product Name:** Naproxen Sodium
- **CAS Number:** 26159-34-2
- **Molecular Formula:** C<sub>14</sub>H<sub>13</sub>NaO<sub>3</sub>
- **Molecular Weight:** 252.24 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized from 2-naphthol via alkylation, acylation and neutralization with sodium hydroxide)
- **Product Trait:** White to off-white crystalline powder, practically odorless, slightly hygroscopic; **freely soluble in water**, soluble in ethanol/methanol, with excellent compatibility with most pharmaceutical excipients (water-based and organic systems).
- **Core Properties:** Potent non-steroidal anti-inflammatory drug (NSAID) with selective cyclooxygenase-2 (COX-2) inhibition, strong anti-inflammatory, analgesic and antipyretic activity; fast water dissolution rate, high bioavailability, suitable for various pharmaceutical formulations.
- **Main Application:** Pharmaceutical intermediate for oral rapid-acting anti-inflammatory analgesic formulations (tablets, capsules, oral suspensions); raw material for topical gels/creams and injectable preparations; veterinary anti-inflammatory analgesic drug raw material; pharmaceutical R&D reagent.

### 2. Technical Specifications (Pharmaceutical Grade)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Naproxen Sodium)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h)
Residue on Ignition	≤ 0.1%	600±25°C ignition method
Heavy Metals (Pb)	≤ 5 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Chloride (Cl <sup>-</sup> )	≤ 0.05%	Volumetric Method
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 0.05%	Turbidimetric Method
Melting Point	154-158°C	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 solution, 25°C)	7.5-9.0	Digital pH Meter
Water Solubility (25°C)	≥ 50 g/L	Solubility Test
Bulk Density	1.38-1.42 g/cm <sup>3</sup>	Pycnometer Method

### 3. Product Advantages

1. **High Purity & Low Impurities:** Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/BP/CP pharmaceutical grade requirements, ensuring the safety and efficacy of finished drug formulations.
2. **Excellent Water Solubility:** Freely soluble in water (55 g/L at 25°C), high dissolution rate in aqueous solution, suitable for **rapid-acting oral and injectable formulations** with fast in-vivo absorption and high bioavailability.

3. **Potent & Selective Pharmacological Activity:** Selective COX-2 inhibitor with strong anti-inflammatory, analgesic and antipyretic effects; long duration of action (12 hours), low administration frequency for clinical use.
4. **Wide Formulation Compatibility:** Soluble in water and common organic solvents, compatible with most pharmaceutical excipients (lactose, MCC, carbomer, glycerol); suitable for oral, topical, injectable and transdermal formulations.
5. **Superior Stability:** 36-month long shelf life under specified storage conditions; slightly hygroscopic, easy to store and transport; stable under normal pharmaceutical processing temperature ( $\leq 60^{\circ}\text{C}$ ).
6. **Controllable Particle Size:** 95% passing 80 mesh, good fluidity and compressibility, suitable for direct compression of oral tablets/capsules, high industrial production efficiency and low production cost.

#### 4. Application Fields

##### 4.1 Pharmaceutical Industry (Human Oral Formulations)

- Core raw material for **rapid-acting oral preparations:** ordinary tablets, sustained-release tablets, hard capsules, oral suspensions; for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal pain, headache, toothache and menstrual pain.
- Key raw material for pediatric oral formulations: oral syrups, chewable tablets; low irritation, suitable for pediatric anti-inflammatory and antipyretic clinical use.

##### 4.2 Pharmaceutical Industry (Human Parenteral & Topical Formulations)

- Raw material for injectable formulations: intravenous injection, intramuscular injection; for severe acute pain and inflammatory diseases that cannot be administered orally.
- Raw material for topical formulations: anti-inflammatory analgesic gels, creams, ointments and sprays; for local soft tissue contusions, sports injuries, joint pain and skin inflammatory pain (external use).

#### 5. Usage & Formulation Guidelines

##### 5.1 Recommended Dosage (in pharmaceutical formulations)

- **Human Rapid-acting Oral Formulations:** 250 mg of naproxen sodium per unit (tablet/capsule), 1 unit per time, 2 times a day for adult use.
- **Human Sustained-release Oral Formulations:** 500 mg per unit, 1 unit per day for adult use.
- **Human Injectable Formulations:** 100-200 mg per vial, intravenous or intramuscular injection, once or twice a day.
- **Human Topical Formulations:** 2.0-3.0% of the total formula (gels/creams), adjust according to clinical needs and formulation type.
- **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 (oral/topical/injectable).

#### 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.