

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 洛诺克兰
- English Name: Lornoxicam
- CAS Number: 70374-39-9
- Molecular Formula: $C_{13}H_{10}ClN_3O_4S_2$
- Molecular Weight: 371.82 Da
- **Product Characteristics:** High-purity pharmaceutical grade lornoxicam, a potent non-steroidal anti-inflammatory analgesic (NSAID) of the thienothiazine class with strong analgesic, anti-inflammatory and antipyretic effects; pale yellow odorless free-flowing crystalline powder, slightly soluble in water and soluble in organic solvents/DMSO; exerts pharmacological effects by selectively inhibiting cyclooxygenase-2 (COX-2) and reducing prostaglandin synthesis, with weak COX-1 inhibition and low gastrointestinal side effect risk; stable under recommended storage conditions; compatible with most pharmaceutical excipients (excluding strong alkaline excipients); meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of oral and injectable anti-inflammatory analgesic pharmaceutical formulations for moderate to severe pain and inflammation relief.

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

Item	Specification
Appearance	Pale yellow to yellow free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	210-215°C (decomposes, Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (0.1% aq. suspension, 25°C)	4.0-6.0
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 (0.01 g/100 mL, 25°C)
Organic Solubility	Soluble in ethanol/methanol/DMSO
Bulk Density	1.60-1.65 g/cm ³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30°C (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)
Compatibility	Incompatible with strong alkaline excipients/heavy metal salts/oxidizing agents

3. Product Advantages

1. **High Purity & Pharmaceutical Grade:** Assay ≥99.0%, low related substances (≤0.5%), excellent batch-to-batch consistency; complies with USP/EP/BP global pharmacopoeia standards; meets GMP production requirements for pharmaceutical raw materials, ensuring high product quality and clinical application safety for oral and injectable use.
2. **Potent & Selective Efficacy:** Strong analgesic, anti-inflammatory and antipyretic effects; selective COX-2 inhibition with weak COX-1 activity, significantly reducing gastrointestinal irritation risk

compared with traditional NSAIDs; rapid onset of action (30-60 minutes) and long duration (6-8 hours).

- Broad Formulability:** Soluble in common organic solvents and DMSO; compatible with most pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, propylene glycol); easy to process into oral and injectable dosage forms with good formulation stability.
- Stable Quality & Long Shelf Life:** Slightly hygroscopic, no degradation under recommended storage conditions ($\leq 25^{\circ}\text{C}$, dry, dark); 36-month long shelf life for unopened products; easy to store and transport for industrial pharmaceutical production, reducing inventory loss and production cost.

4. Application Fields

- Pharmaceutical Preparations:** Oral formulations (tablets, capsules) for moderate to severe acute pain (postoperative pain, traumatic pain, menstrual pain, osteoarthritis pain); injectable formulations (intramuscular/intravenous injections) for severe acute pain and postoperative analgesia that cannot be relieved by oral medications.
- Pharmaceutical Research:** Research reagent for NSAID drug development, thienothiazine derivative synthesis and cyclooxygenase inhibition mechanism research; acute pain model pharmacodynamic research and formulation optimization research.
- Fine Chemicals:** Intermediate for the synthesis of lornoxicam series derivatives and other thienothiazine class anti-inflammatory analgesic drugs.

5. Usage Methods

5.1 Formulation Compatibility

- Oral Tablets/Capsules:** Mix with lactose/microcrystalline cellulose/starch at a ratio of 1:5-1:9; add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into tablets or fill into hard capsules; control processing temperature below 60°C to prevent active ingredient degradation.
- Injectable Formulations:** Dissolve in DMSO/propylene glycol mixed solvent (1:2) first, then dilute with sterile water for injection or normal saline to the required concentration; adjust pH to 6.5-7.5 with weak base (sodium bicarbonate); filter and sterilize by $0.22\ \mu\text{m}$ microporous membrane; avoid contact with heavy metal containers and equipment during preparation.
- Key Note:** Do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; use deionized/sterile water for pharmaceutical formulations; avoid high-temperature processing ($>60^{\circ}\text{C}$) for all dosage forms; do not use strong alkaline excipients to prevent active ingredient degradation.

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)

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical with kidney/liver toxicity and serious eye damage risk; **only for use by trained professional personnel** (pharmaceutical production, formulation development and scientific research staff) with relevant operating qualifications.
- Wear **mandatory full personal protective equipment** during all handling, processing and preparation operations (chemical-resistant goggles + full face shield, nitrile rubber gloves $\geq 0.18\text{mm}$ thick, N95 respirator, impermeable lab coat, protective shoes).
- Avoid direct skin contact, eye exposure and dust inhalation; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention **immediately** (especially for eye contact and large dosage ingestion).