纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 酮洛芬
- English Name: Ketoprofen
- CAS Number: 22071-15-4
- Molecular Formula: $C_{16}H_{14}O_3$
- Molecular Weight: 254.28 Da
- **Product Characteristics**: High-purity pharmaceutical grade ketoprofen, a classic arylpropionic acid non-steroidal anti-inflammatory analgesic (NSAID); white odorless free-flowing crystalline powder, slightly soluble in water and soluble in common organic solvents; exerts potent anti-inflammatory, analgesic and antipyretic effects by inhibiting cyclooxygenase (COX) and prostaglandin synthesis; fast onset of action and long-lasting efficacy; stable under recommended storage conditions; compatible with most pharmaceutical excipients; meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of oral and topical anti-inflammatory analgesic pharmaceutical formulations.

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

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	93-96℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension,25℃)	5.0-7.0
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 (0.04 g/100 mL, 25℃)
Organic Solubility	Soluble in ethanol/methanol/acetone/chloroform
Bulk Density	1.20-1.25 g/cm³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30℃ (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)

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.
2. **Potent & Targeted Pharmacological Activity**: Strong anti-inflammatory, analgesic and antipyretic effects; effective for rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal pain and fever; fast onset (15-30 mins for topical, 1-2 hrs for oral) and long duration (4-6 hrs) of action; lower gastrointestinal irritation compared with traditional NSAIDs.

3. **Good Formulability**: Soluble in common organic solvents; compatible with most pharmaceutical excipients (starch, lactose, microcrystalline cellulose, carbomer, glycerin); no chemical reaction with excipients; easy to process into various dosage forms with good formulation stability and no precipitation.
4. **Stable Quality & Long Shelf Life**: Slightly hygroscopic, no degradation under recommended storage conditions (≤25℃, 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.
5. **Mature Application System**: A classic clinical NSAID with decades of application experience; complete research data on pharmacology, toxicology and formulation; low research and development risk for pharmaceutical formulation development.
6. **Comprehensive Quality Control**: Full test items cover purity, impurities, heavy metals, microorganisms and physical and chemical properties; each batch is accompanied by a detailed Certificate of Analysis (COA); complete production traceability system from raw material procurement to finished product delivery.

4. Application Fields

- **Pharmaceutical Preparations**: Oral formulations (tablets, capsules, sustained-release tablets, oral suspensions) for chronic anti-inflammatory analgesia; topical formulations (gels, creams, liniments, plasters) for local pain and inflammation such as muscle soreness, joint pain and sports injuries; suppositories for rectal administration (suitable for patients with poor oral tolerance).
- **Pharmaceutical Research**: Research reagent for NSAID drug development, arylpropionic acid derivative synthesis and pharmaceutical formulation optimization research.
- **Fine Chemicals**: Intermediate for the synthesis of ketoprofen series derivatives and other anti-inflammatory analgesic drugs.

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Formulations (Tablets/Capsules)**: Mix with lactose/microcrystalline cellulose/starch at a ratio of 1:5-1:10; add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into ordinary or sustained-release tablets, or fill into hard capsules; control processing temperature below 60℃ to prevent active ingredient degradation.
- **Topical Gels/Creams**: Dissolve in ethanol/propylene glycol at a ratio of 1:8-1:12 to form a stock solution first; then mix with carbomer/glycerin/triethanolamine (for gels) or stearic acid/white petrolatum/Tween 80 (for creams); adjust pH to 5.0-7.0 to maximize formulation stability and transdermal absorption; use glass/plastic utensils to avoid metal contact.

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; **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 ≥0.18mm 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).