NEWAY SINOPHC TECH. LIMITED
ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com；Phone:+86-021-50350029 https://www.newayphc.com

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 酮醇酸
- English Name: Ketorolac
- CAS Number: 74103-06-3
- Molecular Formula: $C_{19}H_{21}NO_3$
- Molecular Weight: 311.38 Da
- **Product Characteristics**: High-purity pharmaceutical grade ketorolac, a potent non-steroidal anti-inflammatory analgesic (NSAID) of the pyrrolizine carboxylic acid class with strong analgesic and moderate anti-inflammatory/antipyretic effects; white odorless free-flowing crystalline powder, slightly soluble in water and soluble in common organic solvents/DMSO; exerts pharmacological effects by inhibiting cyclooxygenase (COX-1/COX-2) and reducing prostaglandin synthesis, with a strong peripheral analgesic effect; 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, parenteral, topical and ophthalmic anti-inflammatory analgesic pharmaceutical formulations for acute moderate to severe pain relief.

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	159-163℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension,25℃)	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 (0.05 g/100 mL, 25℃)
Organic Solubility	Soluble in ethanol/methanol/acetone/DMSO
Bulk Density	1.28-1.32 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)
Compatibility	Incompatible with strong alkaline excipients/heavy metal salts

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 parenteral and oral use.

2. **Potent Analgesic Effect**: Strong peripheral analgesic activity, equivalent to opioid analgesics for acute moderate to severe pain relief (e.g., postoperative pain, traumatic pain); no opioid-like dependence or tolerance, low abuse risk.
3. **Broad Formulability**: Soluble in common organic solvents and DMSO; compatible with most pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, carbomer); easy to process into various dosage forms (tablets, injections, gels, eye drops) with good formulation stability.
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 Clinical Application**: A classic clinical NSAID with decades of application experience; complete research data on pharmacology, toxicology and formulation; clear clinical dosage and administration guidelines; low research and development risk for pharmaceutical formulation development.

4. Application Fields

- **Pharmaceutical Preparations**: Oral formulations (tablets, capsules) for acute mild to moderate pain; parenteral formulations (injections, infusions) for postoperative/traumatic acute moderate to severe pain; topical formulations (gels, creams) for local pain and inflammation (muscle soreness, joint pain); ophthalmic formulations (eye drops) for ocular surface pain, conjunctivitis and keratitis anti-inflammatory analgesia.
- **Pharmaceutical Research**: Research reagent for NSAID drug development, pyrrolizine derivative synthesis and cyclooxygenase inhibition mechanism research; acute pain model pharmacodynamic research.

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Tablets/Capsules**: Mix with lactose/microcrystalline cellulose/starch at a ratio of 1:6-1:10; add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into tablets or fill into hard capsules; control processing temperature below 60℃ to prevent active ingredient degradation.
- **Parenteral Injections**: Dissolve in DMSO/ethanol mixed solvent (1:1) first, then dilute with sterile water for injection or normal saline to the required concentration; adjust pH to 6.0-7.0 with weak base (sodium bicarbonate); filter and sterilize by 0.22 μm microporous membrane; avoid contact with heavy metal containers during preparation.

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 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 ≥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 and large dosage ingestion).