纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Diclofenac Potassium
- **CAS Number**: 15307-82-1
- **Molecular Formula**: $C_{14}H_{10}$ Cl_2KNO_2
- **Molecular Weight**: 334.24 g/mol
- **Chemical Source**: Synthetic fine chemical (diclofenac acid neutralized with potassium hydroxide to form a potassium salt)
- **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).
- **Core Properties**: Potent non-steroidal anti-inflammatory drug (NSAID) with strong anti-inflammatory, analgesic and antipyretic activity; fast water dissolution rate, suitable for rapid-acting oral formulations; low skin irritation for topical use.
- **Main Application**: Pharmaceutical intermediate for oral rapid-acting anti-inflammatory analgesic formulations (tablets, granules, oral solutions); raw material for topical gels/creams; 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 (Diclofenac Potassium)	≥ 99.0%	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 Substances	≤ 0.5%	HPLC
Chloride (Cl^-)	≤ 0.05%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Potassium Content	11.5-12.5%	Flame Photometry
Melting Point	156-160℃	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℃)	7.0-8.5	Digital pH Meter
Water Solubility (25℃)	≥ 95 g/L	Solubility Test

3. Product Advantages

1. **High Purity & Low Impurities**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/BP pharmaceutical grade requirements, ensuring the safety and efficacy of finished drug formulations.
2. **Excellent Water Solubility**: Freely soluble in water (100 g/L at 25℃), much higher solubility than diclofenac sodium, suitable for **rapid-acting oral formulations** (oral solution, effervescent tablets) with fast dissolution and absorption.

3. **Potent Pharmacological Activity**: Strong inhibition of cyclooxygenase (COX-1/COX-2), significant anti-inflammatory, analgesic and antipyretic effects; effective for various acute/chronic pain and inflammatory diseases.
4. **Wide Formulation Compatibility**: Soluble in water and organic solvents, compatible with most pharmaceutical excipients (lactose, MCC, carbomer, glycerol); suitable for oral, topical and injectable formulations.
5. **Stable Quality**: 36-month long shelf life under specified storage conditions; slightly hygroscopic, easy to store and transport; stable under normal pharmaceutical processing temperature (≤60℃).
6. **Controllable Particle Size**: 95% passing 80 mesh, good fluidity and compressibility, suitable for direct compression of oral tablets/capsules, high industrial production efficiency.

4. Application Fields

4.1 Pharmaceutical Industry (Human Oral Formulations)

- Core raw material for **rapid-acting oral preparations**: instant tablets, oral granules, effervescent tablets, oral solutions; for the treatment of acute pain (toothache, headache, menstrual pain) and fever.
- Conventional oral formulations: ordinary tablets, hard capsules; for rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and chronic musculoskeletal pain.

4.2 Pharmaceutical Industry (Human Topical Formulations)

- Raw material for anti-inflammatory analgesic gels, creams and lotions; for local soft tissue contusions, sports injuries, joint pain and skin inflammatory pain (external use).

4.3 Pharmaceutical Industry (Veterinary Medicine)

- Anti-inflammatory analgesic raw material for livestock/poultry/pets; used in oral powders, topical sprays and injections for the treatment of animal joint inflammation, postoperative pain and fever.

4.4 Other Fields

- Pharmaceutical formulation R&D reagent; reference substance for analytical testing; raw material for the development of new diclofenac derivatives and composite anti-inflammatory drugs.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in pharmaceutical formulations)

- **Human Rapid-acting Oral Formulations**: 25-50 mg of diclofenac potassium per unit, 1-2 units per time, 3 times a day for adult use.
- **Human Conventional Oral Formulations**: 50-100 mg per unit, 1 unit per time, 2-3 times a day.
- **Human Topical Formulations**: 1.0-2.0% of the total formula (gels/creams), adjust according to clinical needs.
- **Veterinary Formulations**: 2-5 mg/kg body weight for livestock/pets, once or twice a day (oral/topical); 1-2 mg/kg for injectable formulations.

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.
- Wash hands and face thoroughly with soap and water after handling; change contaminated clothing and wash it before reuse.