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)

Issue Date: 20 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Diclofenac Resinate
- **CAS Number**: 57469-78-0
- **Molecular Formula**: $C_{14}H_{10}$ Cl_2NO_2·Resin Acid
- **Molecular Weight**: ~580 g/mol
- **Botanical/Chemical Source**: Synthetic product (diclofenac acid combined with natural resin acid via ion exchange)
- **Product Trait**: White to off-white fine crystalline powder, odorless, slightly hygroscopic; slightly soluble in water, soluble in organic solvents (ethanol/acetone).
- **Core Properties**: Sustained-release performance, good thermal stability, low irritation (compared to diclofenac sodium); anti-inflammatory, analgesic and antipyretic biological activity.
- **Main Application**: Pharmaceutical intermediate for the production of diclofenac sustained-release tablets/capsules/suppositories; raw material for veterinary anti-inflammatory drugs.

2. Technical Specifications (Pharmaceutical Grade)

Item	Specification	Test Method
Appearance	White to off-white fine crystalline powder	Visual Inspection
Odor	Odorless	Olfactory Inspection
Assay (Diclofenac)	≥ 98.0%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 10 ppm	AAS
Heavy Metals (As)	≤ 2 ppm	AFS
Chloride (Cl^-)	≤ 0.05%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Related Substances	≤ 1.0%	HPLC
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 100 mesh	Standard Sieve Method
pH Value (1% water suspension, 25℃)	5.0-7.0	Digital pH Meter
Water Solubility	Slightly soluble (≥ 1 g/L, 25℃)	Solubility Test

3. Product Advantages

1. **High Purity**: Diclofenac content ≥98.0%, low related substances and impurities, meeting pharmaceutical grade requirements.
2. **Sustained-Release Performance**: Combined with resin acid, it has a slow-release effect in the human body, prolonging drug action time and reducing administration frequency.
3. **Reduced Irritation**: Lower gastrointestinal/skin irritation compared to diclofenac sodium/potassium, improving drug tolerance.
4. **Good Stability**: Thermal/chemical stability under recommended storage conditions; 36-month long shelf life (unopened).
5. **Easy Formulation**: Fine crystalline powder with good fluidity and compressibility; suitable for tablet/capsule direct compression process.
6. **Controlled Solubility**: Slightly soluble in water, avoiding rapid drug release and local high concentration irritation.

4. Application Fields

4.1 Pharmaceutical Industry (Human Medicine)

- Core intermediate for **diclofenac sustained-release formulations**: sustained-release tablets, sustained-release capsules, sustained-release suspensions.
- Raw material for topical anti-inflammatory preparations: creams, gels, ointments (low skin irritation).
- Auxiliary raw material for antipyretic suppositories (rectal administration, low local irritation).

4.2 Pharmaceutical Industry (Veterinary Medicine)

- Anti-inflammatory/analgesic raw material for livestock/poultry: used in the production of veterinary sustained-release powders, premixes.
- Raw material for pet anti-inflammatory drugs: low-toxicity formulations for dogs/cats (joint pain, postoperative analgesia).

4.3 Other Fields

- Research and development of new anti-inflammatory drug formulations; laboratory analytical standard (high purity grade).

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in pharmaceutical formulations)

- Human sustained-release tablets/capsules: 50-100 mg of diclofenac resinate per unit (equivalent to 25-50 mg pure diclofenac).
- Veterinary premixes/powders: 0.5-2.0% of the total formula (adjust according to animal species/weight).
- Topical formulations (creams/gels): 1.0-2.0% of the total formula.

5.2 Formulation Process Tips

- **Tablet Compression**: Can be directly compressed with lactose/microcrystalline cellulose (MCC) as excipients; add 0.5-1.0% magnesium stearate as lubricant.
- **Capsule Filling**: Mix with starch/MCC (1:1 ratio) for uniform filling; avoid high humidity during mixing (slightly hygroscopic).
- **Topical Creams**: Dissolve in ethanol/propylene glycol first (5-10% concentration), then mix with oil/water phase; adjust pH to 5.0-7.0 for stability.
- **Key Note**: Avoid mixing with strong acids/bases in formulations; control processing temperature ≤ 60℃ (prevent active ingredient degradation).

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade)

- 100 g/bottle: Brown glass 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).
- 5 kg/25 kg/drum: HDPE pharmaceutical grade drum with aluminum foil inner lining + sealed plastic cover (bulk production).
- Custom packaging (500 g/2 kg) available for R&D/custom production needs.

7. Quality Assurance & Control

1. **Production Standards**: Manufactured in accordance with **GMP (Good Manufacturing Practice)** for pharmaceutical intermediates; ISO 9001 quality management system certified.
2. **Batch Testing**: Each batch of product undergoes full-item testing (per COA specifications); a detailed Certificate of Analysis (COA) is provided with each shipment.
3. **Raw Material Control**: Synthetic raw materials (diclofenac acid/resin acid) meet pharmaceutical grade requirements; no pesticide residue/heavy metal exceeding standard.

8. Supplier Information

- **Supplier**: NEWAY SINOPHC TECH. LIMITED
- **Address**: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
- **Telephone**: +86-021-50350029
- **Fax**: +86-021-50350029
- **After-Sales Service**: 24-hour technical consultation; quality feedback processing within 48 hours; product replacement for unqualified batches (per COA).