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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Diclofenac Epolamine
- **CAS Number**: 83105-74-8
- **Molecular Formula**: $C_{14}H_{10}Cl_2NO_2 \cdot C_5H_{13}NO$
- **Molecular Weight**: 466.30 g/mol
- **Chemical Source**: Synthetic fine chemical (diclofenac acid reacted with 2-diethylaminoethanol to form a salt)
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic; soluble in water, freely soluble in ethanol/propylene glycol, with good compatibility with most pharmaceutical excipients.
- **Core Properties**: Anti-inflammatory, analgesic and antipyretic biological activity; good water solubility (superior to diclofenac sodium); low skin irritation, suitable for external pharmaceutical formulations; stable under normal storage conditions.
- **Main Application**: Pharmaceutical intermediate for external anti-inflammatory and analgesic preparations (gels, transdermal patches, creams, lotions); raw material for veterinary external anti -inflammatory drugs; R&D reagent for pharmaceutical formulation development.

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 Epolamine)	≥ 98.5%	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	≤ 0.8%	HPLC
Chloride (Cl^-)	≤ 0.05%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
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 suspension, 25℃)	6.0-7.5	Digital pH Meter
Water Solubility (25℃)	≥ 50 g/L	Solubility Test

3. Product Advantages

1. **High Purity & Low Impurities**: Assay ≥98.5%, related substances ≤0.8%, meets pharmaceutical grade intermediate requirements, ensuring the safety and efficacy of finished preparations.
2. **Excellent Water Solubility**: Soluble in water (50 g/L at 25℃), superior to diclofenac sodium, suitable for the preparation of water-based external formulations (gels, lotions).
3. **Low Skin Irritation**: Mild skin irritation (GHS Category 2), significantly lower than other diclofenac salts, suitable for transdermal patches and long-term topical use preparations.
4. **Good Compatibility**: Freely soluble in ethanol/propylene glycol, compatible with most pharmaceutical excipients (carbomer, glycerol, propylene glycol), easy for formulation development.

5. **Stable Quality**: 36-month long shelf life under specified storage conditions; slightly hygroscopic, easy to store and transport; no easy decomposition under normal processing temperature (≤60℃).
6. **Controllable Particle Size**: 95% passing 80 mesh, good fluidity and mixability, suitable for industrial production of formulations.

4. Application Fields

4.1 Pharmaceutical Industry (Human External Preparations)

- **Transdermal Patches**: Core raw material for diclofenac epolamine transdermal patches, for the treatment of musculoskeletal pain, joint pain, postoperative pain.
- **Topical Gels/Lotions**: Raw material for anti-inflammatory and analgesic gels, lotions, for the treatment of sports injuries, soft tissue contusions, rheumatoid arthritis.
- **Creams/Ointments**: Used in oil-in-water (O/W) creams, for topical anti-inflammatory and analgesic use in mild to moderate pain.

4.2 Pharmaceutical Industry (Veterinary Medicine)

- External anti-inflammatory and analgesic raw material for livestock and poultry, used in the production of veterinary topical gels and ointments (for joint pain, wound inflammation).
- Low-toxicity anti-inflammatory raw material for pets (dogs/cats), suitable for the preparation of pet-specific external pain relief preparations.

4.3 Other Fields

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

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in external pharmaceutical formulations)

- **Transdermal Patches**: 1-2% of the total formula (drug-loaded layer), equivalent to 50-100 mg diclofenac epolamine per patch.
- **Topical Gels/Lotions**: 0.5-1.0% of the total formula, the optimal concentration for anti-inflammatory analgesia with low irritation.
- **Creams/Ointments**: 0.5-1.5% of the total formula, adjust according to the type of ointment base (oil-based/water-based).
- **Veterinary Preparations**: 1.0-2.0% of the total formula, adjust according to animal species and weight.

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.