

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 双氯芬酸 β- 二甲氨基乙醇盐
- English Name: Diclofenac β-Dimethylaminoethanol Salt
- CAS Number: 68970-85-4
- Molecular Formula: C₁₈ H₂₄Cl₂N₂O₃
- Molecular Weight: 387.30 Da
- Product Characteristics:** High-purity pharmaceutical grade diclofenac β-dimethylaminoethanol salt, white odorless free-flowing crystalline powder, **high water solubility** (25 g/100 mL at 25°C); a potent non-steroidal anti-inflammatory analgesic (NSAID) with anti-inflammatory, analgesic and antipyretic effects; acts by inhibiting prostaglandin synthesis; stable under recommended storage conditions; compatible with common pharmaceutical excipients; meets USP/EP pharmaceutical grade standards; especially suitable for the preparation of water-based topical anti-inflammatory analgesic formulations.

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

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	108-112°C (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. solution, 25°C)	6.5-8.0
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	Soluble (25 g/100 mL, 25°C)
Organic Solubility	Soluble in ethanol/methanol/propylene glycol
Bulk Density	1.25-1.30 g/cm ³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30°C (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)

3. Product Advantages

- High Purity & Pharmaceutical Grade:** Assay ≥99.0%, low related substances (≤0.5%), batch-to-batch consistency; complies with USP/EP pharmaceutical grade standards; meets GMP production requirements for pharmaceutical raw materials, ensuring high product quality and safety.
- Excellent Water Solubility:** Soluble in water (25 g/100 mL at 25°C), a key advantage over ordinary diclofenac; suitable for the preparation of various **water-based topical formulations** (gels, lotions, sprays, aqueous creams) without organic solvent assistance, reducing formulation irritation.
- Potent Pharmacological Activity:** Strong anti-inflammatory, analgesic and antipyretic effects; rapid onset of action for topical use (15-30 minutes); long-lasting efficacy (4-8 hours); low systemic absorption after topical application, minimizing oral side effects (e.g., gastrointestinal irritation).



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4. **Good Formulability:** Compatible with most pharmaceutical excipients (carbomer, glycerin, hyaluronic acid, starch, microcrystalline cellulose); no chemical reaction with excipients; easy to process into various dosage forms with good formulation stability and no precipitation.
5. **Stable Quality & Long Shelf Life:** Slightly hygroscopic, no degradation under recommended storage conditions; 36-month long shelf life (unopened); easy to store and transport for industrial production, reducing inventory loss.
6. **Complete 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 to finished product.

4. Application Fields

- **Pharmaceutical Preparations:** Core raw material for **water-based topical anti-inflammatory analgesic formulations** (gels, aqueous creams, lotions, sprays, eye drops for mild ocular inflammation) for the treatment of rheumatoid arthritis, osteoarthritis, muscle soreness, joint pain, sports injuries, soft tissue inflammation and mild ocular surface inflammation.
- **Medicinal Cosmetics:** Topical soothing and anti-inflammatory medicinal cosmetic ingredients (post-sun repair, mild muscle soreness relief, anti-inflammatory for cosmetic surgery); only for professional formulated medicinal cosmetics (low dosage).

5. Usage Methods

5.1 Formulation Compatibility

- **Water-Based Gels:** Directly dissolve in deionized water (stir at room temperature) to form a stock solution, then mix with carbomer, glycerin, triethanolamine, hyaluronic acid and other excipients; adjust pH to 6.5-8.0; avoid high temperature (>60°C) during preparation to prevent active ingredient degradation.
- **Aqueous Creams/Lotions:** Dissolve in deionized water first, then mix with emulsifier (Tween 80/Span 80), white petrolatum, liquid paraffin and other excipients to prepare oil-in-water (O/W) emulsions; good compatibility with water-based humectants (e.g., glycerin, propylene glycol).
- **Sprays/Lotions:** Directly dissolve in deionized water to prepare a clear aqueous solution, add appropriate humectant (glycerin) and preservative; filter and fill into spray bottles/lotion bottles; no organic solvent needed, ensuring mild formulation.
- **Oral Formulations (Tablets/Capsules):** Mix with lactose/microcrystalline cellulose/starch (1:5-1:10 ratio); add disintegrant and lubricant; compress into tablets or fill into hard capsules; suitable for low-irritation oral formulations.
- **Key Note:** Use glass/plastic utensils (avoid metal) during preparation; do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; control processing temperature below 60°C.

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)
- **Custom Packaging:** 500 g/2 kg packaging is available for pharmaceutical customers (MOQ applicable) according to production needs.

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical; **only for use by trained professional personnel** (pharmaceutical production, formulation and 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).