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: 双氯芬酸二乙胺
- English Name: Diclofenac Diethylamine
- CAS Number: 78213-16-8
- Molecular Formula: $C_{18}H_{22}ClNO_2$
- Molecular Weight: 319.83 Da
- **Product Characteristics**: High-purity pharmaceutical grade diclofenac diethylamine, white free-flowing crystalline powder, odorless, soluble in water and ethanol; potent non-steroidal anti-inflammatory analgesic (NSAID) with anti-inflammatory, analgesic and antipyretic effects; acts by inhibiting the synthesis of prostaglandins; stable under recommended storage conditions; compatible with common pharmaceutical excipients; meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of topical external preparations.

2. Technical Specifications (Complies with USP/EP/BP & Chinese Pharmacopoeia Standards)

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC)	≥ 99.0%
Melting Point	145-150℃
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. solution,25℃)	6.0-7.5
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl^-)	≤ 0.01%
Sulfate (SO_4^{2-})	≤ 0.01%
Related Substances	≤ 0.5%
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Particle Size	≥95% passing 100 mesh
Water Solubility	Soluble (10 g/100 mL, 25℃)
Bulk Density	1.28-1.32 g/cm³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30℃ (assay retention ≥ 98% for 24 months)
Light Stability	Stable under dark storage (assay retention ≥ 98% for 24 months)

3. Product Advantages

1. **High Purity & Standardization**: Assay ≥99.0%, low related substances (≤0.5%), batch-to-batch consistency; complies with USP/EP/BP and Chinese Pharmacopoeia pharmaceutical grade standards; meets GMP production requirements.
2. **Excellent Physicochemical Properties**: Soluble in water and common organic solvents (ethanol, propylene glycol); suitable for the preparation of various topical formulations (gels, creams, liniments, sprays); no precipitation in formulated products.
3. **Potent Pharmacological Activity**: Strong anti-inflammatory, analgesic and antipyretic effects; rapid onset of action for topical use (15-30 minutes); long-lasting effect (4-8 hours); low systemic absorption (minimal side effects).
4. **Good Formulability**: Compatible with most pharmaceutical excipients (carbomer, glycerin, propylene glycol, stearic acid); no chemical reaction with excipients; easy to process into various dosage forms with good stability.
5. **Reliable Quality Control**: Complete quality inspection items; each batch is accompanied by a detailed COA; production in accordance with GMP standards; full production traceability system.

4. Application Fields

- **Pharmaceutical Preparations**: Topical anti-inflammatory analgesic preparations (gels, creams, liniments, sprays) for the treatment of rheumatoid arthritis, osteoarthritis, muscle soreness, joint pain, sports injuries and other soft tissue injuries.
- **Medicinal Cosmetics**: Topical soothing and anti-inflammatory medicinal cosmetic ingredients (for muscle soreness relief, post-sun repair, mild anti-inflammatory); only for professional formulated medicinal cosmetics.
- **Medical Devices**: Auxiliary material for medical massage devices, physical therapy devices (matched with topical application for enhanced analgesic effect).

5. Usage Methods

5.1 Formulation Compatibility

- **Gel Formulation**: Dissolve in water/propylene glycol mixed solvent (1:1) first, then mix with carbomer, glycerin, triethanolamine and other excipients; adjust pH to 6.0-7.5; avoid high temperature (>60℃) during preparation.
- **Cream/Liniment Formulation**: Dissolve in ethanol/propylene glycol (1:2) first, then mix with stearic acid, white petrolatum, liquid paraffin and other oil-based excipients; emulsify with emulsifier (e.g., Tween 80); suitable for oil-in-water (O/W) emulsions.
- **Spray Formulation**: Dissolve in water/ethanol (3:7) mixed solvent, add appropriate humectant (glycerin) and preservative; filter and fill into spray bottles; ensure the solution is clear and free of precipitation.
- **Key Note**: Do not mix with strong acids, strong bases, oxidizing agents and heavy metal salts; avoid direct contact with metal utensils during preparation (use glass/plastic utensils).

5.2 Recommended Dosage

- **Pharmaceutical Gels/Creams**: 1.0-5.0% (w/w) of the total formulation (the most common dosage is 1.16% w/w, equivalent to 1% diclofenac).
- **Liniments/Sprays**: 0.5-2.0% (w/w) of the total formulation; adjust according to the required potency.
- **Medicinal Cosmetics**: 0.1-0.5% (w/w) of the total formulation (low dosage for mild anti-inflammatory and soothing).

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (pharmaceutical grade brown glass bottle, sealed with aluminum foil)
- 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) available for pharmaceutical customers (MOQ applicable)

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical; **only for use by trained professional personnel** (pharmaceutical production/formulation personnel).
- Wear **mandatory full PPE** during all handling and preparation operations (chemical-resistant goggles, face shield, nitrile rubber gloves, impermeable lab coat, N95 respirator).
- Avoid direct skin contact, eye exposure and inhalation of dust; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention immediately if necessary.

8. Quality Assurance

- **Production Standards**: Manufactured in accordance with **GMP pharmaceutical production standards** and ISO 9001 quality management system; the production workshop meets Class D clean room requirements.
- **Quality Inspection**: Each batch of product is tested by an independent third-party pharmaceutical testing institution; a complete **Certificate of Analysis (COA)** with full test results is provided for each batch; all test items comply with USP/EP/BP standards.