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Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 戴亚瑟琳
- English Name: Diacerein
- CAS Number: 13739-02-1
- Molecular Formula: $C_{19}H_{12}O_8$
- Molecular Weight: 368.29 Da
- **Product Characteristics**: High-purity pharmaceutical grade diacerein, a natural anthracene derivative and anti-osteoarthritis drug with anti-inflammatory, analgesic and cartilage protective effects; pale yellow odorless free-flowing crystalline powder, slightly soluble in water and soluble in common organic solvents/DMSO; exerts pharmacological effects by inhibiting interleukin-1β (IL-1β), reducing cartilage degradation and relieving joint inflammation and pain; stable under recommended storage conditions; compatible with most pharmaceutical excipients (excluding strong alkaline excipients); meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of oral anti-osteoarthritis pharmaceutical formulations for the treatment of osteoarthritis of the knee, hip and other joints.

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

Item	Specification
Appearance	Pale yellow to orange free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	213-218℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension,25℃)	3.0-5.0
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	Slightly soluble (0.02 g/100 mL, 25℃)
Organic Solubility	Soluble in ethanol/acetone/DMSO/DMF
Bulk Density	1.50-1.55 g/cm³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30℃ (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)
Compatibility	Incompatible with strong alkaline excipients/heavy metal salts/oxidizing agents

3. Product Advantages

1. **High Purity & Pharmaceutical Grade**: Assay ≥99.0%, low related substances (≤0.5%), excellent batch-to-batch consistency; complies with USP/EP/BP global pharmacopoeia standards; meets GMP production requirements for pharmaceutical raw materials, ensuring high product quality and clinical application safety for oral use.
2. **Multi-Effective for Osteoarthritis**: Integrates anti-inflammatory, analgesic and cartilage protective effects; not only relieves joint pain and inflammation, but also inhibits cartilage degradation and delays osteoarthritis progression, with long-term therapeutic effects.

3. **Unique Mechanism of Action**: Targets interleukin-1β (IL-1β), a key factor in osteoarthritis pathogenesis, with high specificity and low off-target effect; no inhibition of cyclooxygenase (COX), avoiding gastrointestinal and cardiovascular side effects of traditional NSAIDs.
4. **Broad Formulability**: Soluble in common organic solvents and DMSO; compatible with most pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, starch); easy to process into oral dosage forms (tablets, capsules, sustained-release preparations) with good formulation stability.
5. **Stable Quality & Long Shelf Life**: Slightly hygroscopic, no degradation under recommended storage conditions (≤25℃, dry, dark); 36-month long shelf life for unopened products; easy to store and transport for industrial pharmaceutical production, reducing inventory loss and production cost.

4. Application Fields

- **Pharmaceutical Preparations**: Oral formulations (ordinary tablets, hard capsules, sustained-release tablets/capsules) for the treatment of osteoarthritis of the knee, hip, hand and other joints; relief of joint pain, swelling and limited movement caused by osteoarthritis.
- **Pharmaceutical Research**: Research reagent for anti-osteoarthritis drug development, anthracene derivative synthesis and interleukin-1β inhibition mechanism research; osteoarthritis animal model pharmacodynamic research and formulation optimization research.

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Ordinary Tablets/Capsules**: Mix with lactose/microcrystalline cellulose/starch at a ratio of 1:5-1:9; add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into tablets or fill into hard capsules; control processing temperature below 60℃ to prevent active ingredient degradation.
- **Oral Sustained-Release Preparations**: Mix with slow-release excipients (hydroxypropyl methylcellulose, ethyl cellulose) at a ratio of 1:4-1:8; prepare into sustained-release pellets or matrix tablets; achieve 12-hour or 24-hour sustained release, reduce administration frequency and improve patient compliance.

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 sterile packaging available for pharmaceutical customers (MOQ applicable) according to production and formulation development needs.

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical with gastrointestinal and eye irritation risks; **only for use by trained professional personnel** (pharmaceutical production, formulation development and scientific research staff) with relevant operating qualifications.
- Wear **mandatory full personal protective equipment** during all handling, processing and preparation operations (chemical-resistant goggles + face shield, nitrile rubber gloves ≥0.18mm thick, N95 respirator, impermeable lab coat, protective shoes).
- Avoid direct skin contact, eye exposure and dust inhalation; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention immediately (especially for eye contact and large dosage ingestion).