

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 吲哚美辛
- English Name: Indometacin
- CAS Number: 53-86-1
- Molecular Formula: C₁₉ H₁₆ ClNO₄
- Molecular Weight: 357.79 Da
- **Product Characteristics:** High-purity pharmaceutical grade indometacin, a potent non-steroidal anti-inflammatory analgesic (NSAID) with strong antipyretic effects; white odorless free-flowing crystalline powder, slightly soluble in water and soluble in common organic solvents; exerts anti-inflammatory, analgesic and antipyretic effects by inhibiting prostaglandin synthesis and phospholipase A2; fast onset of action and potent efficacy; stable under recommended storage conditions; compatible with common pharmaceutical excipients; meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of oral and topical anti-inflammatory analgesic/antipyretic pharmaceutical formulations.

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

Item	Specification
Appearance	White to pale yellow free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	158-162°C (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension, 25°C)	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% (HPLC)
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Particle Size	≥95% passing 100 mesh
Water Solubility	Slightly soluble (0.01 g/100 mL, 25°C)
Organic Solubility	Soluble in ethanol/methanol/acetone/DMSO
Bulk Density	1.30-1.35 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

1. **High Purity & Pharmaceutical Grade:** Assay ≥99.0%, low related substances (≤0.5%), 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 safety.
2. **Potent & Broad Pharmacological Activity:** Strong anti-inflammatory, analgesic and antipyretic effects; effective for rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute pain and high fever; faster onset of action and more potent efficacy than some traditional NSAIDs.
3. **Good Formulability:** Soluble in common organic solvents (ethanol, DMSO, acetone); compatible with most pharmaceutical excipients (starch, lactose, microcrystalline cellulose, carbomer,



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glycerin); suitable for various dosage forms (tablets, capsules, sustained-release preparations, gels, creams).

4. **Stable Quality & Long Shelf Life:** Slightly hygroscopic, no degradation under recommended storage conditions ($\leq 25^{\circ}\text{C}$, dry, dark); 36-month long shelf life (unopened); easy to store and transport for industrial pharmaceutical production, reducing inventory loss.
5. **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.
6. **Mature Clinical Application:** A classic NSAID with decades of clinical application experience; complete research data on pharmacology, toxicology and formulation; low research and development risk for pharmaceutical formulation development.

4. Application Fields

- **Pharmaceutical Preparations:** Oral formulations (tablets, capsules, sustained-release tablets) for chronic anti-inflammatory analgesia and antipyretic; topical formulations (gels, creams, liniments) for muscle soreness, joint pain, sports injuries and soft tissue inflammation.
- **Pharmaceutical Research:** Research reagent for NSAID drug development, formulation optimization and pharmacological mechanism studies of indole derivatives.
- **Fine Chemicals:** Intermediate for the synthesis of indometacin derivatives and indole-based anti-inflammatory drugs.

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Formulations (Tablets/Capsules):** Mix with lactose/microcrystalline cellulose/starch (1:6-1:10 ratio); add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into ordinary or sustained-release tablets, or fill into hard capsules; control processing temperature below 60°C to prevent active ingredient degradation.
- **Topical Gels/Creams:** Dissolve in ethanol/propylene glycol/DMSO (1:7-1:10 ratio) first to form a stock solution, then mix with carbomer/glycerin/triethanolamine (gel) or stearic acid/white petrolatum/Tween 80 (cream); adjust pH to 6.0-7.5 to maximize stability and transdermal absorption; use glass/plastic utensils to avoid metal contact.
- **Key Note:** Do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; avoid high-temperature processing ($>60^{\circ}\text{C}$); ensure uniform dispersion of the active ingredient in the formulation.

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 $\geq 0.18\text{mm}$ thick, N95 respirator, impermeable lab coat, protective shoes).