

## Technical Data Sheet (TDS)

### 1. Product Overview

- Product Name: 塞莱科西布
- English Name: Celecoxib
- CAS Number: 169590-42-5
- Molecular Formula:  $C_{17}H_{14}F_3N_3O_2S$
- Molecular Weight: 381.37 Da
- Product Characteristics:** High-purity pharmaceutical grade celecoxib, a highly selective cyclooxygenase-2 (COX-2) inhibitor of the pyrazole sulfonamide class with potent anti-inflammatory, analgesic and antipyretic effects; white odorless free-flowing crystalline powder, slightly soluble in water and soluble in common organic solvents/DMSO; exerts pharmacological effects by specifically inhibiting COX-2, reducing prostaglandin synthesis with minimal COX-1 inhibition, significantly lowering gastrointestinal side effect risk; 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-inflammatory analgesic pharmaceutical formulations for rheumatoid arthritis, osteoarthritis and acute pain relief.

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

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	157-161 °C (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. suspension, 25°C)	5.0-7.0
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl <sup>-</sup> )	≤ 0.01%
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 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	1.40-1.45 g/cm <sup>3</sup>
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)
Compatibility	Incompatible with strong alkaline excipients/heavy metal salts/oxidizing agents

### 3. Product Advantages

- 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.



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2. **Selective COX-2 Inhibition:** Highly specific for COX-2 with minimal COX-1 activity, significantly reducing the risk of gastrointestinal ulcers, bleeding and irritation compared with non-selective NSAIDs; improved patient tolerance for long-term use.
3. **Potent & Broad Efficacy:** Strong anti-inflammatory, analgesic and antipyretic effects; effective for relieving rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and various acute mild to moderate pains; rapid onset of action (1-2 hours) and long duration (12-24 hours).
4. **Broad Formulability:** Soluble in common organic solvents and DMSO; compatible with most pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, propylene glycol); easy to process into oral dosage forms (tablets, capsules, softgels) with good formulation stability.
5. **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 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 (tablets, hard capsules, softgels) for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and juvenile idiopathic arthritis; acute pain relief (postoperative pain, traumatic pain, menstrual pain); fever reduction caused by various inflammatory diseases.
- **Pharmaceutical Research:** Research reagent for NSAID drug development, pyrazole sulfonamide derivative synthesis and COX-2 inhibition mechanism research; anti-inflammatory drug pharmacodynamic research and formulation optimization research.

## 5. Usage Methods

### 5.1 Formulation Compatibility

- **Oral Tablets/Capsules:** Mix with lactose/microcrystalline cellulose/starch at a ratio of 1:6-1:10; add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into ordinary or sustained-release tablets, or fill into hard capsules; control processing temperature below  $60^{\circ}\text{C}$  to prevent active ingredient degradation.
- **Oral Softgels:** Dissolve in vegetable oil/PEG400 mixed solvent (1:3) to form an oily suspension; encapsulate into softgels with gelatin shell; adjust the formulation to ensure uniform dispersion of the active ingredient.
- **Key Note:** Do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; use deionized water for pharmaceutical formulations; avoid high-temperature processing ( $>60^{\circ}\text{C}$ ) for all dosage forms; do not use strong alkaline excipients to prevent active ingredient degradation.

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

## 7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical and sulfonamide derivative; **only for use by trained professional personnel** (pharmaceutical production, formulation development and scientific research staff) with relevant operating qualifications and no sulfonamide allergy.
- Wear **mandatory full personal protective equipment** during all handling, processing and preparation operations (chemical-resistant goggles + face shield, nitrile rubber gloves  $\geq 0.18\text{mm}$  thick, N95 respirator, impermeable lab coat, protective shoes).