

Technical Data Sheet (TDS) - Ozagrel Sodium

Revision Date: 26 FEB 2026 **CAS Number:** 82571-53-7 **Molecular Formula:** C₁₃H₁₁N₂O₂Na **Molecular Weight:** 249.23 g/mol

1. Product Overview

Ozagrel Sodium is a high-purity pharmacopoeial-grade selective thromboxane A₂ (TXA₂) synthetase inhibitor, a core pharmaceutical raw material for clinical anti-thrombotic and anti-ischemic therapy. It exerts its pharmacological effect by specifically inhibiting the synthesis of TXA₂, balancing the ratio of TXA₂ and prostacyclin (PGI₂), inhibiting platelet aggregation and vasoconstriction, and improving microcirculation and blood perfusion of ischemic tissues. With high target selectivity, rapid onset of action and good water solubility, it is widely used in the production of clinical injection and oral preparations for acute cerebral infarction, cerebral thrombosis and myocardial infarction.

2. Technical Specifications (Complies with USP 45 & ChP 2025)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Melting Point	223 ~ 227°C
pH Value (1% aqueous solution, 25°C)	7.0 ~ 8.5
Clarity and Color of Solution	Clear, colorless
Solubility	Freely soluble in water; slightly soluble in methanol/ethanol; insoluble in acetone/ether
Stability	Stable at 2~8°C, dark and sealed conditions; degraded by strong light/heat/acid
Microbial Limit	Total bacterial count ≤ 100 CFU/g; E. coli negative; Mold & yeast ≤ 10 CFU/g
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)

3. Product Advantages

- High-Selectivity TXA₂ Synthetase Inhibition:** Precisely targets TXA₂ synthetase without affecting cyclooxygenase (COX) activity, avoiding side effects such as gastrointestinal irritation caused by non-selective COX inhibitors; effectively balances TXA₂/PGI₂ ratio with strong anti-platelet aggregation effect.
- Excellent Water Solubility:** Freely soluble in water, suitable for the preparation of injection formulations (the main clinical dosage form), with rapid dissolution and high bioavailability after intravenous administration.
- Rapid Onset & Broad Therapeutic Spectrum:** Rapid onset of action (30 minutes after intravenous administration), rapid improvement of ischemic tissue perfusion; applicable to acute cerebral infarction, cerebral thrombosis, myocardial infarction and other thrombotic diseases, as well as secondary prevention of cardiovascular and cerebrovascular thrombosis.
- High Purity & Stable Quality:** Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; good chemical stability under recommended storage conditions, compatible with common pharmaceutical excipients for injection and oral solid formulations.
- Proven Clinical Efficacy:** Definite curative effect in the treatment of acute ischemic cerebrovascular diseases; can reduce the incidence of thrombotic recurrence and improve the



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prognosis of patients with cardiovascular and cerebrovascular diseases, with a good clinical safety profile.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anti-Thrombotic Therapy:

- **Cerebrovascular Diseases:** Acute cerebral infarction, cerebral thrombosis, transient ischemic attack (TIA), cerebral vasospasm after subarachnoid hemorrhage.
- **Cardiovascular Diseases:** Acute myocardial infarction, unstable angina pectoris, peripheral arterial occlusive disease.
- **Other Indications:** Secondary prevention of cardiovascular and cerebrovascular thrombotic diseases; anti-platelet adjuvant therapy for percutaneous coronary intervention (PCI).
- **Dosage form production:** 40mg/80mg for injection (lyophilized powder for injection), 20mg/40mg oral tablets, 10mg/mL oral liquid.

5. Usage Methods (for Pharmaceutical Formulation)

Injection Formulation (Lyophilized Powder for Injection)

- **80mg Lyophilized Powder for Injection:** Mix Ozagrel Sodium with mannitol (bulking agent) and sodium citrate (buffering agent), dissolve in sterile water for injection, adjust pH to 7.5-8.0 with sodium hydroxide, filter through 0.22 μ m sterile membrane, fill into sterile vials, and freeze-dry to prepare lyophilized powder.
- **Processing Requirements:** All operations in GMP clean room (Class 10000); strict sterile operation; control freeze-drying temperature and time to ensure good reconstitution property; the reconstituted solution is clear and colorless, no insoluble particles.

Oral Solid Formulation (Tablets)

- **40mg Oral Tablet:** Mix Ozagrel Sodium with microcrystalline cellulose (filler), crospovidone (disintegrant) and magnesium stearate (lubricant), adopt direct powder compression process, compress and coat with enteric coating to prepare oral tablets.
- **Processing Requirements:** Avoid strong light and high temperature during production; control the moisture content of powder \leq 0.5% to prevent drug hydrolysis; tablet disintegration time \leq 30 minutes (artificial intestinal juice).

6. Packaging & Storage

Packaging Specifications

- 1 g / brown glass sealed bottle (nitrogen-filled, R&D/laboratory use)
- 5 g / aluminum foil vacuum-sealed brown glass bottle (pilot production)
- 25 g / stainless steel sealed drum (nitrogen-filled, industrial GMP production)
- 100 g / HDPE light-proof sealed drum (for oral formulation raw material)
- 500 g / sterile glass drum (for injection formulation raw material, GMP sterile packaging)
- Custom GMP-compliant nitrogen-filled light-proof/sterile packaging for bulk orders available.

Storage Conditions

- **Storage Temperature:** 2 ~ 8 $^{\circ}$ C (refrigerated, dark place); avoid freezing and high temperature (>25 $^{\circ}$ C).
- **Sealing Requirement:** Nitrogen-filled tight sealing to prevent oxidation and moisture absorption; strict light protection to avoid photodegradation (especially for injection grade raw materials).
- **Incompatibilities:** Store separately from strong acids, oxidizing agents, heavy metal ions and photosensitizers.
- **Shelf Life:** 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated, used up as soon as possible with strict record).

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable light-proof protective clothing) during handling; sterile gloves and sterile protective clothing for injection grade raw material operation.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; apply mild emollient if irritation occurs.