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Technical Data Sheet (TDS) - Brinzolamide

Revision Date: 22 FEB 2026**CAS Number**: 138890-62-7**Molecular Formula**: $C_{12}H_{21}N_3O_5S_3$**Molecular Weight**: 383.50 g/mol

1. Product Overview

Brinzolamide is a high-purity pharmacopoeial-grade carbonic anhydrase inhibitor (CAI), a core pharmaceutical raw material for clinical ophthalmic anti-glaucoma therapy. It selectively inhibits carbonic anhydrase II isoenzyme in the ciliary body of the eye, reduces aqueous humor secretion by the ciliary epithelium, and lowers intraocular pressure (IOP) without significant systemic side effects. With high ocular tissue selectivity, long-acting IOP-lowering effect, good biocompatibility with ocular tissues and mild local adverse reactions, it is widely used in the production of clinical ophthalmic topical preparations for open-angle glaucoma and ocular hypertension.

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	175 ~ 179℃
Optical Rotation (25℃, c=1 in DMSO)	0° ± 2°
pH Value (0.1% DMSO solution, 25℃)	6.0 ~ 8.0
Solubility	Sparingly soluble in water; freely soluble in DMSO/ethanol; soluble in methanol/acetonitrile
Stability	Stable at 2~8℃, dark and sealed conditions; degraded by strong light/heat/alkali
Microbial Limit	Total bacterial count ≤ 100 CFU/g; E. coli negative; Mold & yeast ≤ 10 CFU/g
Particle Size	95% pass through 200-mesh sieve (ophthalmic grade)
Ocular Biocompatibility	No obvious irritation (in vitro rabbit corneal test)

3. Product Advantages

1. **High Ocular Selectivity**: Precisely targets ocular carbonic anhydrase II isoenzyme, minimal systemic absorption after topical ocular administration, reducing systemic adverse effects (e.g., electrolyte disturbance, gastrointestinal discomfort) compared with oral CAIs.
2. **Long-Acting IOP-Lowering**: Sustained reduction of intraocular pressure for 12-24 hours after administration, supporting twice-daily topical use and improving patient medication compliance.
3. **Good Ocular Tolerability**: Excellent biocompatibility with corneal and conjunctival tissues, low incidence of local adverse reactions (mild stinging, blurred vision), suitable for long-term clinical use.
4. **High Purity & Ophthalmic Grade**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content, 200-mesh fine particle size, meets strict ophthalmic pharmaceutical raw material standards.
5. **Synergistic Efficacy**: Can be combined with prostaglandin analogs, beta-blockers for combined glaucoma therapy, producing synergistic IOP-lowering effects for refractory glaucoma.

4. Application Fields

Pharmaceutical Raw Material for Clinical Ophthalmology Therapy:

- **Glaucoma**: Open-angle glaucoma, primary angle-closure glaucoma (post-surgery), normal-tension glaucoma, refractory glaucoma (combined therapy).
- **Ocular Hypertension**: Reduces elevated intraocular pressure in asymptomatic ocular hypertension patients, preventing glaucoma onset.
- **Dosage form production**: 1% ophthalmic suspension (main dosage form), 0.5% ophthalmic gel (sustained-release formulation), compound ophthalmic drops (combined with timolol).

5. Usage Methods (for Pharmaceutical Formulation)

1% Ophthalmic Suspension (Main Formulation)

- **Formula Ratio**: Brinzolamide 10 g, carbomer 940 1.5 g, sodium chloride 8.0 g, benzalkonium chloride 0.01 g, disodium edetate 0.1 g, purified water to 1000 mL.
- **Preparation Process**: Dissolve auxiliaries in purified water under aseptic conditions; disperse Brinzolamide powder in the solution with high-speed shearing (10000 rpm, 15 min); adjust pH to 6.5-7.5 with sodium hydroxide; add purified water to full volume; aseptic filtration (0.22 μm membrane) and filling into sterile ophthalmic drop bottles.
- **Processing Requirements**: Aseptic GMP workshop operation; avoid strong light and high temperature (≤25℃) during preparation; control particle size of the suspension D90 ≤ 5 μm to ensure ocular comfort; no preservative-free formulation available for single-use vials.

0.5% Ophthalmic Sustained-Release Gel

- Use hydroxypropyl methylcellulose (HPMC K4M) as the sustained-release matrix; mix with Brinzolamide and isotonic agents; prepare gel by cold gelation method; the gel forms a uniform film on the ocular surface after instillation, realizing slow drug release and 24-hour IOP control.

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 (ophthalmic formulation raw material)
- Custom GMP-compliant nitrogen-filled light-proof packaging for bulk orders available.

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **Sealing Requirement**: Nitrogen-filled tight sealing to prevent oxidation and moisture absorption; strict light protection (UV-proof packaging) to avoid photodegradation.
- **Incompatibilities**: Store separately from strong bases, 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).

Transportation

- Classified as pharmaceutical raw material for clinical ophthalmic preparations; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8℃) with real-time temperature monitoring; use shockproof, light-proof, moisture-proof packaging (brown glass/stainless steel with UV coating); avoid package collision and light exposure during transport.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable light-proof protective clothing) during handling to avoid skin/mucosa contact and dust inhalation, especially ocular contact.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; apply mild emollient if irritation occurs.
- In case of **ocular contact**: Immediately rinse eyes with sterile normal saline for 15-20 minutes; consult an ophthalmologist immediately even if no irritation is felt initially.