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Technical Data Sheet (TDS) - Bilastine

Revision Date: 20 FEB 2026**CAS Number**: 200800-47-7**Molecular Formula**: C_{28} H_{37} N_3O_2**Molecular Weight**: 447.62 g/mol

1. Product Overview

Bilastine is a high-purity pharmacopoeial-grade second-generation non-sedating H1 histamine receptor antagonist, a core pharmaceutical raw material for clinical anti-allergic therapy. It exerts its anti-allergic effect by selectively and competitively binding to peripheral H1 receptors, blocking the combination of histamine and its receptors, and inhibiting the release of allergic mediators. With high receptor selectivity, no blood-brain barrier penetration, and long-acting anti-allergic activity, it is widely used in the production of clinical oral solid preparations for the treatment of allergic rhinitis and chronic spontaneous urticaria in adults and adolescents.

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	215 ~ 219℃
Optical Rotation (25℃, c=1 in DMSO)	0° ± 2°
pH Value (0.1% DMSO suspension, 25℃)	6.0 ~ 8.0
Solubility	Practically insoluble in water; freely soluble in dimethyl sulfoxide (DMSO), methanol; soluble in ethanol, acetone
Stability	Stable at 2~8℃, 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

1. **High-Selectivity Peripheral H1 Receptor Antagonism**: Precisely binds to peripheral H1 receptors with no affinity for central nervous system H1 receptors; no sedative effect, no impact on cognitive function and driving ability.
2. **Long-Acting Anti-Allergic Activity**: Rapid onset of action (30 minutes after oral administration) and long duration (24 hours); once-daily administration, significantly improving patient compliance.
3. **Broad Anti-Allergic Spectrum**: Effective for both upper respiratory tract allergy (allergic rhinitis) and skin allergy (chronic spontaneous urticaria); relieves sneezing, runny nose, pruritus, wheal and other symptoms comprehensively.
4. **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 oral solid formulations.
5. **Excellent Safety Profile**: No obvious cardiotoxicity and liver/kidney toxicity; low drug-drug interaction risk (no inhibition of CYP450 enzyme system); suitable for long-term continuous medication.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anti-Allergic Therapy:

- **Allergic Rhinitis**: Seasonal allergic rhinitis and perennial allergic rhinitis in adults and adolescents (≥12 years old).
- **Chronic Spontaneous Urticaria**: Relieve skin pruritus and wheal symptoms in adults and adolescents (≥12 years old).
- Dosage form production: 20mg oral tablets (main dosage form), 10mg hard capsules (pediatric/adolescent reduced dosage).

5. Usage Methods (for Pharmaceutical Formulation)

Oral Solid Formulation (Tablets/Capsules)

- **20mg Oral Tablet**: Mix bilastine with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), hypromellose (binder) and magnesium stearate (lubricant), adopt wet granulation process (ethanol-water as wetting agent), granulate at low temperature (<60℃), compress and coat with film coating to prepare oral tablets.
- **Processing Requirements**: Avoid strong light and high temperature during the whole production process; control the moisture content of granules ≤ 0.5% to prevent drug hydrolysis; tablet disintegration time ≤ 30 minutes (artificial gastric juice).
- **10mg Hard Capsule**: Mix the granulated bilastine with lactose monohydrate (diluent) evenly, fill into hard gelatin capsules of appropriate size; the capsule shell uses light-proof medical grade material to avoid photodegradation.

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)
- 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 to avoid photodegradation.
- **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).

Transportation

- Classified as pharmaceutical raw material for clinical anti-allergic 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); 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.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; no special treatment needed if no irritation occurs.
- In case of eye contact: Rinse with sterile water for injection for 15 minutes; consult a physician immediately if irritation persists.
- Do not ingest; accidental oral intake may cause mild gastrointestinal discomfort—seek emergency medical treatment at once and conduct symptomatic treatment.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection and light-proof facilities; avoid strong light and high temperature during material transfer and processing.