

Technical Data Sheet (TDS) - Bomeprazole

Revision Date: 25 FEB 2026 **CAS Number:** 73590-58-6 **Molecular Formula:** C₁₇ H₁₉ N₃O₃S **Molecular Weight:** 345.42 g/mol

1. Product Overview

Bomeprazole is a high-purity pharmacopoeial-grade proton pump inhibitor (PPI), a core pharmaceutical raw material for clinical treatment of acid-related gastrointestinal diseases. It exerts a selective and irreversible inhibitory effect on the H⁺/K⁺-ATPase (proton pump) in the parietal cells of the gastric mucosa, blocking the final step of gastric acid secretion, and effectively reducing basal and stimulated gastric acid output. With high target selectivity, long-acting acid suppression, good oral bioavailability and mild adverse reactions, it is widely used in the production of clinical oral solid preparations for peptic ulcer, gastroesophageal reflux disease and erosive esophagitis.

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	156 ~ 160°C
Optical Rotation (25°C, c=1 in CH ₃ OH)	0° ± 2°
pH Value (0.1% methanol solution, 25°C)	5.0 ~ 7.0
Solubility	Sparingly soluble in water; freely soluble in methanol/ethanol; soluble in acetonitrile/DMSO
Stability	Stable at 2~8°C, 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 100-mesh sieve (pharmaceutical grade)
Plasma Protein Binding Rate	≈ 95% (in vitro human plasma test)

3. Product Advantages

- High-Selectivity Acid Suppression:** Precisely targets gastric parietal cell proton pumps with no significant affinity for other enzymes, reducing off-target side effects and achieving targeted acid inhibition.
- Long-Acting Therapeutic Effect:** Irreversible binding to the proton pump, with a long acid-suppression duration (24 hours), supporting once-daily administration and conforming to clinical medication habits.
- Broad Clinical Efficacy:** Effectively relieves symptoms of acid-related gastrointestinal diseases, promotes ulcer healing, and reduces recurrence rate; suitable for multiple acid-related disease indications.
- 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.



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5. **Favorable Safety Profile:** Low incidence of adverse reactions (mild headache, diarrhea), no obvious effect on liver and kidney function at clinical doses, suitable for long-term clinical administration.

4. Application Fields

Pharmaceutical Raw Material for Clinical Gastroenterology Therapy:

- **Peptic Ulcer:** Gastric ulcer, duodenal ulcer, promotes ulcer mucosal healing and relieves pain.
- **Gastroesophageal Reflux Disease (GERD):** Erosive esophagitis, non-erosive reflux disease, relieves heartburn, regurgitation and other symptoms.
- **Other Acid-Related Diseases:** Zollinger-Ellison syndrome, stress ulcer prophylaxis, non-steroidal anti-inflammatory drug (NSAID) induced gastric mucosal damage.
- **Dosage form production:** 10mg/20mg/40mg oral tablets (main dosage form), 20mg enteric-coated capsules (to avoid gastric acid degradation), 10mg chewable tablets (pediatric/elderly dosage).

5. Usage Methods (for Pharmaceutical Formulation)

Oral Solid Formulation (Enteric-Coated Tablets/Capsules)

- **20mg Enteric-Coated Tablet:** Mix Bomeprazole with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), hypromellose (binder) and magnesium stearate (lubricant); adopt wet granulation process (ethanol-water as wetting agent) at low temperature (<60°C); compress and coat with enteric coating (to resist gastric acid and dissolve in intestinal fluid).
- **Processing Requirements:** Avoid strong light, high temperature and high humidity during production; control granule moisture $\leq 0.5\%$ to prevent drug degradation; enteric coating dissolution: no dissolution in 0.1 mol/L HCl (2h), complete dissolution in phosphate buffer (pH 6.8, 1h).
- **20mg Enteric-Coated Capsule:** Mix granulated Bomeprazole with lactose monohydrate (diluent) evenly, fill into hard gelatin capsules; the capsule shell is matched with enteric pellets to avoid drug degradation in gastric acid.

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°C (refrigerated, dark place); avoid freezing and high temperature (>25°C).
- **Sealing Requirement:** Nitrogen-filled tight sealing to prevent oxidation and moisture absorption; strict light protection 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 gastroenterology preparations; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8°C) 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.