

## Technical Data Sheet (TDS) - Cimetidine

**Revision Date:** 20 FEB 2026 **Product Name:** Cimetidine 西咪替丁 **CAS Number:** 51481-61-9 **Formula:** C<sub>10</sub> H<sub>16</sub> N<sub>6</sub> S **Molecular Weight:** 252.34 g/mol

### 1. Product Overview

Cimetidine is a high-purity pharmaceutical-grade H<sub>2</sub> receptor antagonist, a core raw material for clinical acid-suppressing and anti-ulcer preparations. It exerts a potent and selective inhibitory effect on gastric acid secretion by blocking the histamine H<sub>2</sub> receptors on the parietal cells of the gastric mucosa, reducing basal and stimulated gastric acid output, and alleviating the damage of gastric acid to the gastric and duodenal mucosa. It is a white crystalline powder with slight water solubility, stable physical and chemical properties under recommended storage conditions, and is widely used in the production of oral solid, liquid and injectable pharmaceutical preparations for the treatment of peptic ulcer, gastroesophageal reflux disease and other acid-related digestive system diseases.

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

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	98.5 ~ 101.5%
Related Substances	Total ≤ 1.0%; Single Impurity ≤ 0.2%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
pH Value (1% aq. suspension, 25°C)	4.5 ~ 6.0
Melting Point	139 ~ 144°C
Total Bacterial Count	≤ 100 CFU/g
E. coli/Salmonella	Negative
Water Solubility (25°C)	≥ 1 g/100 mL
Density (25°C, solid)	1.32-1.36 g/cm <sup>3</sup>
Viscosity (5% aq. suspension, 25°C)	50-100 mPa·s
Temperature Stability	Stable at 0-30°C (assay retention ≥ 98%)
pH Stability	Stable at pH 4.0-7.0 (activity retention ≥ 95%)

### 3. Product Advantages

- Potent Acid-Suppressing Effect:** Selectively blocks gastric mucosal H<sub>2</sub> receptors, rapidly reducing gastric acid secretion with obvious curative effect on acid-related digestive diseases.
- High Safety:** Low adverse reaction rate, only occasional mild dizziness, dry mouth and other symptoms, good tolerance for long-term use in clinical practice.
- Excellent Formulation Compatibility:** Compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol), suitable for tablets, capsules, oral solutions and injections.
- High Purity & Stable Quality:** Pharmacopoeial grade purity, ultra-low impurity and heavy metal content, stable physical and chemical properties under recommended storage conditions.
- Broad Clinical Application:** Effective for peptic ulcer, acute gastric mucosal lesion, gastroesophageal reflux disease and other diseases, applicable to adults and children (age-appropriate dosage).
- Good Bioavailability:** Rapid oral absorption, peak plasma concentration in 1-2 hours, long duration of action (6-8 hours), and significant therapeutic effect.

### 4. Application Fields

- Pharmaceutical Acid-Suppressing & Anti-Ulcer Preparations:** Production of 200mg/400mg oral tablets, 200mg hard capsules, 100mg/mL injectable solutions, and oral syrups for pediatric use.



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- **Clinical Application:** Treatment of gastric ulcer, duodenal ulcer, acute gastric mucosal injury, gastroesophageal reflux disease, and prevention of stress ulcer in hospitals, clinics and family medicine.

## 5. Usage Methods

### Dosage for Formulation (Adjust according to preparation type)

- **200mg Oral Tablet:** Add 200mg of Cimetidine per tablet, mixed with lactose monohydrate (150mg), microcrystalline cellulose (80mg), cross-linked carboxymethylcellulose sodium (10mg) and magnesium stearate (2mg) for direct compression.
- **100mg/mL Injectable Solution:** Dissolve Cimetidine with water for injection, add an appropriate amount of sodium chloride (isotonic adjustment) and disodium hydrogen phosphate (pH adjustment), filter and sterilize for injection preparation.
- **Oral Syrup (50mg/mL):** Dissolve Cimetidine with purified water, add sucrose (600g/L) and glycerin (50g/L) as flavoring and humectant, and prepare oral syrup by filtration.

### Processing Requirements

- Operate in a dry and well-ventilated environment (RH ≤ 60%) to prevent moisture absorption of the raw material.
- Ensure uniform mixing of the raw material and excipients to guarantee the content uniformity of the preparation.
- Avoid high temperature (>60°C) during processing to prevent the degradation of active ingredients; the injectable preparation shall comply with GMP sterile production specifications.

## 6. Packaging & Storage

### Packaging Specifications

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

### Storage Conditions

- Store in a cool, dry, dark warehouse at 15~25°C; avoid high temperature (>30°C) and direct sunlight.
- Keep the container tightly closed to prevent moisture absorption and oxidation; store separately from strong acids, strong bases and oxidizing agents.
- **Shelf Life:** 36 months (unopened, under specified storage conditions); 6 months after opening (sealed, dry condition, used up as soon as possible).

### Transportation

- Classified as non-hazardous pharmaceutical raw material; transport in compliance with national pharmaceutical raw material transportation regulations.
- Ambient temperature transport (15~25°C) with temperature monitoring; use shockproof, light-proof, moisture-proof packaging; avoid package collision and direct sunlight during transport.

## 7. Safety & Protection

- The product is a pharmaceutical raw material, not for direct human use; wear professional pharmaceutical PPE (nitrile rubber gloves, chemical safety goggles, dust mask) during handling.
- In case of skin contact: Rinse with plenty of running water and soap for 10 minutes; no special treatment for mild contact.
- In case of eye contact: Rinse with sterile water for injection for 15 minutes; consult a physician if irritation persists.
- Do not ingest; accidental oral intake may cause dizziness, dry mouth—rinse mouth with water and consult a doctor if discomfort occurs.
- Operate in a well-ventilated GMP workshop with dry and light-proof facilities.

## 8. Quality Assurance

- The product is manufactured in accordance with GMP and ICH Q7 pharmaceutical raw material production guidelines, complying with ISO 9001 quality management system and ISO 14001 environmental management system standards.