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# Technical Data Sheet (TDS)
# - Rimantadine Hydrochloride

**Revision Date**: 28 FEB 2026**CAS Number**: 1501-84-4**Molecular Formula**: $C_{12}H_{21}N \cdot HCl$**Molecular Weight**: 217.76 g/mol

## 1. Product Overview

Rimantadine Hydrochloride is a high-purity pharmacopoeial-grade anti-influenza virus pharmaceutical raw material, a derivative of adamantane with selective inhibitory activity against influenza A virus. It exerts its antiviral effect by blocking the M2 ion channel of influenza A virus, inhibiting viral uncoating and nucleic acid release in host cells, thereby preventing viral replication and spread. As a classic anti-influenza raw material, it features a clear mechanism of action, high antiviral potency, good oral bioavailability, and stable quality, and is widely used in the production of clinical oral solid and liquid pharmaceutical preparations for the prevention and treatment of influenza A virus infections.

## 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 | 134 ~ 138℃ |
| Specific Rotation (25℃, c=5 in $H_2O$) | +6.0° ~ +8.0° |
| pH Value (1% aqueous solution, 25℃) | 4.0 ~ 6.0 |
| Solubility | Freely soluble in water and ethanol; soluble in methanol; slightly soluble in acetone |
| 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 |

## 3. Product Advantages

1. **Selective Anti-Influenza Activity**: Potent inhibitory effect on various subtypes of influenza A virus (H1N1, H3N2, etc.), the first-line raw material for the prevention and treatment of influenza A.
2. **Excellent Pharmacokinetic Properties**: Rapid and complete absorption after oral administration, high bioavailability (≈90%), long half-life (≈24h), once-daily administration, improving patient compliance.
3. **High Purity & Stable Quality**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; good chemical stability under recommended storage conditions, no obvious degradation within the shelf life.
4. **Diverse Formulation Potential**: Can be prepared into oral tablets, capsules, granules, and oral syrups, adapting to the medication needs of different populations (adults, children, the elderly).
5. **High Safety Profile**: Low adverse reaction rate at clinical doses, mild side effects (minor gastrointestinal discomfort, dizziness), and the side effects are reversible after drug withdrawal.

## 4. Application Fields

**Pharmaceutical Raw Material for Clinical Anti-Influenza A Virus Therapy**:

- **Prevention of influenza A**: Prophylactic administration for high-risk groups (medical staff, the elderly, children, immunocompromised populations) during influenza A epidemic periods.
- **Treatment of influenza A**: Early treatment of acute influenza A virus infections, alleviating clinical symptoms (fever, cough, myalgia) and shortening the course of the disease.
- **Dosage form production**: 50mg/100mg oral tablets, 50mg capsules, 50mg/5mL oral granules/syrups.

**5. Usage Methods (for Pharmaceutical Formulation)**

**Oral Solid Formulation (Tablets/Capsules)**

- **100mg Oral Tablet**: Mix rimantadine hydrochloride with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), and magnesium stearate (lubricant), dry granulate at low temperature (<60℃), compress and coat to prepare oral tablets.
- **Processing Requirements**: Control the moisture content of granules ≤ 0.5% to avoid drug hydrolysis; tablet disintegration time ≤ 15 minutes (water).

**Oral Liquid Formulation (Granules/Syrups)**

- **50mg/5mL Oral Syrup**: Dissolve rimantadine hydrochloride with purified water, add sucrose (sweetener), citric acid (flavor adjuster), and methylparaben (preservative), stir to dissolve, and fix the volume to prepare a clear oral syrup.
- **Processing Requirements**: Adjust the pH value of the syrup to 4.5-5.5 to improve drug stability; sterile filtration before filling.

**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 sealed drum (for oral formulation raw material)
- Custom GMP-compliant nitrogen-filled packaging available for bulk orders.

**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; protect from direct light.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents, and hygroscopic substances.
- **Shelf Life**: 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated).

**Transportation**

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

**7. Safety & Protection**

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable 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; apply mild emollient if 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 gastrointestinal discomfort and dizziness—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.