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Technical Data Sheet (TDS) - Pentoxyverine Citrate

Revision Date: 20 FEB 2026**Product Name**: Pentoxyverine Citrate 戊氧维林柠檬酸盐**CAS Number**: 23142-01-0**Formula**: $C_{24}H_{31}NO_3 \cdot C_6H_8O_7$ **Molecular Weight**: 527.59 g/mol

1. Product Overview

Pentoxyverine Citrate is a high-purity pharmaceutical-grade non-narcotic central antitussive raw material. It exerts an antitussive effect by selectively inhibiting the medullary cough center, with mild anticholinergic and local anesthetic effects, and no respiratory depression or addiction risk. It is a white crystalline powder with good water solubility and high oral bioavailability. The product neutralizes the cough reflex by acting on the central nervous system, and is widely used in the production of oral solid and liquid pharmaceutical preparations for the treatment of dry cough caused by upper respiratory tract infections such as bronchitis, pharyngitis and laryngitis.

2. Technical Specifications (Complies with Industry & Pharmacopoeial Standard)

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
Acidity/Alkalinity (1% aq. solution)	3.0 ~ 4.0
Melting Point	87 ~ 92℃
Optical Rotation (25℃, c=5 in H_2O)	-62° ~ -68°
Total Bacterial Count	≤ 100 CFU/g
E. coli	Negative
Water Solubility (25℃)	≥ 10 g/100 mL
Viscosity (5% aq. solution, 25℃)	20-50 mPa·s
Density (25℃, solid)	1.28-1.32 g/cm³
Temperature Stability	Stable at 0-30℃ (assay retention ≥ 98%)
pH Stability	Stable at pH 2.0-5.0 (activity retention ≥ 95%)

3. Product Advantages

1. **Non-narcotic & Non-addictive**: No respiratory depression, no physical or psychological dependence, suitable for long-term clinical use.
2. **High Antitussive Efficacy**: Rapid onset (30 minutes after oral administration) and long duration (4-6 hours), significant effect on various dry coughs.
3. **Good Biocompatibility**: Mild side effects, only occasional dry mouth, dizziness and other mild anticholinergic reactions, high patient tolerance.
4. **Excellent Formulation Compatibility**: Good water solubility, compatible with common pharmaceutical excipients (lactose, sucrose, microcrystalline cellulose), suitable for tablets, syrups, oral solutions and other dosage forms.
5. **High Purity & Stable Quality**: Pharmacopoeial grade purity, ultra-low impurity and heavy metal content, stable physical and chemical properties under recommended storage conditions.
6. **Broad Application**: Effective for dry cough caused by acute bronchitis, chronic bronchitis acute attack, pharyngitis, laryngitis and other upper respiratory tract infections, applicable to adults and children (age-appropriate dosage).

4. Application Fields

- **Pharmaceutical Antitussive Preparations**: Production of 25mg oral tablets, 0.2% antitussive syrup, 5mg/mL oral solution, pediatric chewable tablets and other oral antitussive drugs.

- **Clinical Application**: Treatment of dry cough caused by upper respiratory tract infections, bronchitis, pharyngitis, laryngitis and other respiratory system diseases in hospitals, clinics and family medicine.

5. Usage Methods

Dosage for Formulation (Adjust according to preparation type)

- **Oral Tablets (25mg)**: Add 25mg of Pentoxyverine Citrate per tablet, mixed with lactose, microcrystalline cellulose and other excipients for direct compression or wet granulation compression.
- **Antitussive Syrup (0.2%)**: Dissolve 2g of Pentoxyverine Citrate in 1000mL of purified water with sucrose, glycerin and other auxiliary materials to prepare oral syrup.
- **Oral Solution (5mg/mL)**: Dilute the raw material with purified water to the specified concentration, add appropriate flavoring and preservative, filter and fill.

Processing Requirements

- Operate in a low-humidity environment (RH ≤ 50%) to prevent hygroscopy 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℃) during processing to prevent the degradation of active ingredients.

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℃; avoid high temperature (>30℃) and direct sunlight.
- Keep the container tightly closed to prevent moisture absorption and oxidation; store separately from strong bases, oxidizing agents and high-humidity materials.
- **Shelf Life**: 36 months (unopened, under specified storage conditions); 6 months after opening (sealed, low humidity, 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℃) 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 dry mouth, dizziness—rinse mouth with water and consult a doctor if discomfort occurs.
- Operate in a well-ventilated GMP workshop with low-humidity 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.
- Each batch of product is subject to full-item testing and accompanied by a detailed Certificate of Analysis (COA) to ensure compliance with pharmacopoeial and industrial standards.