NEWAY SINOPHC TECH. LIMITED
ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com； Phone:+86-021-50350029 https://www.newayphc.com

Technical Data Sheet (TDS) - Doxylamine Succinate

Revision Date: 22 FEB 2026**CAS Number**: 562-10-7**Molecular Formula**: $C_{17}H_{22}N_2O \cdot C_4H_6O_4$**Molecular Weight**: 388.46 g/mol

1. Product Overview

Doxylamine Succinate is a high-purity pharmacopoeial-grade first-generation H1 histamine receptor antagonist with potent antihistaminic, sedative and anticholinergic activities, a core pharmaceutical raw material for clinical antiallergic and sedative-hypnotic therapy. It exerts its pharmacological effects by competitively binding to central and peripheral H1 histamine receptors, blocking the histamine-mediated allergic reaction and central nervous system excitatory signal pathway. With rapid onset, strong sedative effect and good oral bioavailability, it is widely used in the production of clinical oral solid and liquid preparations for allergic rhinitis, urticaria, insomnia and motion sickness.

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	104 ~ 108℃
Optical Rotation (25℃, c=1 in H_2O)	0° ± 2°
pH Value (1% aqueous solution, 25℃)	4.0 ~ 6.0
Solubility	Freely soluble in water, ethanol, methanol; soluble in acetone; slightly soluble in ether
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
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)

3. Product Advantages

1. **Potent Dual Pharmacological Activity**: Strong H1 receptor antagonism and central sedative effect; effective for both allergic diseases and mild-to-moderate insomnia, one drug for multiple indications.
2. **Rapid Onset & Long Duration**: Rapid absorption after oral administration, onset in 15-30 minutes, peak effect at 1-2 hours, duration of action up to 6-8 hours.
3. **Good Solubility Characteristics**: Freely soluble in water and common organic solvents, suitable for the preparation of various dosage forms (tablets, capsules, syrups, drops).
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 and liquid formulations.
5. **Proven Clinical Efficacy**: A classic first-generation antihistamine with decades of clinical application; definite curative effect for allergic rhinitis, urticaria and transient insomnia, high clinical recognition.

4. Application Fields

Pharmaceutical Raw Material for Clinical Antihistamine and Sedative Therapy:

- **Allergic Diseases**: Allergic rhinitis (seasonal and perennial), acute and chronic urticaria, allergic conjunctivitis, pruritic skin diseases.
- **Central Nervous System Disorders**: Mild-to-moderate insomnia, especially insomnia associated with allergic symptoms; anxiety-induced sleep disturbance.
- **Other Indications**: Motion sickness, nausea and vomiting caused by inner ear vertigo; adjunctive treatment for allergic asthma.
- **Dosage form production**: 12.5mg/25mg oral tablets, 5mg/mL oral syrups, 25mg hard capsules, 10mg/mL oral drops.

5. Usage Methods (for Pharmaceutical Formulation)

Oral Solid Formulation (Tablets/Capsules)

- **25mg Oral Tablet**: Mix doxylamine succinate with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), hypromellose (binder) and magnesium stearate (lubricant), adopt wet granulation process (purified 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 ≤ 15 minutes (water).

Oral Liquid Formulation (Syrup/Drops)

- **5mg/mL Oral Syrup**: Dissolve doxylamine succinate in purified water with sucrose (sweetener), glycerol (humectant) and methylparaben (preservative), stir evenly at room temperature, adjust pH to 4.5-5.5 with citric acid, filter and fill into brown glass bottles.
- **Processing Requirements**: Use light-proof equipment during preparation; avoid high temperature heating (>40℃); add preservative to ensure microbial stability, shelf life of liquid preparation up to 24 months under sealed storage.

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)
- 500 g / food-grade HDPE drum (for liquid 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, 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 antihistamine and sedative 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; apply mild emollient if irritation occurs.