

Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name:** Phenylephrine Hydrochloride
- **CAS Number:** 61-76-7
- **Molecular Formula:** C₉ H₁₃NO₂·HCl
- **Molecular Weight:** 203.67 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized via phenol alkylation, amination and hydrochloric acid salification; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for aqueous pharmaceutical preparations).
- **Product Trait:** White to off-white crystalline powder, practically odorless, slightly hygroscopic and light/air-sensitive; freely soluble in water/organic alcohols, insoluble in non-polar solvents; stable in dry, dark and weakly acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with light protection and low temperature.
- **Core Properties: Selective alpha-1 adrenergic receptor agonist** with potent vasoconstrictor activity; constricts arterioles in nasal/ocular mucous membranes and systemic blood vessels, rapidly relieving nasal congestion/ocular redness and elevating blood pressure; low systemic side effects, high safety for topical/parenteral use; classic pharmaceutical raw material for clinical ophthalmic, nasal and cardiovascular formulations.
- **Main Application:** Pharmaceutical raw material for human ophthalmic/nasal/cardiovascular formulations (eye drops, nasal drops, injection solutions); treatment of nasal congestion, ocular redness, hypotension and shock; pharmaceutical R&D reference reagent for alpha-adrenergic receptor pharmacology research.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification
Appearance	White to off-white crystalline powder
Odor	Practically odorless
Assay (Phenylephrine Hydrochloride)	≥ 98.5%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 2 ppm
Heavy Metals (As)	≤ 1 ppm
Related Substances	≤ 1.0%
Melting Point	140-145°C
pH Value (1% aqueous solution, 25°C)	4.5-5.5
Solubility in Water	Freely soluble
Total Bacterial Count	≤ 10 CFU/g
E. coli	Negative
Yeast & Mold	≤ 10 CFU/g
Particle Size	95% passing 100 mesh
Bulk Density	1.28-1.32 g/cm ³
Photostability	≤ 0.5% related substances after 7 days (25°C, light exposure)
Water Solubility	≥ 60 g/L (25°C)

3. Product Advantages

1. **High Alpha-1 Receptor Selectivity:** Selectively binds to vascular smooth muscle alpha-1 receptors; no significant affinity for beta receptors, minimizing systemic cardiovascular side effects (e.g., tachycardia) compared with non-selective vasoconstrictors.



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- 2. Fast & Long-Acting Efficacy:** Rapidly constricts mucous membrane arterioles within 3-5 minutes; relieves nasal congestion/ocular redness for 4-6 hours with single topical administration; elevates blood pressure for 1-2 hours via injection, ideal for emergency hypotension treatment.
- 3. Low Systemic Absorption:** Minimal systemic absorption after topical ophthalmic/nasal use; low blood concentration, no significant impact on systemic blood pressure in normal topical use, high safety for long-term application.
- 4. Pharmaceutical Grade Purity:** Meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal/microbial limits; high assay ($\geq 98.5\%$) and low related substances; suitable for GMP production of clinical sterile topical/injection formulations.
- 5. Excellent Formulation Compatibility:** Freely soluble in water, compatible with common pharmaceutical excipients (boric acid, sodium chloride, methylparaben); easy to prepare sterile eye drops, nasal drops and injection solutions; stable in autoclaving sterilization (121 °C, 15 minutes).

4. Application Fields

4.1 Pharmaceutical Industry (Topical/Parenteral Formulations)

- Nasal Drops/Sprays:** Core raw material for 0.5-1.0% nasal drops/sprays; treatment of acute/chronic rhinitis/sinusitis-induced nasal congestion; safe for adult/older pediatric use.
- Eye Drops:** Formulation for 0.12-0.25% sterile eye drops; relieves ocular redness/conjunctival congestion caused by conjunctivitis/eye fatigue; mild irritation, high patient tolerance.
- Injection Solutions:** 0.1-1.0% sterile injection solutions; emergency treatment of hypotension, shock and spinal anesthesia-induced hypotension; rapid onset and controllable efficacy.
- Combination Formulations:** Adjuvant raw material for ophthalmic/nasal combination formulations (with antihistamines/antibiotics); simultaneous relief of congestion and anti-inflammatory/antibacterial effects.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- Nasal Drops (Adults):** 0.5-1.0% w/v aqueous solution; 1-2 drops per nostril, 3-4 times daily.
- Eye Drops (Adults):** 0.12-0.25% w/v sterile aqueous solution; 1-2 drops per eye, 2-3 times daily.
- Injection Solution:** 0.1% w/v sterile aqueous solution; intravenous injection (50-100 μg per dose) for hypotension emergency treatment.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with aluminum foil seal (R&D/analytical use, light protection).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch production, light protection).
- 5 kg/25 kg/drum: HDPE brown pharmaceutical drum with aluminum foil inner lining (bulk production, light protection).
- Custom packaging (500 g/2 kg) available for R&D/custom formulation (all light-proof + moisture-proof).

7. Safety & Protection

- The product is a selective alpha-1 agonist pharmaceutical raw material with mild cardiovascular toxicity and irritant effects; **all operations by trained professional personnel** with full PPE (N95 dust mask, safety goggles, nitrile gloves, impermeable lab coat).
- Avoid eye/skin/mucous membrane/respiratory tract contact; operate in a well-ventilated dust-free fume hood with light protection; monitor blood pressure/heart rate for personnel with prolonged handling exposure.
- In case of eye contact: Rinse with plenty of water for 15 minutes and call a doctor immediately. In case of skin contact: Rinse with water/soap for 5 minutes; seek medical advice if irritation persists. If swallowed: Rinse mouth, do not induce vomiting, call a POISON CENTER at once.
- Collect all production waste/cleaning water for professional hazardous waste disposal; no discharge to the environment.