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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Naphazoline Hydrochloride
- **CAS Number**: 550-99-2
- **Molecular Formula**: $C_{14}H_{14}N_2 \cdot HCl$
- **Molecular Weight**: 246.74 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via naphthalene formaldehyde condensation, imidazoline ring formation and hydrochloric acid salification; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for ophthalmic/nasal aqueous preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in water and 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**: **Potent and selective alpha-adrenergic receptor agonist** with strong vasoconstrictor activity; constricts arterioles in nasal and ocular mucous membranes, rapidly relieving nasal congestion and ocular redness; fast onset of action (5-10 minutes), long duration (4-8 hours); low systemic absorption, high safety for topical ophthalmic/nasal use; the classic pharmaceutical raw material for clinical topical vasoconstrictor formulations.
- **Main Application**: Pharmaceutical raw material for human ophthalmic/nasal topical formulations (nasal drops, eye drops, nasal sprays); treatment of nasal congestion caused by rhinitis/sinusitis and ocular redness caused by conjunctivitis; pharmaceutical R&D reference reagent for cardiovascular pharmacology and alpha-receptor research.

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

Item	Specification
Appearance	White to off-white crystalline powder
Odor	Practically odorless
Assay (Naphazoline 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	254-260℃ (dec.)
pH Value (1% aqueous solution,25℃)	5.5-6.5
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	1.21-1.25 g/cm³
Photostability	≤ 0.5% related substances after 7 days (25℃, light exposure)
Water Solubility	≥ 50 g/L (25℃)

3. Product Advantages

1. **High Alpha-Receptor Selectivity**: Potent and highly selective binding to alpha-adrenergic receptors in vascular smooth muscle; no significant affinity for beta-receptors, reducing systemic cardiovascular side effects (e.g., tachycardia) compared with non-selective vasoconstrictors.

2. **Fast & Long-Acting Vasoconstriction**: Rapidly constricts mucous membrane arterioles within 5-10 minutes; relieves nasal congestion and ocular redness for 4-8 hours with single topical administration, reducing reapplication frequency and improving patient compliance.
3. **Low Systemic Absorption**: Minimal systemic absorption after topical ophthalmic/nasal use; low blood concentration, no significant impact on systemic blood pressure and heart rate in normal use, high safety for long-term topical application.
4. **Pharmaceutical Grade Purity**: Meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits; high assay (≥98.5%) and low related substances; suitable for GMP production of clinical ophthalmic/nasal sterile aqueous formulations.
5. **Excellent Formulation Compatibility**: Freely soluble in water, compatible with common ophthalmic/nasal pharmaceutical excipients (boric acid, sodium chloride, methylparaben); easy to prepare sterile aqueous drops/sprays for clinical topical use; stable in sterilization and filling processes (autoclaving at 121℃ for 15 minutes).

4. Application Fields

4.1 Pharmaceutical Industry (Ophthalmic/Nasal Topical Formulations)

- **Nasal Drops/Sprays**: Core raw material for 0.05%/0.1% nasal drops/sprays; treatment of acute/chronic rhinitis, sinusitis and allergic rhinitis-induced nasal congestion; 1-2 drops/sprays per nostril, 3-4 times a day, safe for adult use.
- **Eye Drops**: Formulation for 0.01%/0.02% sterile eye drops; treatment of ocular redness, conjunctival congestion caused by acute conjunctivitis, keratitis and eye fatigue; 1-2 drops per eye, 2-3 times a day, mild irritation, high patient tolerance.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Nasal Drops (Adults)**: 0.05-0.1% w/v aqueous solution; 1-2 drops per nostril, 3-4 times daily; maximum concentration not exceeding 0.1% to avoid excessive vasoconstriction.
- **Eye Drops (Adults)**: 0.01-0.02% w/v sterile aqueous solution; 1-2 drops per eye, 2-3 times daily; dilute to 0.005% for pediatric use (≥6 years old).
- **Nasal Sprays**: 0.05% w/v aqueous solution; 1 spray per nostril, 3 times daily; continuous use no more than 7 days to avoid rebound congestion.

6. Packaging & Storage

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

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

7. Safety & Protection

- The product is a potent alpha-adrenergic receptor agonist and pharmaceutical raw material with mild cardiovascular toxicity and irritant effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/mucous membranes/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **light protection**; monitor cardiovascular function (blood pressure, heart rate) for personnel with prolonged handling exposure.
- Avoid direct sunlight and high humidity in the work area; keep the operation tools clean and dry; do not mix with other pharmaceutical raw materials (especially beta-blockers and cardiovascular toxic drugs) randomly.