

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 四卡因
- English Name: Tetracaine
- CAS Number: 94-24-6
- Molecular Formula: C₁₅ H₂₄N₂O₂
- Molecular Weight: 264.36 Da
- **Product Characteristics:** High-purity pharmaceutical grade Tetracaine, a potent long-acting ester-type local anesthetic with slow onset and prolonged duration; white off-white free-flowing crystalline powder with slight ester odor, slightly soluble in water and freely soluble in organic solvents (ethanol, chloroform); exerts pharmacological effects by blocking sodium ion channels in nerve cell membranes, inhibiting nerve impulse conduction and producing reversible local anesthesia; stable under recommended storage conditions; compatible with most pharmaceutical excipients (excluding strong alkaline/esterase-containing excipients); meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of topical/surface anesthetic pharmaceutical formulations for clinical ophthalmic, otorhinolaryngological and dermatological use.

2. Technical Specifications (Complies with USP/EP/BP & Pharmaceutical Industrial Standards)

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	41-45°C (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. solution, 25°C)	5.0-7.0
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl ⁻)	≤ 0.01%
Sulfate (SO ₄ ²⁻)	≤ 0.01%
Related Substances	≤ 0.5% (HPLC)
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Particle Size	≥95% passing 80 mesh
Water Solubility	Slightly soluble (0.1 g/100 mL, 25°C)
Organic Solubility	Freely soluble in ethanol/methanol/chloroform/ether
Bulk Density	1.02-1.06 g/cm ³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30°C (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)
Compatibility	Incompatible with strong alkaline/esterase-containing excipients, heavy metal salts, oxidizing agents

3. Product Advantages

1. **High Purity & Pharmaceutical Grade:** Assay ≥99.0%, low related substances (≤0.5%), excellent batch-to-batch consistency; complies with USP/EP/BP global pharmacopoeia standards; meets GMP production requirements for pharmaceutical raw materials, ensuring high product quality and clinical application safety for topical/surface use.

2. **Long-Acting Local Anesthesia:** Prolonged anesthetic duration (2-4 hours for surface anesthesia), significantly longer than procaine/lidocaine; suitable for long-duration clinical minor operations (ophthalmic examination, otorhinolaryngological treatment).
3. **Potent Anesthetic Effect:** High anesthetic potency (8-10 times that of procaine); low dosage achieves effective anesthesia, reducing systemic toxicity risk in clinical use.
4. **Good Formulability:** Freely soluble in organic solvents, easy to prepare oil-based/ethanol-based topical formulations (eye drops, ointments, sprays); compatible with common pharmaceutical stabilizers and humectants, meeting diverse clinical dosage form needs.

4. Application Fields

- **Pharmaceutical Preparations:** Topical/surface anesthetic formulations (eye drops, ointments, sprays, gels) for clinical ophthalmic (tonometry, cataract surgery), otorhinolaryngological (tonsil examination, nasal endoscopy) and dermatological (minor skin surgery, wart removal) use; spinal/epidural anesthetic auxiliary formulations (with epinephrine to prolong duration).
- **Pharmaceutical Research:** Research reagent for local anesthetic drug development, sodium ion channel inhibitor research and ester-type anesthetic metabolism research; clinical anesthetic formulation optimization and new dosage form development research.

5. Usage Methods

5.1 Formulation Compatibility

- **Ophthalmic Anesthetic Eye Drops:** Dissolve in sterile normal saline with 1-2% ethanol as cosolvent to prepare 0.5-1% concentration solution; add boric acid buffer to adjust pH to 6.0-7.0; add preservative (benzalkonium chloride) and antioxidant; filter and sterilize by 0.22 μm microporous membrane; store in brown glass vials.
- **Topical Anesthetic Ointment:** Mix with white petrolatum/lanolin at a ratio of 1-2% (w/w); add liquid paraffin to adjust consistency; control processing temperature below 50°C to prevent active ingredient degradation; prepare in a sterile environment for dermatological use.
- **Mucosal Anesthetic Spray:** Dissolve in 5% ethanol solution to prepare 1-2% concentration spray; add propylene glycol as humectant; fill in pressure-free spray bottles with light-proof packaging.
- **Key Note:** Do not mix with strong acids, strong bases, oxidizing agents, heavy metal salts or esterase-containing excipients; use sterile water for injection and pharmaceutical grade excipients for all formulations; avoid high-temperature processing (>60°C); do not mix with ester-type anesthetic allergy drugs.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (pharmaceutical grade brown glass bottle, aluminum foil sealed, light-proof and moisture-proof)
- 1 kg/bag (pharmaceutical grade aluminum foil bag, vacuum sealed, light-proof)
- 5 kg/10 kg/drum (sealed HDPE drum with inner pharmaceutical grade aluminum foil bag, light-proof)
- 25 kg/drum (pharmaceutical grade fiber drum with inner vacuum-sealed aluminum foil bag, light-proof)
- **Custom Packaging:** 500 g/2 kg sterile packaging available for ophthalmic formulation production (MOQ applicable) according to customer requirements.

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical with CNS/cardiovascular toxicity and eye irritation risk; **only for use by trained professional personnel** (pharmaceutical production, clinical medical staff, scientific research staff) with relevant operating qualifications.
- Wear **mandatory full personal protective equipment** during all handling, processing and preparation operations (chemical-resistant goggles + face shield, nitrile rubber gloves $\geq 0.18\text{mm}$ thick, N95 respirator, impermeable lab coat, protective shoes).
- Avoid direct skin contact, eye exposure and dust inhalation; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention **immediately** (especially for eye contact, large dosage ingestion and cardiac discomfort).