

Technical Data Sheet (TDS)

Issue Date: 28 FEB 2026 Version: V1.0

1. Product Overview

- **Product Name:** Tetracaine Hydrochloride
- **CAS Number:** 136-47-0
- **Molecular Formula:** C₁₅ H₂₄N₂O₂·HCl
- **Molecular Weight:** 300.82 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized from 4-butylaminobenzoic acid and 2-dimethylaminoethanol via esterification and hydrochlorination, purified by recrystallization and light protection processing)
- **Product Trait:** White crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; soluble in water, freely soluble in ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and acidic environment, easy to hydrolyze in alkaline/moist environment.
- **Core Properties:** Classic long-acting ester local anesthetic with strong anesthetic activity; fast onset (2-5 minutes), long duration of action (2-4 hours); high potency (8-10 times that of procaine), suitable for topical and mucosal anesthesia; poor water solubility compared with amide anesthetics, mainly used for surface anesthesia formulations.
- **Main Application:** Pharmaceutical intermediate for human topical/mucosal anesthetic formulations (ophthalmic drops, dental ointments, urological gels, skin sprays); veterinary drug raw material for animal ocular, oral and skin surface anesthesia; pharmaceutical R&D and analytical reference reagent for local anesthetic research.

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

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Tetracaine Hydrochloride)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25°C ignition method
Heavy Metals (Pb)	≤ 5 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Chloride (Cl ⁻)	11.8-12.4%	Volumetric Method
Sulfate (SO ₄ ²⁻)	≤ 0.05%	Turbidimetric Method
Melting Point	147-153°C	Melting Point Apparatus (light protection)
pH Value (1% aqueous solution, 25°C)	4.5-6.0	Digital pH Meter
Total Bacterial Count	≤ 10 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	Plate Count Method
Particle Size	95% passing 80 mesh	Standard Sieve Method (light protection)
Water Solubility (25°C)	≥ 35 g/L	Solubility Test
Bulk Density	1.27-1.31 g/cm ³	Pycnometer Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25°C, 60% RH, light protection)	HPLC

3. Product Advantages



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1. **High Purity & Low Impurities:** Assay $\geq 99.0\%$, related substances $\leq 0.5\%$, meets USP/EP/CP pharmaceutical grade requirements, no harmful impurities, ensures the safety and efficacy of surface anesthetic formulations.
2. **Long-Acting & Potent Anesthesia:** Strong anesthetic activity, long duration of action (2-4 hours), 8-10 times the potency of procaine, reduces reapplication frequency, suitable for long-time surface anesthesia operations (ophthalmic, dental).
3. **Fast Onset of Action:** Rapid onset (2-5 minutes) after topical/mucosal application, fast pain relief, improves clinical operation efficiency, suitable for emergency surface anesthesia.
4. **Good Formulation Compatibility:** Soluble in water and common organic solvents, compatible with most pharmaceutical excipients (mannitol, glycerol, carbomer, borax buffer); suitable for various topical formulations (drops, ointments, gels, sprays).

4. Application Fields

4.1 Pharmaceutical Industry (Human Topical/Mucosal Formulations)

- **Ophthalmic Anesthesia:** Core raw material for ophthalmic anesthetic drops; used for surface anesthesia of ophthalmic examinations (tonometry, slit lamp) and minor surgeries (cataract, glaucoma), non-irritating to ocular tissue with proper formulation.
- **Dental Anesthesia:** Raw material for dental anesthetic ointments/gels; used for surface anesthesia of dental caries, tooth extraction and gingival surgery, fast pain relief and long duration.
- **Urological Anesthesia:** Formulations for urethral/bladder mucosal anesthetic gels; used for surface anesthesia of urological examinations (cystoscopy) and minor operations, reduces mucosal irritation and pain.
- **Skin Anesthesia:** Raw material for skin anesthetic sprays/ointments; used for surface anesthesia of minor skin surgeries (suture, mole removal) and cosmetic procedures (laser, micro-needle), fast onset and good tolerance.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Ophthalmic Drops:** 0.5-1.0% concentration, 1-2 drops per eye, administered 2-3 times at 5-minute intervals before operation.
- **Dental Ointments/Gels:** 2-4% concentration, apply an appropriate amount to the affected area and keep for 3-5 minutes before operation.
- **Urological Gels:** 1-2% concentration, instill or apply an appropriate amount to the mucosal surface, keep for 5 minutes before operation.
- **Skin Sprays/Ointments:** 1-2% concentration, spray/apply an appropriate amount to the operation site, cover with a film for 5-10 minutes.

6. Packaging & Storage

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

- 100 g/bottle: Brown 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).

7. Safety & Protection

- The product is a toxic pharmaceutical intermediate with serious eye damage risk; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant full face shield, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes, skin and respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with light protection.
- In case of eye contact, **immediately rinse with plenty of running water for at least 20 minutes** and call a POISON CENTER/ophthalmologist for professional treatment (irreversible damage may occur without timely treatment).