纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 盐酸普罗莫卡因
- English Name: Promocaine Hydrochloride
- CAS Number: 637-58-1
- Molecular Formula: $C_{16}H_{27}ClN_2O_2$
- Molecular Weight: 314.85 Da
- **Product Characteristics**: High-purity pharmaceutical grade Promocaine Hydrochloride, a potent ester-type local anesthetic with long duration and low systemic toxicity; white to off-white free-flowing crystalline powder with slight ester odor, **freely soluble in water** and soluble in organic solvents; 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/local anesthetic pharmaceutical formulations for clinical dermatology, dentistry and urology.

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	148-152℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. solution,25℃)	4.0-6.0
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl^-, Calculated)	9.5-10.5%
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	Freely soluble (≥10 g/100 mL, 25℃)
Organic Solubility	Soluble in ethanol/methanol; slightly soluble in chloroform/ether
Bulk Density	1.10-1.15 g/cm³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30℃ (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%), accurate chloride content (9.5-10.5%); 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 use.

2. **Superior Water Solubility**: Freely soluble in water (≥10 g/100 mL), no need for organic cosolvents for aqueous formulations; low viscosity of aqueous solution, easy to prepare and apply, suitable for clinical topical/spray anesthetic formulations.
3. **Excellent Pharmacological Properties**: Potent local anesthetic effect, long duration of action (4-8 hours for surface anesthesia); moderate onset speed (3-5 minutes) with deep and lasting anesthesia; minimal systemic absorption when used topically, low CNS/cardiovascular toxicity risk.
4. **Good Formulability**: Soluble in water and common organic solvents; compatible with most pharmaceutical excipients (normal saline, glycerol, propylene glycol); can be prepared into various dosage forms (ointment, gel, spray, solution) to meet different clinical topical anesthesia needs.

4. Application Fields

- **Pharmaceutical Preparations**: Topical anesthetic formulations (ointment, gel, spray) for dermatological minor surgery, wound dressing and cosmetic procedure anesthesia; dental anesthetic solution/spray for oral mucosal and gingival anesthesia; urological topical solution for urethral surface anesthesia.
- **Pharmaceutical Research**: Research reagent for local anesthetic drug development, esterase metabolism research and anesthetic mechanism research; clinical anesthetic formulation optimization and new water-soluble dosage form development research.
- **Fine Chemicals**: Intermediate for the synthesis of ester-type local anesthetic derivatives and chloride-containing pharmaceutical raw materials.

5. Usage Methods

5.1 Formulation Compatibility

- **Topical Anesthetic Solution/Spray**: Dissolve in sterile normal saline to prepare 1-2% concentration solution; add small amount of citrate buffer to adjust pH to 4.5-5.5; add preservative (benzalkonium chloride) as needed; filter and sterilize by 0.22 μm microporous membrane; store in brown glass vials.
- **Dermal Anesthetic Ointment/Gel**: Mix with white petrolatum/carbomer gel matrix at a ratio of 2-5% (w/w); heat matrix to 40-50℃ (no higher than 60℃) and add dissolved Promocaine Hydrochloride; stir evenly and cool to room temperature; avoid high temperature to prevent active ingredient degradation.

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)

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical with CNS toxicity, serious eye irritation and moderate skin 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 ≥0.18mm 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 and large dosage ingestion).