

## Technical Data Sheet (TDS)

### 1. Product Overview

- Product Name: 普洛卡因
- English Name: Prilocaine
- CAS Number: 721-50-6
- Molecular Formula: C<sub>13</sub>H<sub>20</sub> N<sub>2</sub>O
- Molecular Weight: 220.31 Da
- **Product Characteristics:** High-purity pharmaceutical grade prilocaine, a potent amide-type local anesthetic with fast onset, long duration and low toxicity; white off-white free-flowing crystalline powder with slight amine odor, highly soluble in water and 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 excipients); meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of injectable/topical local anesthetic pharmaceutical formulations for clinical surface, infiltration, nerve block and epidural anesthesia.

### 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	37-41 °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 <sup>-</sup> )	≤ 0.01%
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 0.01%
Related Substances	≤ 0.5% (HPLC)
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Particle Size	≥95% passing 80 mesh
Water Solubility	Soluble (25 g/100 mL, 25 °C)
Organic Solubility	Freely soluble in ethanol/methanol/chloroform/ether
Bulk Density	1.04-1.08 g/cm <sup>3</sup>
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 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 injectable/topical use.
2. **Superior Pharmacological Properties:** Fast onset of action (3-5 minutes for infiltration anesthesia), long duration (2-4 hours); low systemic toxicity, significantly lower risk of central nervous system

and cardiovascular adverse reactions compared with lidocaine; no cross-sensitivity with ester-type local anesthetics, suitable for patients with ester anesthetic allergy.

3. **Unique Solubility Advantage:** Highly soluble in water (25 g/100 mL), no need for organic cosolvents for injectable formulations; freely soluble in organic solvents, easy to prepare topical anesthetic creams/ointments; broad formulability for various dosage forms.
4. **Low Methemoglobinemia Risk:** The lowest methemoglobinemia incidence among amide local anesthetics, safe for long-term use and application in pediatric/geriatric patients (under medical supervision).
5. **Stable Quality & Long Shelf Life:** Slightly hygroscopic, no degradation under recommended storage conditions ( $\leq 25^{\circ}\text{C}$ , dry, dark); 36-month long shelf life for unopened products; easy to store and transport for industrial pharmaceutical production, reducing inventory loss and production cost.

#### 4. Application Fields

- **Pharmaceutical Preparations:** Injectable formulations (injection solution) for clinical infiltration, nerve block, epidural and spinal anesthesia; topical formulations (cream, ointment, spray) for surface anesthesia of skin/mucosa (dermatology, dentistry, gynecology); compound anesthetic formulations with epinephrine/ lidocaine for prolonged anesthetic effect.
- **Pharmaceutical Research:** Research reagent for local anesthetic drug development, sodium ion channel inhibitor research and anesthetic mechanism research; clinical anesthetic formulation optimization and new dosage form development research.

#### 5. Usage Methods

##### 5.1 Formulation Compatibility

- **Injectable Solution:** Dissolve in sterile normal saline/5% glucose solution to prepare 1-4% concentration anesthetic solution; add epinephrine (1:200,000-1:100,000) to prolong anesthetic duration (excluding spinal/epidural anesthesia); adjust pH to 6.0-7.0 with weak base (sodium bicarbonate) to reduce injection pain; filter and sterilize by 0.22  $\mu\text{m}$  microporous membrane.
- **Topical Anesthetic Cream:** Mix with white petrolatum/mineral oil/lanolin at a ratio of 5-10% (w/w); add appropriate emulsifier (Tween 80) to improve skin penetration; control processing temperature below  $50^{\circ}\text{C}$  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)
- **Custom Packaging:** 500 g/2 kg sterile packaging available for injectable 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).