

## Technical Data Sheet (TDS)

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### 1. Product Overview

- **Product Name:** Prilocaine Hydrochloride
- **CAS Number:** 4360-75-4
- **Molecular Formula:** C<sub>13</sub>H<sub>20</sub> N<sub>2</sub>O·HCl
- **Molecular Weight:** 256.77 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized from 2-methylaniline via acylation, amination and hydrochlorination, purified by recrystallization; chiral synthesis ensures high optical purity).
- **Product Trait:** White crystalline powder, practically odorless, slightly hygroscopic; freely soluble in water, soluble in ethanol/methanol, slightly soluble in organic solvents such as acetone/ether; stable in dry air, slow hydrolysis in moist air.
- **Core Properties:** Amide local anesthetic with **low toxicity and no cardiac side effects**; fast onset of action (3-5 minutes), moderate duration of action (2-4 hours); good water solubility and tissue compatibility, suitable for various local anesthetic formulations (infiltration, nerve block, surface anesthesia).
- **Main Application:** Pharmaceutical intermediate for human local anesthetic formulations (injectable infiltration, peripheral nerve block, topical surface anesthesia); veterinary drug raw material for animal surgical local 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 (Prilocaine Hydrochloride)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h)
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 <sup>-</sup> )	13.8-14.5%	Volumetric Method
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 0.05%	Turbidimetric Method
Melting Point	167-171°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	4.0-6.0	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
Water Solubility (25°C)	≥ 70 g/L	Solubility Test
Bulk Density	1.28-1.32 g/cm <sup>3</sup>	Pycnometer Method
Optical Purity (S-enantiomer)	≥ 99.5%	Chiral HPLC

### 3. Product Advantages

1. **High Purity & Chiral Purity:** Assay ≥99.0%, S-enantiomer ≥99.5%, low related substances, meets USP/EP/CP pharmaceutical grade requirements, ensures the safety and efficacy of local anesthetic formulations.

- Superior Safety Profile: No cardiac toxicity** at clinical relevant doses, low central nervous system toxicity, the first choice for local anesthesia in patients with cardiovascular diseases or high-risk groups.
- Fast Onset & Moderate Duration:** Rapid onset of action (3-5 minutes) with moderate duration (2-4 hours), suitable for short-to-medium time surgical operations, reduces the risk of prolonged anesthesia-related complications.
- Excellent Tissue Compatibility:** Low irritation to skin, mucous membrane and injection site, high patient tolerance, suitable for topical surface anesthesia and subcutaneous infiltration anesthesia.
- Good Water Solubility & Formulation Compatibility:** Freely soluble in water (75 g/L at 25°C), soluble in common organic solvents, compatible with most pharmaceutical excipients (mannitol, sodium citrate, carbomer); suitable for injectable, topical and mucosal formulations.
- Stable Batch Quality:** Optimized synthetic process, strict quality control, low batch-to-batch variation, good fluidity and compressibility, easy for pharmaceutical production and formulation.

## 4. Application Fields

### 4.1 Pharmaceutical Industry (Human Local Anesthetic Formulations)

- Injectable Infiltration Anesthesia:** Core raw material for subcutaneous/intradermal injection formulations, used for minor surgical operations (suture, mole removal, biopsy), low irritation and fast pain relief.
- Peripheral Nerve Block:** Formulations for brachial plexus, femoral nerve and intercostal nerve block, used for limb and thoracic minor surgeries, minimal systemic side effects.
- Topical Surface Anesthesia:** Raw material for skin/mucosal anesthetic gels, creams and sprays, used for cosmetic surgery (laser, micro-needle), dental examination and mucosal minor operations.

### 4.2 Pharmaceutical Industry (Veterinary Medicine)

- Local anesthetic raw material for livestock, poultry and pets (dogs/cats); used for surgical local anesthesia (wound suture, tumor resection) and traumatic pain relief; low toxicity, high safety for animal physiology, suitable for various animal species.

## 5. Usage & Formulation Guidelines

### 5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- Injectable Infiltration Anesthesia:** 0.5-1.0% concentration in injection, dosage adjusted according to operation scope (5-15 mL per time for adult).
- Peripheral Nerve Block:** 1.0-2.0% concentration in injection, 10-20 mL per dose (adult), based on nerve block site and animal species for veterinary use.
- Topical Surface Anesthesia:** 2-5% concentration in gel/cream/spray, apply an appropriate amount to the affected area and cover with a film for 10-15 minutes before operation.
- Veterinary Use:** 0.5-1.5% concentration in injection/ointment, dosage 0.1-0.4 mL/kg body weight (injectable/topical).

## 6. Packaging & Storage

### 6.1 Packaging Specifications (Pharmaceutical Grade, Anti-Hygroscopic)

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

## 7. Safety & Protection

- The product is a pharmaceutical intermediate with mild irritation and slight hygroscopicity; wear specified PPE during all handling operations (N95 dust mask, chemical splash goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes, skin and respiratory tract; avoid inhaling dust and swallowing raw powder.
- In case of eye contact, rinse with plenty of running water for at least 15 minutes and seek immediate medical advice if irritation persists.