

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 利多卡因
- English Name: Lidocaine
- CAS Number: 137-58-6
- Molecular Formula: C₁₄H₂₂N₂O
- Molecular Weight: 234.34 Da
- **Product Characteristics:** High-purity pharmaceutical grade lidocaine, a classic amide-type local anesthetic and class Ib antiarrhythmic drug with potent, fast-acting and long-lasting effects; white off-white free-flowing crystalline powder with slight amine odor, soluble in water and freely soluble in organic solvents; exerts local anesthetic effect by blocking sodium ion channels in nerve cell membranes to inhibit nerve impulse conduction, and antiarrhythmic effect by suppressing abnormal cardiac pacemaker activity and conduction; 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 formulations and antiarrhythmic drug preparations for clinical 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	68-72°C (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (1% aq. solution, 25°C)	6.0-8.0
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	Soluble (1.0 g/100 mL, 25°C)
Organic Solubility	Freely soluble in ethanol/methanol/chloroform/ether
Bulk Density	1.05-1.10 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 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.



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2. **Double Pharmacological Efficacy:** Serves as both a potent local anesthetic and effective antiarrhythmic drug; one raw material for two clinical applications, reducing pharmaceutical production and R&D costs.
3. **Superior Local Anesthetic Properties:** Fast onset of action (2-3 minutes for infiltration anesthesia), long duration (1-3 hours); moderate potency with low systemic toxicity; wide clinical application range for surface, infiltration, nerve block and epidural anesthesia.
4. **Proven Antiarrhythmic Effect:** Class Ib antiarrhythmic drug with definite curative effect on ventricular arrhythmias caused by myocardial infarction, cardiac surgery and digitalis poisoning; rapid onset and high safety under medical supervision.
5. **Good Formulability:** Soluble in water and freely soluble in organic solvents; compatible with most pharmaceutical excipients (normal saline, glucose solution, epinephrine); can be prepared into various dosage forms (injection, cream, ointment, spray) to meet different clinical needs.

4. Application Fields

- **Local Anesthetic 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, urology); compound anesthetic formulations with epinephrine to prolong anesthetic duration.
- **Antiarrhythmic Preparations:** Injectable formulations (intravenous injection solution) for the treatment of ventricular premature beats, ventricular tachycardia and ventricular fibrillation caused by myocardial infarction, cardiac surgery, trauma and digitalis poisoning.

5. Usage Methods

5.1 Formulation Compatibility

- **Injectable Local Anesthetic Solution:** Dissolve in sterile normal saline/5% glucose solution to prepare 0.5-2% concentration anesthetic solution; add epinephrine (1:200,000-1:100,000) to prolong anesthetic duration (excluding spinal/epidural anesthesia); adjust pH to 6.5-7.5 with weak base (sodium bicarbonate) to reduce injection pain; filter and sterilize by 0.22 μ m microporous membrane.

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 ≥ 0.18 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).