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Technical Data Sheet (TDS)

Issue Date: 25 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Lidocaine Hydrochloride
- **CAS Number**: 6108-05-0
- **Molecular Formula**: $C_{14}H_{22}N_2O \cdot HCl$
- **Molecular Weight**: 288.80 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 2,6-dimethylaniline via acylation, amination and hydrochlorination, purified by recrystallization)
- **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; stable in dry air, slow hydrolysis in moist air.
- **Core Properties**: Classic amide local anesthetic with strong local anesthetic activity and antiarrhythmic effect; fast onset of action (3-5 minutes), long duration of action (1-3 hours), low toxicity; good water solubility, suitable for various pharmaceutical formulations.
- **Main Application**: Pharmaceutical intermediate for human local anesthetic formulations (injectable, topical, mucosal); raw material for antiarrhythmic drugs; veterinary drug raw material for animal surgical local anesthesia; pharmaceutical R&D and analytical reference reagent.

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 (Lidocaine Hydrochloride)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 5 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Chloride (Cl^-)	12.0-12.6%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	75-79℃	Melting Point Apparatus
pH Value (1% aqueous solution,25℃)	4.0-5.5	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℃)	≥ 75 g/L	Solubility Test
Bulk Density	1.29-1.33 g/cm³	Pycnometer Method

3. Product Advantages

1. **High Purity & Low Impurities**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmaceutical grade requirements, no harmful impurities, ensures the safety and efficacy of finished drug formulations.
2. **Excellent Water Solubility**: Freely soluble in water (80 g/L at 25℃), high dissolution rate in aqueous solution, suitable for **injectable and mucosal anesthetic formulations** with fast in-vivo absorption and high bioavailability.

3. **Potent Pharmacological Activity**: Classic amide local anesthetic with strong local anesthetic effect, fast onset and long duration; also has antiarrhythmic activity, wide clinical application.
4. **Low Toxicity & High Safety**: Low acute toxicity, no obvious cumulative toxicity, small irritation to skin and mucous membrane, suitable for clinical and veterinary use.
5. **Wide Formulation Compatibility**: Soluble in water and common organic solvents, compatible with most pharmaceutical excipients (mannitol, lactose, carbomer, glycerol); suitable for injectable, topical, mucosal and transdermal formulations.
6. **Superior Stability**: 36-month long shelf life under dry sealed storage conditions; slightly hygroscopic, easy to store and transport; stable under normal pharmaceutical processing temperature (≤60℃).

4. Application Fields

4.1 Pharmaceutical Industry (Human Local Anesthetic Formulations)

- **Injectable formulations**: Spinal anesthesia, epidural anesthesia, local infiltration anesthesia and nerve block anesthesia injections; core raw material for clinical surgical local anesthesia.
- **Topical formulations**: Skin anesthetic gels, creams and sprays; for surface anesthesia of minor surgery, cosmetic surgery and skin trauma.
- **Mucosal formulations**: Oral, nasal and ophthalmic mucosal anesthetic solutions and sprays; for local anesthesia of mucosal examination and minor operation.
- **Antiarrhythmic formulations**: Oral and injectable preparations for the treatment of ventricular arrhythmia caused by myocardial infarction and cardiac surgery.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage (in pharmaceutical formulations)

- **Human Injectable Local Anesthesia**: 0.5-2.0% concentration in injection, dosage adjusted according to surgical site and scope (5-20 mL per time).
- **Human Topical Anesthesia**: 5-10% concentration in gel/cream, apply an appropriate amount to the affected area and cover with a film for 15-20 minutes.
- **Human Mucosal Anesthesia**: 1-2% concentration in solution/spray, spray or apply an appropriate amount to the mucosal surface (0.5-5 mL per time).
- **Veterinary Local Anesthesia**: 1-2% concentration in injection/ointment, dosage 0.1-0.5 mL/kg body weight (oral/topical/injectable).

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Sealed 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.
- In case of skin contact, rinse with plenty of water and soap for 10-15 minutes; apply mild emollient if irritation occurs.
- If accidentally swallowed in large amounts, do not induce vomiting and call a poison center/doctor immediately.