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Technical Data Sheet (TDS)

Issue Date: 20 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Ropivacaine Hydrochloride
- **CAS Number**: 84057-95-4
- **Molecular Formula**: $C_{17}H_{26}N_2O \cdot HCl$
- **Molecular Weight**: 310.86 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from (S)-2-piperidinecarboxylic acid 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 (acetone/ether); stable in dry air, slow hydrolysis in moist air.
- **Core Properties**: Long-acting amide local anesthetic with **S-enantiomer optical purity**; low cardiac/central nervous system toxicity (safer than bupivacaine); fast onset (5-10 minutes), long duration of action (4-8 hours, up to 12 hours with adjuvants); good water solubility, suitable for injectable local anesthetic formulations.
- **Main Application**: Pharmaceutical intermediate for human injectable long-acting local anesthetic formulations (epidural/spinal/peripheral nerve block, postoperative analgesia); veterinary drug raw material for large animal (cattle/horses) surgical local anesthesia; pharmaceutical R&D/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 (Ropivacaine 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^-)	11.4-12.0%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	144-148℃	Melting Point Apparatus
pH Value (1% aqueous solution,25℃)	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℃)	≥ 65 g/L	Solubility Test
Bulk Density	1.31-1.35 g/cm³	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 formulation safety/efficacy.
2. **Superior Safety Profile**: Low cardiac/central nervous system toxicity, minimal risk of severe arrhythmia (safer for high-risk patients), the first choice for clinical long-acting local anesthesia.
3. **Long-Acting Pharmacological Effect**: Duration of action 4-8 hours (can be extended to 12 hours with epinephrine), reduces postoperative re-administration frequency, suitable for major surgery/postoperative analgesia.
4. **Excellent Water Solubility**: Freely soluble in water (70 g/L at 25℃), high dissolution rate, suitable for injectable formulations (epidural/spinal injection) with fast in-vivo absorption.
5. **Wide Formulation Compatibility**: Soluble in water/common organic solvents, compatible with most pharmaceutical excipients (mannitol, sodium citrate, normal saline); suitable for single-dose/ multi-dose injectable formulations.
6. **Stable Batch Quality**: Optimized chiral synthesis process, strict quality control, low batch-to-batch variation, good fluidity/compressibility for pharmaceutical production.

4. Application Fields

4.1 Pharmaceutical Industry (Human Injectable Formulations)

- **Epidural/Spinal Anesthesia**: Core raw material for epidural/spinal injection formulations, used for obstetric delivery, abdominal surgery, orthopedic surgery, with long-acting analgesic effect.
- **Peripheral Nerve Block**: Formulations for brachial plexus/femoral nerve block, used for limb surgery, minimal systemic side effects.
- **Postoperative Analgesia**: Low-concentration injectable formulations for continuous postoperative epidural analgesia, improve patient postoperative comfort.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Epidural Anesthesia**: 0.5-0.75% concentration injection, 10-20 mL per dose (adult).
- **Peripheral Nerve Block**: 0.25-0.5% concentration injection, dosage adjusted according to nerve block scope (5-30 mL per dose).
- **Postoperative Analgesia**: 0.125-0.2% low-concentration continuous infusion, 5-10 mL/h infusion rate.
- **Veterinary Use**: 0.5-1.0% concentration injection, 0.1-0.3 mL/kg body weight for large animals.

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/custom formulation needs.

7. Safety & Protection

- Wear specified PPE (N95 dust mask, chemical splash goggles, nitrile rubber gloves, impermeable lab coat) during all handling operations.
- Avoid direct contact with eyes/skin/respiratory tract; do not inhale dust or swallow 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 water/soap for 10-15 minutes; apply mild emollient if irritation occurs.