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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Levobupivacaine Hydrochloride
- **CAS Number**: 160708-40-7
- **Molecular Formula**: $C_{18}H_{28}N_2O \cdot HCl$
- **Molecular Weight**: 324.89 g/mol
- **Chemical Source**: Synthetic fine chemical (chiral synthesis of S-enantiomer from 2,6-dimethylaniline via acylation, asymmetric amination and hydrochlorination; purified by recrystallization to ensure high optical purity and low impurity content).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic; soluble in water, freely soluble in ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and acidic environment, mild hydrolysis in alkaline/moist environment; **optical purity remains stable** under specified storage conditions.
- **Core Properties**: Long-acting amide local anesthetic (S-enantiomer of bupivacaine) with **ultra-low cardiac toxicity**; fast onset (5-10 minutes), long duration of action (6-12 hours, extendable to 24 hours with adjuvants); strong sensory nerve block effect, weak motor nerve block effect; the gold standard for clinical long-acting local anesthesia in high-risk patients (cardiovascular disease, elderly, pregnant women).
- **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/sheep) surgical local anesthesia; pharmaceutical R&D and analytical reference reagent for chiral 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 (Levobupivacaine Hydrochloride)	≥ 99.0%	HPLC
Optical Purity (S-enantiomer)	≥ 99.5%	Chiral 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^-)	10.9-11.5%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	258-262℃	Melting Point Apparatus
pH Value (1% aqueous solution,25℃)	4.5-6.0	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℃)	≥ 20 g/L	Solubility Test
Bulk Density	1.34-1.38 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25℃, 60% RH)	HPLC

3. Product Advantages

1. **Chiral Purity & Low Toxicity**: S-enantiomer with optical purity ≥99.5%, **cardiac toxicity is 1/8 of racemic bupivacaine**, no severe cardiac adverse effects at clinical doses; the first choice for local anesthesia in cardiovascular disease, elderly and pregnant patients.
2. **High Purity & Low Impurities**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmaceutical grade requirements, no harmful impurities, ensures the safety of clinical injectable formulation with high patient tolerance.
3. **Long-Acting & Selective Block**: Duration of action 6-12 hours (extendable to 24 hours with epinephrine); strong sensory nerve block, weak motor nerve block, fast recovery of motor function, improves patient postoperative activity.
4. **Good Formulation Compatibility**: Soluble in water and common organic solvents, compatible with most pharmaceutical excipients (mannitol, sodium citrate, epinephrine); suitable for single/multi-dose injectable formulations (epidural/spinal/peripheral nerve block).

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/orthopedic/thoracic major surgery; low cardiac toxicity is suitable for high-risk pregnant women and cardiovascular patients.
- **Peripheral Nerve Block**: Formulations for brachial plexus/femoral/sciatic nerve block, used for limb major surgery; selective sensory-motor block, fast motor function recovery, reduces postoperative bed rest time.
- **Postoperative Analgesia**: Low-concentration injectable formulations for continuous postoperative epidural analgesia, improve patient postoperative comfort, reduce opioid drug usage, and avoid opioid-related adverse reactions.

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), adjusted according to surgical site/body weight; 0.25% low concentration for elderly/cardiovascular patients.
- **Spinal Anesthesia**: 0.5% concentration heavy density injection, 2-3 mL per dose (adult), for lower limb/pelvic surgery; no high concentration for spinal anesthesia to avoid neurotoxicity.
- **Peripheral Nerve Block**: 0.25-0.5% concentration injection, 10-30 mL per dose, adjusted according to nerve block scope.
- **Postoperative Analgesia**: 0.125-0.2% low-concentration continuous infusion, 5-10 mL/h infusion rate.
- **Veterinary Use**: 0.5-1.0% concentration injection, 0.1-0.4 mL/kg body weight for large animals, adjusted according to animal species/surgical type.

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 chiral toxic pharmaceutical intermediate with low cardiac toxicity; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant full face shield, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood.
- In case of eye contact, **immediately rinse with plenty of running water for at least 20 minutes** and call a POISON CENTER/ophthalmologist for professional treatment (severe irritation may occur).