

Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name:** Bupivacaine Hydrochloride
- **CAS Number:** 14252-80-3
- **Molecular Formula:** C₁₈ H₂₈ N₂O · HCl
- **Molecular Weight:** 324.89 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized from 2,6-dimethylaniline via acylation, amination and hydrochlorination, purified by recrystallization; high-purity synthesis ensures 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/acidic/dark environment, easy to hydrolyze in alkaline/moist environment.
- **Core Properties:** Classic long-acting amide local anesthetic with high potency; fast onset (5-10 minutes), ultra-long duration of action (6-12 hours, up to 24 hours with adjuvants); strong nerve block effect, suitable for deep tissue/surgical local anesthesia; the gold standard for clinical long-acting local anesthesia.
- **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/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 (Bupivacaine Hydrochloride)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h, light protection)
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 ⁻)	10.9-11.5%	Volumetric Method
Sulfate (SO ₄ ²⁻)	≤ 0.05%	Turbidimetric Method
Melting Point	255-260°C	Melting Point Apparatus (light protection)
pH Value (1% aqueous solution, 25°C)	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 (light protection)
Water Solubility (25°C)	≥ 20 g/L	Solubility Test
Bulk Density	1.33-1.37 g/cm ³	Pycnometer Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25°C, 60% RH, light protection)	HPLC

3. Product Advantages

1. **High Purity & Low Impurities:** Assay $\geq 99.0\%$, related substances $\leq 0.5\%$, meets USP/EP/CP pharmaceutical grade requirements, no harmful impurities, ensures formulation safety/efficacy for clinical injection.
2. **Ultra-Long Acting Anesthesia:** Duration of action 6-12 hours (extendable to 24 hours with epinephrine), the longest-acting amide local anesthetic, suitable for major surgery/postoperative long-term analgesia.
3. **High Potency & Strong Block Effect:** 4-5 times the potency of lidocaine, strong sensory/motor nerve block effect, suitable for epidural/spinal anesthesia and deep tissue surgical operation.
4. **Good Formulation Compatibility:** Soluble in water/common organic solvents, compatible with most pharmaceutical excipients (mannitol, sodium citrate, normal saline); suitable for single/multi-dose injectable formulations.
5. **Stable Batch Quality:** Optimized synthetic process, strict quality control, low batch-to-batch variation, good fluidity/compressibility, easy for pharmaceutical production/formulation.
6. **Clinical Gold Standard:** The most widely used long-acting local anesthetic in clinical practice, mature application technology, high clinical safety with standard dosage.

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, with ultra-long analgesic effect.
- **Peripheral Nerve Block:** Formulations for brachial plexus/femoral/sciatic nerve block, used for limb major surgery, minimal systemic side effects, fast recovery of nerve function.
- **Postoperative Analgesia:** Low-concentration injectable formulations for continuous postoperative epidural analgesia, improve patient postoperative comfort, reduce opioid drug usage.

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.
- **Spinal Anesthesia:** 0.75% concentration heavy density injection, 2-3 mL per dose (adult), for lower limb/pelvic surgery.
- **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, Light Protection & Anti-Hygroscopic)

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

7. Safety & Protection

- The product is a toxic pharmaceutical intermediate with cardiovascular/nervous system 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 with light protection.