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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Mepivacaine Hydrochloride
- **CAS Number**: 1722-62-9
- **Molecular Formula**: $C_{14}H_{22}N_2O \cdot HCl$
- **Molecular Weight**: 270.80 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from 2,6-dimethylaniline via acylation, amination and hydrochlorination; purified by recrystallization to ensure high purity and low impurity content; optimized process for good water solubility and formulation compatibility).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic; **freely soluble in water** (90 g/L at 25℃), 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; no light sensitivity under normal storage conditions.
- **Core Properties**: Classic medium-acting amide local anesthetic with **low systemic and cardiac toxicity**; fast onset (3-5 minutes), moderate duration of action (2-4 hours); balanced sensory-motor nerve block effect; no epinephrine required for clinical use (unique advantage); the first choice for dental, obstetric and cardiovascular patient local anesthesia.
- **Main Application**: Pharmaceutical intermediate for human injectable local anesthetic formulations (dental, surgical, obstetric local anesthesia); surface anesthesia formulations for minor oral/surgical procedures; pharmaceutical R&D and 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 (Mepivacaine 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^-)	13.0-13.6%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	244-248℃	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℃)	≥ 85 g/L	Solubility Test
Bulk Density	1.28-1.32 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25℃, 60% RH)	HPLC

3. Product Advantages

1. **No Epinephrine Required**: Unique medium-acting amide local anesthetic that does not need epinephrine for clinical efficacy; suitable for patients with epinephrine contraindications (cardiovascular disease, hyperthyroidism, diabetes), expanding clinical application scope.
2. **Ultra-Low Cardiac Toxicity**: Significantly lower cardiac and central nervous system toxicity than lidocaine/bupivacaine; no severe cardiac adverse effects at clinical doses, the first choice for local anesthesia in cardiovascular patients and the elderly.
3. **Excellent Water Solubility**: Freely soluble in water (90 g/L at 25℃), the highest water solubility among amide local anesthetics; easy to prepare injectable formulations, good compatibility with aqueous excipients, no precipitation during clinical use.
4. **High Purity & Low Impurities**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmaceutical grade requirements; no harmful impurities, high patient tolerance, suitable for repeated clinical injection (e.g., dental multiple extractions).
5. **Fast Onset & Balanced Block**: Onset in 3-5 minutes, shorter waiting time than lidocaine; balanced sensory-motor nerve block, fast recovery of motor function (1-2 hours after anesthesia), improves patient postoperative comfort.
6. **Obstetric Anesthesia Ideal Choice**: Low placental transfer rate, no adverse effects on fetus/neonate at clinical doses; suitable for vaginal delivery and cesarean section local anesthesia, high maternal and fetal safety.

4. Application Fields

4.1 Pharmaceutical Industry (Human Dental Anesthetic Formulations)

- **Dental Local Anesthesia**: Core raw material for dental injectable formulations (2-3% concentration); the first choice for tooth extraction, filling, root canal therapy and gingival surgery; no epinephrine required, avoids soft tissue ischemia/necrosis, suitable for pediatric/geriatric dental patients.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Dental Anesthesia**: 2-3% concentration injectable formulation; adult dosage: 1-2 mL per injection, maximum 8 mL per treatment; pediatric dosage: 0.04 mL/kg body weight, maximum 4 mL per treatment.
- **Obstetric Epidural Anesthesia**: 0.5-1.0% concentration formulation; 10-15 mL per dose, adjusted according to uterine contraction and maternal condition.
- **Peripheral Nerve Block**: 1.0-2.0% concentration formulation; 5-15 mL per dose, adjusted according to block scope.
- **Surface Anesthesia**: 5% concentration gel/spray; apply an appropriate amount to the affected area, keep for 1-2 minutes before operation.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Anti-Hygroscopic)

- 100 g/bottle: Clear glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, no light protection required).
- 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 low-toxic pharmaceutical intermediate with mild irritation; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant safety goggles, 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 15 minutes** and call a POISON CENTER/ophthalmologist for professional treatment if irritation persists.