

Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name:** Articaine Hydrochloride
- **CAS Number:** 23964-57-0
- **Molecular Formula:** C₁₃H₂₀ N₂O₃·HCl
- **Molecular Weight:** 288.77 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized from 4-methylthiophene-2-carboxylic acid via esterification, acylation and hydrochlorination, purified by recrystallization and light protection processing; high-purity synthesis ensures low impurity content).
- **Product Trait:** White crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in water and ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and acidic environment, mild hydrolysis in alkaline/moist environment.
- **Core Properties:** Dental-specific amide local anesthetic with **fast onset and strong tissue penetration**; ultra-fast onset (1-3 minutes), moderate duration of action (1-3 hours); unique thiophene ring structure enhances tissue permeability, suitable for all dental clinical anesthesia (extraction, filling, root canal therapy); low systemic toxicity with standard dental dosage.
- **Main Application:** Pharmaceutical intermediate for human dental injectable local anesthetic formulations (the first choice for dental clinical anesthesia); minor surgical surface anesthesia formulations (oral/mucosal); 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 (Articaine 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 ⁻) | 12.2-12.8% | Volumetric Method |
| Sulfate (SO ₄ ²⁻) | ≤ 0.05% | Turbidimetric Method |
| Melting Point | 174-178°C | Melting Point Apparatus (light protection) |
| pH Value (1% aqueous solution, 25°C) | 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 (light protection) |
| Water Solubility (25°C) | ≥ 75 g/L | Solubility Test |
| Bulk Density | 1.30-1.34 g/cm ³ | Pycnometer Method |
| Hydrolysis Stability | ≤ 0.3% related substances after 7 days (25°C, 60% RH, light protection) | HPLC |

3. Product Advantages



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1. **Dental-Specific & Ultra-Fast Onset:** Unique thiophene ring structure with strong tissue penetration, onset in 1-3 minutes - the fastest-acting amide local anesthetic for dentistry, shortens clinical waiting time and improves operation efficiency.
2. **High Purity & Low Impurities:** Assay $\geq 99.0\%$, related substances $\leq 0.5\%$, meets USP/EP/CP pharmaceutical grade requirements, no harmful impurities, ensures the safety of dental clinical injection with high patient tolerance.
3. **Strong Tissue Penetration:** Better permeability to hard and soft dental tissues than lidocaine/prilocaine, suitable for all dental procedures (including difficult extractions and deep root canal therapy) with a single injection.
4. **Excellent Water Solubility & Formulation Compatibility:** Freely soluble in water (80 g/L at 25°C), compatible with most pharmaceutical excipients (epinephrine, sodium chloride, citrate buffer); suitable for dental injectable formulations (with/without epinephrine).
5. **Low Systemic Toxicity:** Low blood-brain barrier penetration, no significant cardiac/central nervous system toxicity with standard dental dosage, suitable for special populations (elderly, children with proper dosage adjustment).

4. Application Fields

4.1 Pharmaceutical Industry (Human Dental Anesthetic Formulations)

- **Dental Injectable Anesthesia:** Core raw material for dental clinical injectable formulations (4% concentration with 1:100,000/1:200,000 epinephrine); the first choice for tooth extraction, dental filling, root canal therapy, gingival surgery and other dental procedures, fast pain relief and long enough anesthesia duration.
- **Oral Mucosal Surface Anesthesia:** Raw material for oral mucosal anesthetic gels/sprays, used for pre-injection surface anesthesia of children/elderly patients, reducing injection pain and improving treatment compliance.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Dental Injectable Anesthesia (with epinephrine):** 4.0% concentration, 1:100,000/1:200,000 epinephrine added to prolong duration; adult dosage: 1-3 mL per injection, maximum 7 mL per treatment; pediatric dosage: 0.05 mL/kg body weight, maximum 3 mL per treatment.
- **Dental Injectable Anesthesia (without epinephrine):** 4.0% concentration, for patients with cardiovascular diseases; adult dosage: 1-2 mL per injection, maximum 5 mL per treatment.
- **Oral Mucosal Surface Anesthesia:** 2-4% concentration in gel/spray, apply an appropriate amount to the affected area and keep for 1-2 minutes before injection/surgery.

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 and custom dental formulation production needs (all light protection).

7. Safety & Protection

- The product is a dental-specific toxic pharmaceutical intermediate with mild irritation; **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 and respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with light protection.
- 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).