

Technical Data Sheet (TDS)

1. Product Overview

- Name: Dibucaine Hydrochloride
- CAS: 22616-39-1
- Formula: $C_{20}H_{29}N_3O_2 \cdot HCl$
- MW: 379.93 Da
- Description: High-purity long-acting amide-type topical anesthetic. White crystalline powder, freely soluble in water. Acts by blocking sodium channels, providing long-lasting surface anesthesia. Mainly used for skin, mucosa, hemorrhoid and dental topical anesthesia.

2. Technical Specifications (USP/EP/BP)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (dry basis)	$\geq 99.0\%$
Melting Point	96–100°C
Loss on Drying	$\leq 0.5\%$
Residue on Ignition	$\leq 0.1\%$
pH (1% aqueous solution)	4.5–6.5
Heavy Metals (Pb / As)	$\leq 10 / \leq 2$ ppm
Related Substances	$\leq 0.5\%$
Microbiological	≤ 100 CFU/g; E. coli negative
Particle Size	$\geq 95\%$ pass 80 mesh
Water Solubility	Freely soluble

3. Product Advantages

1. **High potency & long-acting:** Strongest topical anesthetic; duration up to 4–6 hours.
2. **Excellent water solubility:** Freely soluble in water, easy to formulate solutions, gels, creams.
3. **Stable quality:** 36-month shelf life; slightly hygroscopic, easy to store.
4. **Pharmaceutical grade:** GMP production; complies with USP/EP/BP.
5. **Wide application:** For skin, mucosa, dental, hemorrhoid and cosmetic anesthesia.

4. Application Fields

- Pharmaceuticals: Topical creams, gels, solutions, sprays, hemorrhoid ointments.
- Research: Local anesthetic mechanism study, sodium channel inhibition research.
- Fine chemicals: Intermediate for amide-type anesthetic derivatives.

5. Formulation & Usage Guidelines

- **Topical solution:** 0.25–1.0% in purified water.
- **Gel/ointment:** 0.5–1.0% in carbomer / petrolatum base.
- Processing: $\leq 60^\circ C$; avoid strong bases and metal ions.
- Clinical dosage: Apply thin layer to affected area; max single dose ≤ 50 mg.



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

6. Packaging & Storage

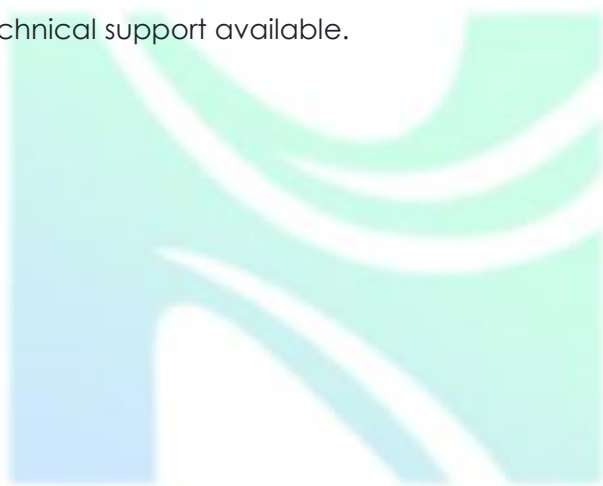
- Packaging: 100 g bottle, 1 kg bag, 5/10/25 kg drum (light-proof, sealed).
- Storage: ≤25°C, dry, dark, tightly closed.
- Shelf life: 36 months (unopened).

7. Safety & Protection

Irritating to eyes and skin; harmful if swallowed. Use only by trained personnel. Full PPE required.
Store locked and away from children.

8. Quality Assurance

- Manufactured under GMP & ISO 9001.
- Full COA provided per batch.
- Third-party testing and technical support available.



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