

## Technical Data Sheet (TDS)

### 1. Product Overview

- Product Name: 布比卡因
- English Name: Bupivacaine
- CAS Number: 2180-92-9
- Molecular Formula:  $C_{18}H_{28}N_2O$
- Molecular Weight: 288.43 Da
- Description: High-purity long-acting amide-type local anesthetic. White crystalline powder, slightly soluble in water. Acts by blocking sodium channels, providing 4–8 hours of anesthesia. Used for infiltration, nerve block, epidural and spinal anesthesia.

### 2. Technical Specifications (USP/EP/BP)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (dry basis)	≥ 99.0%
Melting Point	104–108 °C
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH (1% suspension)	6.0–8.0
Heavy Metals (Pb/As)	≤10 / ≤2 ppm
Related Substances	≤ 0.5%
Microbiological Limits	≤100 CFU/g; E. coli negative
Particle Size	≥95% pass 80 mesh

### 3. Product Advantages

1. **Long-acting:** 4–8 hours per administration.
2. **High potency:** Stronger analgesic effect than lidocaine.
3. **Stable quality:** 36-month shelf life; low hygroscopicity.
4. **Good formulability:** Suitable for injections, creams, gels, solutions.
5. **Pharmaceutical grade:** GMP production; meets USP/EP/BP standards.

### 4. Application Fields

- Pharmaceuticals: Injectable solutions (epidural, nerve block, spinal anesthesia); topical anesthetic creams/gels.
- Research: Local anesthetic mechanism, sodium channel inhibitor studies.
- Fine chemicals: Intermediate for amide-type anesthetic derivatives.

### 5. Formulation Guidelines

- Injectable: 0.25%–0.75% solution in saline/glucose.
- Topical: 0.5%–1% cream/gel with petrolatum/carbomer.
- Processing temperature ≤60 °C; avoid strong bases and metal ions.



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### 6. Packaging & Storage

- Packaging: 100g bottle, 1kg bag, 5/10/25kg drum (light-proof, sealed).
- Storage:  $\leq 25^{\circ}\text{C}$ , dry, dark, tightly closed.
- Shelf life: 36 months (unopened).

### 7. Safety & Protection

Irritating to eyes and skin; toxic if misused. 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 available.
- Technical support for formulation development.



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