

## Technical Data Sheet (TDS)

### 1. Product Overview

- **Product Name:** Bacitracin (杆菌素)
- **CAS Number:** 1405-87-0
- **Formula:** C<sub>66</sub> H<sub>103</sub> N<sub>17</sub> O<sub>16</sub> S
- **Formula Weight:** 1422.70 g/mol
- **Molecular Form:** Polypeptide antibiotic (mixture of bacitracin A/B/C, main component A)
- **Product Characteristics:** High-purity pharmaceutical/industrial grade Bacitracin is a natural polypeptide antibiotic produced by *Bacillus licheniformis*, with potent bacteriostatic activity against Gram-positive bacteria (*Staphylococcus aureus*, *Streptococcus*). Off-white crystalline powder with slight characteristic odor, slightly soluble in water, stable under refrigerated storage. Non-systemic toxicity via topical use, FDA/EMA approved for topical pharmaceutical and veterinary use, widely used as industrial antimicrobial and food/feed additive.

### 2. Technical Specifications (CP/USP/EP/FDA Compliant)

Item	Specification (Pharmaceutical Grade)
Appearance	White to pale yellow crystalline powder
Assay (Potency, dry basis)	≥ 65.0 IU/mg (Microbiological Assay)
Loss on Drying (60°C, vacuum)	≤ 5.0%
Residue on Ignition (600°C)	≤ 1.0%
Heavy Metals (Pb)	≤ 10 ppm (AAS)
Heavy Metals (As)	≤ 1 ppm (AFS)
pH Value (1% aqueous suspension, 25°C)	5.5-7.5
Water Content (Karl Fischer)	≤ 5.0%
Related Substances	≤ 5.0% (RP-HPLC)
Total Aerobic Count	≤ 100 CFU/g
Pathogens ( <i>E. coli</i> / <i>Staph. aureus</i> )	Negative
Solubility	Slightly soluble in water, methanol
Particle Size	100-200 mesh
Hygroscopy	Slight (stable at RH ≤60%)
Storage Stability	24 months (2-8°C, unopened); 3 months (RT, after opening)

### 3. Product Advantages

1. **Natural Antibiotic:** Produced by microbial fermentation, high biocompatibility, low toxic side effects via topical use.
2. **Targeted Antibacterial Activity:** Potent bacteriostatic effect against Gram-positive bacteria; no activity against Gram-negative bacteria/fungi, low flora disturbance risk.
3. **High Purity & Potency:** ≥65.0 IU/mg biological potency, ≥95.0% chemical purity, meets global pharmacopoeia (CP/USP/EP/FDA) standards.
4. **Stable Physical Properties:** Crystalline powder with low hygroscopy; stable under refrigerated storage, easy for formulation and storage.
5. **Versatile Application:** Suitable for pharmaceutical, veterinary, industrial and food/feed fields; compatible with various excipients/formulations.
6. **Low Resistance Risk:** Low antibiotic resistance development with proper use; no cross-resistance with other antibiotic classes.

### 4. Application Fields

- **Pharmaceutical Industry:** Production of topical antibacterial formulations (ointments, creams, sprays) for skin/wound/eye infections; oral lozenges for oropharyngeal infections (limited use).
- **Veterinary Medicine:** Livestock/poultry antibacterial drugs (topical/oral); feed additive for animal growth promotion and disease prevention.



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- **Food & Feed Industry:** Food preservative (low-concentration); feed antimicrobial additive (Gram-positive bacteria control).
- **Industrial Use:** Antimicrobial for cosmetics, personal care products, industrial coatings (low-concentration); laboratory antimicrobial reagent.

## 5. Usage Methods

- **Pharmaceutical Formulation (Topical):** Blend with excipients (petrolatum, lanolin, glycerol) to prepare 500-1000 IU/g ointment/cream; dissolve in sterile water (0.1-0.5%) for wound irrigation.
- **Veterinary Use:** Mix with feed at 5-20 IU/g for livestock/poultry; dilute to 0.5-1.0% for topical wound application.
- **Food/Feed Additive:** Add at 1-5 ppm (food) / 5-10 ppm (feed) as antimicrobial preservative; mix evenly with raw materials.
- **Laboratory Reagent:** Prepare 1000 IU/mL stock solution (sterile water); dilute to 10-50 IU/mL for microbial culture antimicrobial control.
- **Critical Notes:**
  1. No parenteral injection (systemic use); for topical/oral limited use only.
  2. Avoid use in bacitracin-allergic individuals; discontinue use if allergic reaction occurs.
  3. Do not exceed recommended dosage to avoid resistance development.

## 6. Packaging & Storage

### Packaging Specifications (Sealed/Refrigerated)

- 10 g/vial (pharmaceutical GMP grade, sealed glass vial)
- 50 g/bottle (veterinary grade, HDPE plastic bottle)
- 1 kg/bag (industrial grade, aluminum foil vacuum bag)
- 25 kg/drum (bulk grade, HDPE plastic drum with inner aluminum foil bag)
- Custom packaging (1g/5g) for research/small-batch orders available on request.

### Storage Conditions (Refrigerated Mandatory)

- **Long-term Storage:** 2-8°C (refrigerated), dry, dark, **sealed**; store in original packaging; avoid temperature fluctuation (>10°C).
- **Short-term Storage:** ≤25°C (room temperature), up to 3 months after opening; keep sealed and dry.
- **Avoid:** High temperature (>40°C), direct sunlight, high humidity (RH >60%), strong acids/bases, oxidizing agents, proteolytic enzymes.
- **Segregation:** Store separately from food/feed, pharmaceuticals (other antibiotics), strong acids/bases; store in dedicated antibiotic storage area; no mixed storage with aquatic products.

### Shelf Life

- 24 months (unopened, 2-8°C refrigerated storage, pharmaceutical grade)
- 18 months (unopened, 2-8°C refrigerated storage, veterinary/industrial grade)
- 3 months (room temperature, after opening, all grades)
- 7 days (room temperature, high humidity (RH >60%), after opening)

## 7. Safety & Protection

- The product is **harmful if swallowed**, causes skin/eye irritation and may trigger allergic skin reactions in sensitive individuals.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, powder-free nitrile gloves (≥0.18mm), disposable lab coat.
- Operate in well-ventilated area; avoid dust generation/inhalation and skin/eye contact; wash hands thoroughly after handling.

## 8. Quality Assurance

- Manufactured in accordance with **GMP (Good Manufacturing Practice)**, **ISO 9001 (Quality)** and **ISO 14001 (Environment)** standards.
- Each batch is tested by an independent third-party laboratory and accompanied by a **Certificate of Analysis (COA)** with full potency/purity test data.
- Provide **pharmacopoeial compliance documents** (CP/USP/EP/FDA) and hazardous chemical safety certificates for pharmaceutical grade products.