

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Polymyxin B Sulfate (多菌素 B 硫酸盐)
- **CAS Number:** 1404-26-8
- **Formula:** C₅₆ H₁₀₈ N₁₆ O₁₃·H₂SO₄
- **Formula Weight:** 1301.65 g/mol
- **Molecular Form:** Cyclic polypeptide antibiotic (sulfate salt, mixture of Polymyxin B1/B2)
- **Product Characteristics:** High-purity pharmaceutical/industrial grade Polymyxin B Sulfate is a natural cyclic polypeptide antibiotic produced by *Bacillus polymyxa*, with potent bactericidal activity against Gram-negative bacteria (*E. coli*, *Pseudomonas aeruginosa*, *Klebsiella*). White hygroscopic powder, soluble in water, stable under refrigerated hermetic storage. Potent systemic/topical activity, FDA/EMA approved for pharmaceutical/veterinary use, used as last-line antibiotic for multidrug-resistant Gram-negative infections; high aquatic toxicity, strict environmental use control.

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

| Item | Specification (Pharmaceutical Grade) |
|--|--|
| Appearance | White to pale pink hygroscopic powder |
| Assay (Potency, dry basis) | ≥ 6000 IU/mg (Microbiological Assay) |
| Loss on Drying (60°C, vacuum) | ≤ 7.0% |
| Residue on Ignition (600°C) | ≤ 2.0% |
| Heavy Metals (Pb) | ≤ 10 ppm (AAS) |
| Heavy Metals (As) | ≤ 1 ppm (AFS) |
| pH Value (1% aqueous solution, 25°C) | 5.0-7.5 |
| Water Content (Karl Fischer) | ≤ 7.0% |
| Sulfate Content | 10.0-14.0% (Titrimetric Method) |
| Related Substances | ≤ 6.0% (RP-HPLC) |
| Total Aerobic Count | ≤ 100 CFU/g |
| Pathogens (<i>E. coli</i> / <i>Pseudomonas aeruginosa</i>) | Negative |
| Solubility | Soluble in water, methanol |
| Particle Size | 200-300 mesh |
| Hygroscopy | High (stable at RH ≤40%) |
| Storage Stability | 36 months (2-8°C, unopened); 1 month (RT, after opening) |

3. Product Advantages

1. **Potent Gram-Negative Bactericidal Activity:** Rapid bactericidal effect on multidrug-resistant Gram-negative bacteria; last-line antibiotic for severe infections (*Pseudomonas aeruginosa*, *Acinetobacter baumannii*).
2. **High Purity & Potency:** ≥6000 IU/mg biological potency, ≥95.0% chemical purity (as sulfate), meets global pharmacopoeia (CP/USP/EP/FDA) standards; GMP compliant.
3. **Versatile Administration:** Suitable for systemic (injection) and topical use; high water solubility, easy for pharmaceutical formulation (injection, ointment, eye drops).
4. **Stable Under Controlled Storage:** Hygroscopic but stable under refrigerated hermetic storage with desiccant; long shelf life (36 months) for unopened batches.
5. **Low Cross-Resistance:** No cross-resistance with other antibiotic classes (aminoglycosides, cephalosporins); effective for multidrug-resistant strains.
6. **Proven Clinical Efficacy:** FDA/EMA approved for severe Gram-negative infections; well-documented clinical safety and efficacy at therapeutic dosages.

4. Application Fields



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- **Pharmaceutical Industry:** Production of injectable formulations (intravenous/intramuscular) for severe systemic Gram-negative infections; topical formulations (ointments, eye drops, sprays) for skin/wound/ocular infections; nebulizer solutions for respiratory tract infections.
- **Veterinary Medicine:** Livestock/poultry injectable/topical antibiotics for severe Gram-negative infections; limited feed additive use (strict dosage control).
- **Laboratory Use:** Antimicrobial reagent for microbial culture (Gram-negative bacteria control); antibiotic susceptibility testing standard.
- **Industrial Use:** Low-concentration biocide for industrial water treatment (Gram-negative bacteria control); strict environmental release control (high aquatic toxicity).

5. Usage Methods

- **Pharmaceutical Formulation (Systemic):** Dissolve in sterile water for injection to prepare 50,000-100,000 IU/mL injectable solution; adjust pH to 5.5-6.5 with buffer; sterile filtration for intravenous/intramuscular use.
- **Pharmaceutical Formulation (Topical):** Blend with excipients to prepare 10,000-20,000 IU/g ointment/cream; dissolve in sterile saline to prepare 5,000-10,000 IU/mL eye drops/wound irrigation solution.
- **Veterinary Use:** Injectable formulation (10,000-50,000 IU/kg body weight) for severe infections; dilute to 5,000 IU/mL for topical wound/ocular application.
- **Laboratory Reagent:** Prepare 100,000 IU/mL stock solution (sterile water); dilute to 50-100 IU/mL for microbial culture antimicrobial control; avoid use in aquatic culture media.
- **Critical Notes:**
 1. Strict dosage control for systemic use (renal/neurotoxicity risk); monitor renal function during treatment.
 2. Avoid overuse to prevent antibiotic resistance; use as last-line antibiotic for multidrug-resistant infections only.
 3. No environmental discharge (high aquatic toxicity); contain all waste/solution for hazardous disposal.
 4. Avoid use in polymyxin-allergic individuals; discontinue use if adverse reactions occur.

6. Packaging & Storage

Packaging Specifications (Hermetic/Refrigerated/Hygroscopic Protection)

- 1 g/vial (pharmaceutical GMP grade, hermetic glass vial with rubber stopper + aluminum crimp seal, anhydrous desiccant inside)
- 5 g/bottle (veterinary grade, HDPE plastic bottle with screw cap, anhydrous desiccant inside)
- 500 g/bag (industrial grade, aluminum foil vacuum bag with anhydrous desiccant)
- 10 kg/drum (bulk grade, HDPE plastic drum with inner aluminum foil vacuum bag, anhydrous desiccant inside)
- Custom packaging (0.1g/0.5g) for research/small-batch orders available on request (hermetic vials).

Storage Conditions (Strict Refrigerated & Low-Humidity Mandatory)

- **Long-term Storage:** 2-8°C (refrigerated), dry, dark, **hermetically sealed**; low-humidity environment (RH ≤40%); store in original packaging with anhydrous desiccant; avoid temperature fluctuation/repeated freeze-thaw.
- **Short-term Storage:** ≤25°C (room temperature), low-humidity (RH ≤40%), up to 1 month after opening; keep hermetically sealed with fresh anhydrous desiccant.

7. Safety & Protection

- The product is **toxic if swallowed**, harmful via skin contact, causes serious eye irritation and may cause kidney/neurological damage via prolonged/repeated systemic exposure; **highly toxic to aquatic life**.
- **Mandatory PPE** for handling: chemical safety goggles + face shield, N95/P95 dust mask (PAPR for large-scale handling), powder-free nitrile gloves (≥0.2mm, double-layer), impermeable lab coat, shoe covers.