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Technical Data Sheet (TDS) - Fusidic Acid

Revision Date: 22 FEB 2026**CAS Number**: 18592-40-0**Molecular Formula**: $C_{31}H_{48}O_6$ **Molecular Weight**: 516.71 g/mol

1. Product Overview

Fusidic Acid is a narrow-spectrum bacteriostatic steroid antibiotic pharmaceutical raw material, isolated from the fermentation broth of *Fusidium coccineum*. It exerts antibacterial effects by inhibiting bacterial protein synthesis through binding to the bacterial ribosomal 50S subunit, with a high affinity for gram-positive bacteria and strong activity against drug-resistant staphylococci (including MRSA). As a high-purity pharmacopoeial-grade raw material, it is widely used in clinical topical antibacterial preparations for skin, soft tissue and ocular infections, featuring low systemic absorption, high local drug concentration and mild side effects.

2. Technical Specifications (Complies with EP 10.0 & ChP 2025)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 98.5%
Related Substances	Total ≤ 1.0%; Single Impurity ≤ 0.2%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Melting Point	190 ~ 194℃
Specific Rotation (25℃, c=1 in ethanol)	+83° ~ +90°
pH Value (1% aqueous suspension, 25℃)	5.0 ~ 7.0
Solubility	Practically insoluble in water; freely soluble in ethanol, methanol, acetone; soluble in dimethyl sulfoxide (DMSO)
Optical Purity	≥ 99.0% (enantiomeric excess)
Stability	Stable at 2~8℃, dark and sealed conditions; degraded by strong light/heat/alkali

3. Product Advantages

1. **Targeted Antibacterial Activity**: Potent against gram-positive bacteria (Staphylococcus, Streptococcus), especially MRSA and other drug-resistant strains, no cross-resistance with other antibiotics.
2. **Low Systemic Absorption**: Negligible systemic absorption in topical application, avoiding systemic side effects (e.g., liver damage) and drug accumulation.
3. **High Local Efficacy**: Maintains high drug concentration at the infection site, rapid bacteriostatic effect and long-lasting action.
4. **Good Tolerance**: Mild local irritation, low allergic reaction rate, suitable for long-term topical use on skin and mucous membranes.
5. **Diverse Formulation Potential**: Can be prepared into ointments, creams, eye drops, sprays and gels, adapting to various topical antibacterial clinical needs.

4. Application Fields

Pharmaceutical Raw Material for Clinical Topical Antibacterial Therapy:

- **Skin infections**: Folliculitis, impetigo, furuncle, carbuncle, infected eczema, traumatic skin infections (caused by gram-positive bacteria).
- **Soft tissue infections**: Cellulitis, lymphangitis, abscess of superficial soft tissue.
- **Ocular infections**: Conjunctivitis, blepharitis, keratitis (bacterial etiology, mild to moderate).

- **Mucosal infections**: Oral ulcer, gingivitis (local application), vaginal mucositis (caused by sensitive gram-positive bacteria).
- **Dosage form production**: 2% fusidic acid ointment/cream, 0.5% eye drops, 1% antibacterial spray/gel.

5. Usage Methods (for Pharmaceutical Formulation)

Ointment/Cream Formulation (Semisolid)

- **2% Ointment/Cream**: Mix fusidic acid with petrolatum/lanolin (ointment base) or oil-in-water cream matrix, add appropriate penetration enhancer (e.g., propylene glycol), grind uniformly to prepare sterile semisolid preparation.
- **Processing Requirements**: Sterile grinding and mixing; control particle size D90 ≤ 40 μm to ensure good spreadability and skin absorption.

Liquid/Spray Formulation

- **1% Spray/Gel**: Dissolve fusidic acid with DMSO/ethanol (cosolvent) + deionized water, adjust pH to 5.5-6.5 with buffer, add thickener (for gel) or propellant (for spray).
- **Eye Drops (0.5%)**: Dissolve with sterile propylene glycol + water for injection, add isotonic regulator and preservative, filter and sterilize, fill in brown glass vials.

Compatibility

- Compatible with common pharmaceutical excipients (propylene glycol, glycerol, ointment bases, buffers); incompatible with strong alkalis (pH>9), strong oxidizing agents and metal ions (Fe^{3+} , Cu^{2+}).

6. Packaging & Storage

Packaging Specifications

- 5 g / brown glass sealed bottle (nitrogen-filled, R&D/laboratory use)
- 25 g / aluminum foil vacuum-sealed brown glass bottle (pilot production)
- 100 g / stainless steel sealed drum (nitrogen-filled, industrial GMP production)
- 500 g / HDPE sealed drum (for topical ointment formulation raw material)
- Custom GMP-compliant nitrogen-filled packaging for bulk orders available.

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **Sealing Requirement**: Nitrogen-filled tight sealing, protect from direct light and moisture; prevent contact with air to avoid oxidation.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents, reducing agents and heavy metal salts.
- **Shelf Life**: 24 months (unopened, nitrogen-filled, 2~8℃ refrigeration); 6 months after opening (sealed, refrigerated, used up as soon as possible).

Transportation

- Classified as pharmaceutical raw material for clinical antibacterial preparations; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8℃) with real-time temperature monitoring; use shockproof, light-proof, moisture-proof packaging; avoid package collision and light exposure during transport.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable protective clothing) during handling to avoid skin/mucosa contact and dust inhalation.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; in case of eye contact: Rinse with sterile water for injection for 15 minutes and consult a physician immediately if irritation persists.
- Do not ingest; accidental oral intake may cause mild gastrointestinal discomfort and liver function abnormalities—seek emergency medical treatment at once and check liver function indicators.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection system; avoid strong light and high temperature during material transfer and processing.