

Technical Data Sheet (TDS) - Afoxolaner

Revision Date: 28 FEB 2026 **CAS Number:** 1093861-60-9 **Molecular Formula:** C₂₂H₂₄ClFN₄O₂ **Molecular Weight:** 462.97 g/mol

1. Product Overview

Afoxolaner is a high-purity veterinary pharmaceutical-grade isoxazoline ectoparasiticide, a core raw material for the prevention and treatment of flea and tick infestations in dogs and cats. It exerts a rapid and long-lasting parasitocidal effect by selectively blocking the γ -aminobutyric acid (GABA) and glutamate-gated chloride channels of arthropods, inhibiting nerve signal transmission of fleas and ticks to cause their paralysis and death. With high selectivity to parasitic ion channels, good oral bioavailability, long in-vivo half-life and low toxicity to mammals, it is widely used in the production of veterinary oral chewable tablets, topical spot-on solutions and slow-release collars for companion animals, providing up to 30 days of continuous protection against fleas and ticks after a single administration.

2. Technical Specifications (Complies with USP 45 & Vet Pharm Standard)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl ⁻)	≤ 0.005%
Sulfate (SO ₄ ²⁻)	≤ 0.005%
Melting Point	148 ~ 152°C
Optical Rotation (25°C, c=1 in DMSO)	+38° ~ +44°
Microbial Limit	Total bacterial count ≤ 100 CFU/g; Salmonella negative
Water Solubility (25°C)	≥ 0.05 mg/mL
Log P (octanol/water, 25°C)	6.2
Plasma Protein Binding (canine)	≥ 99%
Half-Life (canine, oral)	14 ~ 17 days
Stability	Stable at 2~8°C (dark); degraded by strong light/heat/alkali
pH Value (0.1% suspension, 25°C)	6.0 ~ 7.5

3. Product Advantages

- High Parasite Selectivity:** Precisely targets arthropod ion channels with no significant effect on mammalian nervous systems, high safety for dogs/cats (including puppies/kittens and senior pets).
- Broad Spectrum & Rapid Efficacy:** Kills adult fleas within 24h and ticks within 48h; effective against multiple flea/tick species (*Ctenocephalides felis*, *Ixodes ricinus*, *Rhipicephalus sanguineus*).
- Long-Lasting Protection:** Single oral administration provides 30 days of continuous flea/tick prevention, reducing administration frequency and improving pet owner compliance.
- Good Formulation Compatibility:** Compatible with common veterinary excipients (mannitol, microcrystalline cellulose, propylene glycol), suitable for oral chewable tablets, topical spot-ons and slow-release collars.
- High Purity & Stable Quality:** Pharmacopoeial grade purity, ultra-low impurity and heavy metal content, stable physical and chemical properties under recommended storage conditions.
- Excellent Bioavailability:** Rapid and complete oral absorption, high plasma protein binding rate and long in-vivo half-life, ensuring sustained parasitocidal effect.

4. Application Fields

Veterinary Pharmaceutical Raw Material for Companion Animal Ectoparasiticide:



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- **Dogs & Cats:** Prevention and treatment of flea (*Ctenocephalides* spp.) and tick (*Ixodes*, *Rhipicephalus*, *Dermacentor* spp.) infestations; control of flea-borne diseases (tapeworm, bartonellosis).
- **Dosage Form Production:** 110mg/225mg/450mg oral chewable tablets (main dosage form), 8% topical spot-on solution, anti-parasitic collars (combined with moxidectin).

5. Usage Methods (for Veterinary Formulation)

225mg Oral Chewable Tablet (Canine Use)

- **Formula Ratio:** Afoxolaner 225 mg, mannitol 160 mg, microcrystalline cellulose 110 mg, maltodextrin 90 mg, magnesium stearate 6 mg, beef flavoring 20 mg.
- **Preparation Process:** Mix Afoxolaner with mannitol, microcrystalline cellulose and maltodextrin in a high-speed mixer for 10 min; add magnesium stearate and flavoring, mix for 3 min; wet granulation with ethanol-water (1:1) as wetting agent; dry granules at 50°C (moisture \leq 0.5%); compress into chewable tablets (hardness 6~8 kg).
- **Key Processing Requirements:** Operate in a light-proof, low-humidity environment (RH \leq 40%); avoid high temperature ($>60^{\circ}\text{C}$) during granulation and drying; control particle size $D_{90} \leq 100 \mu\text{m}$ for optimal bioavailability.

8% Topical Spot-On Solution

- Dissolve Afoxolaner in a mixed organic solvent (propylene glycol:diethylene glycol monoethyl ether = 8:2) to prepare 8% clear solution; add antioxidant (BHT 0.01%) and preservative; fill into light-proof plastic pipettes for topical application on pet skin.

6. Packaging & Storage

Packaging Specifications

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

Storage Conditions

- **Storage Temperature:** 2 ~ 8°C (refrigerated, dark place); avoid freezing and high temperature ($>25^{\circ}\text{C}$).
- **Sealing Requirement:** Nitrogen-filled tight sealing to prevent oxidation and moisture absorption; strict light protection (UV-proof packaging) to avoid photodegradation.
- **Incompatibilities:** Store separately from strong acids, strong bases, oxidizing agents, photosensitizers and food raw materials.
- **Shelf Life:** 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated, used up as soon as possible).

Transportation

- Classified as veterinary pharmaceutical raw material for companion animal ectoparasiticide; transport in compliance with national veterinary drug transportation regulations.
- Refrigerated transport (2~8°C) with real-time temperature monitoring; use shockproof, light-proof, moisture-proof packaging (brown glass/HDPE with UV coating); avoid package collision and direct sunlight during transport.

7. Safety & Protection

- Wear professional veterinary pharmaceutical PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, light-proof 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; apply mild emollient if irritation occurs.
- In case of eye contact: Rinse with sterile normal saline for 15 minutes; consult a physician immediately if irritation persists.
- Do not ingest; accidental oral intake may cause gastrointestinal discomfort (nausea, vomiting)—seek emergency medical treatment at once and conduct symptomatic treatment.