

## Technical Data Sheet (TDS) - Sarolaner

**Revision Date:** 29 FEB 2026 **CAS Number:** 847100-72-5 **Molecular Formula:** C<sub>21</sub>H<sub>25</sub> FN<sub>4</sub>O<sub>2</sub>S **Molecular Weight:** 416.51 g/mol

### 1. Product Overview

Sarolaner is a high-purity veterinary pharmaceutical-grade isoxazoline ectoparasiticide, a core raw material for the prevention and treatment of parasitic infestations in dogs and cats. It is a white crystalline powder with high selective activity against arthropod  $\gamma$ -aminobutyric acid (GABA) and glutamate-gated chloride channels, blocking nerve signal transmission of ectoparasites (ticks, fleas) to achieve rapid killing effect. With the characteristics of high potency, broad spectrum, long-lasting efficacy, good oral bioavailability and low toxicity to mammals, it is widely used in the production of veterinary oral chewable tablets, topical spot-ons and collars for the prevention and treatment of flea and tick infestations in companion animals.

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

Item	Specification
Appearance	White to off-white crystalline powder
Assay (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; (As) ≤ 2 ppm	≤ 10 ppm; ≤ 2 ppm
Chloride (Cl <sup>-</sup> )	≤ 0.005%
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 0.005%
Melting Point	152 ~ 156°C
Optical Rotation (25°C, c=1 in DMSO)	+42° ~ +48°
Microbial Limit	Total bacterial count ≤ 100 CFU/g; Salmonella negative
Water Solubility (25°C)	≥ 0.1 mg/mL
Log P (octanol/water, 25°C)	5.8
Plasma Protein Binding (canine)	≥ 99%
Half-Life (canine, oral)	11 ~ 14 days
Stability	Stable at 2~8°C (dark); degraded by strong light/heat/alkali
pH Value (0.1% suspension, 25°C)	6.5 ~ 8.0

### 3. Product Advantages

- High Ectoparasite Selectivity:** Precisely targets arthropod ion channels, no significant effect on mammalian nervous systems, high safety for dogs and cats (including puppies/kittens).
- Broad Spectrum & Rapid Efficacy:** Kills adult fleas within 24h, 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 flea/tick prevention, reducing administration frequency and improving pet owner compliance.
- Good Formulation Compatibility:** Compatible with common veterinary excipients (mannitol, microcrystalline cellulose, glycerin), 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.
- Good Bioavailability:** Oral absorption is rapid and complete, high plasma protein binding rate, long half-life in animal body, 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:** 150mg/200mg/400mg oral chewable tablets (main dosage form), 10% topical spot-on solution, slow-release anti-parasitic collars (combined with moxidectin).

## 5. Usage Methods (for Veterinary Formulation)

### 200mg Oral Chewable Tablet (Canine Use)

- **Formula Ratio:** Sarolaner 200 mg, mannitol 150 mg, microcrystalline cellulose 100 mg, maltodextrin 80 mg, magnesium stearate 5 mg, chicken flavoring 15 mg.
- **Preparation Process:** Mix Sarolaner 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 good bioavailability.

### 10% Topical Spot-On Solution

- Dissolve Sarolaner in a mixed organic solvent (propylene glycol:diethylene glycol monoethyl ether = 7:3) to prepare 10% clear solution; add antioxidant (BHT 0.01%) and preservative; fill into light-proof plastic pipettes for topical application.

## 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.