

Technical Data Sheet (TDS)

Issue Date: 25 FEB 2026 Version: V1.0

1. Product Overview

- **Product Name:** Fluralaner
- **CAS Number:** 654056-75-8
- **Molecular Formula:** C₂₄H₁₉ F₇ N₄O₂
- **Molecular Weight:** 556.42 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized via isoxazoline ring formation, halogenation, amidation and fluorination; purified by recrystallization and column chromatography to ensure high purity and low impurity content; optimized process for good formulation compatibility for veterinary oral/topical formulations).
- **Product Trait:** White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in organic solvents (acetone/DMSO), insoluble in water; stable in dry, dark and neutral/weakly acidic environment, mild decomposition in strong alkaline environment; good stability in veterinary pharmaceutical processing with light protection.
- **Core Properties:** **Highly selective isoxazoline acaricide/insecticide** with potent flea and tick killing activity; blocks GABA-gated chloride channels and glutamate-gated chloride channels in arthropods, leading to nerve cell depolarization and death; long-acting (up to 12 weeks for dogs, 8 weeks for cats), broad-spectrum, fast-acting (kills fleas within 24 hours, ticks within 48 hours); the classic veterinary pharmaceutical raw material for treating and preventing flea/tick infestations in companion animals (dogs/cats).
- **Main Application:** Pharmaceutical raw material for veterinary oral/topical acaricidal/insecticidal formulations (chewable tablets, spot-on solutions); treatment and prevention of flea (*Ctenocephalides felis/Ctenocephalides canis*) and tick (*Ixodes/Rhipicephalus*) infestations in dogs and cats; veterinary R&D reference reagent for parasitology and arthropod pharmacology research.

2. Technical Specifications (Veterinary Pharmaceutical Grade, Complies with EP/USP/VICH)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Fluralaner)	≥ 98.5%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25°C ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 1.0%	HPLC
Melting Point	145-150°C	Melting Point Apparatus (light protection)
Total Bacterial Count	≤ 10 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method (light protection)
Solubility in Acetone	Freely soluble	Solubility Test
Bulk Density	1.48-1.52 g/cm ³	Pycnometer Method
Photostability	≤ 0.5% related substances after 7 days (25°C, light exposure)	HPLC



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Item	Specification	Test Method
log P (n-octanol/water)	7.4-7.6	HPLC Partition Method

3. Product Advantages

1. **High Target Selectivity:** Potent and highly selective binding to arthropod GABA/glutamate-gated chloride channels; no affinity for mammalian ion channels, low toxicity to dogs/cats and humans, high safety for companion animals and handlers.
2. **Long-Acting & Broad-Spectrum:** Single administration provides 8-12 weeks of flea/tick protection; kills all major flea/tick species infesting dogs and cats; fast-acting, eliminates fleas within 24 hours and prevents egg hatching, breaking the flea life cycle.
3. **Excellent Pharmacokinetics:** Good oral bioavailability in dogs/cats ($\approx 90\%$); rapid absorption in the gastrointestinal tract, long half-life (≈ 14 days in dogs, ≈ 10 days in cats); lipophilic property (log P=7.5) leads to high tissue distribution, persistent efficacy in skin and hair follicles.
4. **Veterinary Pharmaceutical Grade Purity:** Meets EP/USP/VICH international veterinary drug standards; ultralow heavy metal and microbial limits; high assay ($\geq 98.5\%$) and low related substances; suitable for GMP production of clinical veterinary oral/topical formulations.

4. Application Fields

4.1 Veterinary Pharmaceutical Industry (Oral/Topical Acaricidal/Insecticidal Formulations)

- **Canine Chewable Tablets:** Core raw material for 250mg/500mg/1000mg chewable tablets; for dogs of different body weights (2-50kg); single oral administration, provides 12 weeks of flea/tick protection; palatable chewable form, high pet compliance.
- **Feline Spot-On Solutions:** Formulation for 50mg/100mg cat spot-on solutions; topical application on the back of the neck, provides 8 weeks of flea/tick protection; transdermal absorption, no oral administration required, suitable for cats with poor oral compliance.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Veterinary Formulations)

- **Canine Chewable Tablets:** 25-50 mg/kg body weight; single oral administration every 12 weeks; e.g., 250mg for 5-10kg dogs, 500mg for 10-20kg dogs, 1000mg for 20-50kg dogs.
- **Feline Spot-On Solutions:** 10-20 mg/kg body weight; topical application every 8 weeks; e.g., 50mg for ≤ 5 kg cats, 100mg for 5-10kg cats.

6. Packaging & Storage

6.1 Packaging Specifications (Veterinary Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, **light protection**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection and moisture-proof**).

7. Safety & Protection

- The product is a highly selective isoxazoline veterinary acaricidal/insecticidal raw material with mild human toxic/irritant effects and severe aquatic environmental hazard; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust, skin absorption and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **light protection**; monitor hepatic/renal function for personnel with prolonged handling exposure.
- **Strictly prevent any product contact with water sources and aquatic environments**; collect all production waste and cleaning water for professional hazardous waste disposal, no discharge to the environment; avoid direct sunlight and high humidity in the work area; keep the operation tools clean and dry.