



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Afoxolaner)

Issue Date: 28 FEB 2026 Quality Release Date: 28 FEB 2026

Product Name

Afoxolaner 阿福克索拉纳

Product Information

Product Number AFO-20260228

Batch Number AFO-SH2026022801

Brand SIGALD

CAS Number 1093861-60-9

MDL Number MFCD22457058

Formula $C_{22}H_{24}ClFN_4O_2S$

Formula Weight 462.97 g/mol

Test Results

Test	Specification (Veterinary Pharmaceutical Standard & USP 45)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection (25°C)
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection (25°C)
Assay (on dry basis)	≥ 99.0%	99.6%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.07%	%	HPLC (USP 45 Method)
Single Impurity	≤ 0.1%	0.02%	%	HPLC (USP 45 Method)
Loss on Drying	≤ 0.5%	0.05%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.03 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride (Cl ⁻)	≤ 0.005%	ND	%	Silver Nitrate Titration
Sulfate (SO ₄ ²⁻)	≤ 0.005%	ND	%	Barium Sulfate Turbidimetry
Melting Point	148 ~ 152°C	150.5°C	°C	Melting Point Apparatus
Optical Rotation (25°C, c=1 in DMSO)	+38° ~ +44°	+41.2°	°	Polarimetry
Microbial Limit	Total bacterial count ≤ 100 CFU/g	10 CFU/g	CFU/g	Plate Count Method
Salmonella	Negative	Negative	-	Microbiological Detection
Water Solubility (25°C)	≥ 0.05 mg/mL	0.08 mg/mL	mg/mL	Shake Flask Method

Certification

This batch of Afoxolaner has been tested in accordance with the **United States Pharmacopeia (45 Edition)** and **National Veterinary Pharmaceutical Raw Material Standards (China)**. All test results meet the specified quality requirements for veterinary isoxazoline ectoparasiticide raw materials, and the product is qualified for use in the production of veterinary oral and topical anti-flea and tick preparations for dogs and cats.