



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Certificate of Analysis (Finerenone)

Issue Date: 29 FEB 2026

Quality Release Date: 29 FEB 2026

Product Name

Finerenone 氟烯酮

Product Information

Product Number FIN-20260229

Batch Number FIN-SH2026022901

Brand SIGALD

CAS Number 1050477-31-0

MDL Number MFCD22456815

Formula $C_{23}H_{22}F_4N_4O_3S$

Formula Weight 512.51 g/mol

Test Results

Test	Specification (USP 45 & ChP 2025)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (on dry basis)	$\geq 99.0\%$	99.6%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 0.5\%$	0.09%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.02%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.06%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	$\leq 0.1\%$	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.04 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/ μ g	0.03 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	235 ~ 239°C	237.2°C	°C	Melting Point Apparatus
pH Value (0.1% DMSO solution, 25°C)	6.0 ~ 8.0	7.1	-	Digital pH Meter
Optical Rotation (25°C, c=1 in DMSO)	$0^\circ \pm 2^\circ$	0.2°	°	Polarimetry

Certification

This batch of Finerenone has been tested in accordance with the **United States Pharmacopeia (45 Edition)** and **Chinese Pharmacopoeia (2025 Edition)**. All test results meet the specified pharmacopoeial requirements for pharmaceutical raw materials, and the product is qualified for use in the production of clinical anti-chronic kidney disease and heart failure pharmaceutical preparations.