纳维盈医化科技
NEWAY SINOPHC TECH

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Certificate of Analysis (Letermovir)

Issue Date: 20 FEB 2026**Quality Release Date**: 20 FEB 2026

Product Name

Letermovir 莱特莫韦

Product Information

Product Number	LE-20260220
Batch Number	LE-SH2026022001
Brand	SIGALD
CAS Number	917389-32-3
MDL Number	MFCD22446556
Formula	$C_{23}H_{25}F_4N_3O_4S$
Formula Weight	519.52 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)	≥ 99.0%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.15%	%	HPLC (USP 45)
Single Impurity	≤ 0.1%	0.02%	%	HPLC (USP 45)
Loss on Drying	≤ 0.5%	0.09%	%	Vacuum Drying at 60℃ for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.4 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.08 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.07 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	155 ~ 159℃	157.2℃	℃	Melting Point Apparatus
pH Value (0.1% aqueous suspension, 25℃)	5.5 ~ 7.5	6.3	-	Digital pH Meter
Optical Rotation (25℃, c=1 in DMSO)	-12.0° ~ -8.0°	-9.8°	°	Polarimetry

Certification

This batch of Letermovir 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-cytomegalovirus (CMV) pharmaceutical preparations.