



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Ruxolitinib Phosphate)

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

Product Name

Ruxolitinib Phosphate 鲁索替尼磷酸盐

Product Information

Product Number RP-20260228
Batch Number RP-SH2026022801
Brand SIGALD
CAS Number 1092939-17-7
MDL Number MFCD18383566
Formula $C_{18}H_{22}N_4O_2 \cdot H_3PO_4$
Formula Weight 404.38 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)	$\geq 99.0\%$	99.8%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 0.5\%$	0.11%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.02%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.08%	%	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	0.05 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/ μ g	0.04 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	155 ~ 159°C	157.1°C	°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	4.0 ~ 6.0	5.2	-	Digital pH Meter
Optical Rotation (25°C, c=1 in H ₂ O)	0° \pm 2°	0.4°	°	Polarimetry

Certification

This batch of Ruxolitinib Phosphate 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-myelofibrosis and anti-psoriasis pharmaceutical preparations.