



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis

### Product Information

Item	Details
Product Name	Alectinib Hydrochloride
Product Number	AH-20260225
Batch Number	AH-SH2026022501
Brand	SIGALD
CAS Number	1256589-74-8
MDL Number	N/A
Formula	C <sub>30</sub> H <sub>34</sub> ClN <sub>5</sub> O <sub>2</sub>
Formula Weight	519.08 g/mol
Quality Release Date	25 FEB 2026

### Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (Alectinib Hydrochloride)	≥ 99.0%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	0.06%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.003%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 2 ppm	0.02 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.01 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	≤ 0.5%	0.08%	%	High Performance Liquid Chromatography (HPLC)
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 0.02%	0.001%	%	Turbidimetric Method
pH Value (1% aqueous suspension, 25°C)	5.5-7.5	6.3	-	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Solubility in Dimethyl sulfoxide	Freely soluble	Complies	-	Pharmacopoeia Method
Supplier Information	Confirmed	Confirmed	-	-

### Certification

This batch of product has been tested in accordance with the industrial standards for Alectinib Hydrochloride and meets all specified requirements. It is qualified for use.

Issue Date: 25 FEB 2026