



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (COA)

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

### Product Information

Product Name Recombinant Human Interferon  $\alpha$ -2b (rIFN  $\alpha$ -2b)  
Product Number IFN-20260228  
Batch Number IFN-SH2026022801  
Brand SIGALD  
CAS Number 98530-12-2  
MDL Number MFCD00131068  
Formula  $C_{148}H_{2344}N_{412}O_{46}S_{18}$   
Formula Weight 31000 Da (approx)  
Molecular Form Recombinant Glycoprotein (165 amino acid residues)

### Test Results

Test	Specification (Industry/Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Lyophilized powder	Lyophilized powder	-	Visual Inspection
Assay (Biological Activity)	$\geq 1.0 \times 10^8$ IU/mg	$1.2 \times 10^8$ IU/mg	IU/mg	Vero Cell Viral Inhibition Method
Protein Purity (Main Peak)	$\geq 99.0\%$	99.6%	%	Reverse-Phase HPLC (RP-HPLC)
Loss on Drying	$\leq 2.0\%$	0.8%	%	Gravimetric Method (60°C, 4h, vacuum)
Residue on Ignition	$\leq 0.5\%$	0.1%	%	Ignition at 600°C $\pm$ 50°C
Heavy Metals (Pb)	$\leq 5$ ppm	0.6 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 1$ ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
pH Value (1 mg/mL aqueous, 25°C)	6.5-7.5	7.0	-	Digital pH Meter
Water Content (Karl Fischer)	$\leq 2.0\%$	0.7%	%	Karl Fischer Titration
Bacterial Endotoxins	$\leq 0.1$ EU/ $\mu$ g	0.03 EU/ $\mu$ g	EU/ $\mu$ g	Limulus Amebocyte Lysate (LAL) Test
Host Cell Protein Residue	$\leq 10$ ppm	2 ppm	ppm	Enzyme-Linked Immunosorbent Assay (ELISA)
Plasmid DNA Residue	$\leq 10$ pg/mg	1 pg/mg	pg/mg	Real-Time Polymerase Chain Reaction (RT-PCR)
Total Aerobic Count	$\leq 10$ CFU/g	3 CFU/g	CFU/g	Plate Count Method
Pathogens (E. coli/Salmonella)	Negative	Negative	-	Microbiological Detection
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

### Certification

This batch of product has been tested in accordance with Chinese Pharmacopoeia (CP), USP and EP standards for Recombinant Human Interferon  $\alpha$ -2b and meets all specified requirements. It is qualified for pharmaceutical GMP grade and research use.