



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Quality Release Date: 18 FEB 2026 Issue Date: 18 FEB 2026

Product Information

Product Name Recombinant Human Growth Hormone (rhGH)
 Product Number rhGH-20260218
 Batch Number rhGH-SH2026021801
 Brand SIGALD
 CAS Number 9002-72-6
 MDL Number MFCD00131056
 Formula $C_{99}O_{10}H_{152}N_{26}O_3$
 Formula Weight 22124.77 g/mol
 Molecular Form Recombinant Polypeptide Hormone (191 amino acids)

Test Results

Test	Specification (Pharmacopoeial/Industrial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Lyophilized powder	Lyophilized powder	-	Visual Inspection
Assay (Potency, on dry basis)	≥ 3.0 IU/mg	3.2 IU/mg	IU/mg	Biological Assay (Rat Weight Gain Method)
Peptide Purity (Main Peak)	≥ 99.0%	99.7%	%	Reverse-Phase High Performance Liquid Chromatography (RP-HPLC)
Loss on Drying	≤ 1.0%	0.28%	%	Gravimetric Method (60°C, 4h, vacuum)
Residue on Ignition	≤ 0.1%	0.01%	%	Ignition at 600°C±50°C
Heavy Metals (Pb)	≤ 2 ppm	0.3 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 0.5 ppm	0.06 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Peptides	≤ 1.0%	0.2%	%	RP-HPLC
Water Content (Karl Fischer)	≤ 1.0%	0.35%	%	Karl Fischer Titration
Bacterial Endotoxins	≤ 0.05 EU/μg	0.02 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Total Aerobic Count	≤ 5 CFU/g	2 CFU/g	CFU/g	Plate Count Method
E. coli/Staphylococcus aureus/Salmonella	Negative	Negative	-	Microbiological Detection
Protein Homogeneity	≥ 99.0%	99.6%	%	Size-Exclusion Chromatography (SEC)
Host Cell Protein Residue	≤ 10 ppm	3 ppm	ppm	ELISA
Plasmid DNA Residue	≤ 10 pg/mg	2 pg/mg	pg/mg	Real-Time PCR
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 Growth Hormone and meets all specified requirements. It is qualified for pharmaceutical GMP grade use.