



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Product Information

Item	Details
Product Name	Somatropin (Recombinant Human Growth Hormone)
Product Number	SOM-20260229
Batch Number	SOM-SH2026022901
Brand	SIGALD
CAS Number	12629-01-5
MDL Number	MFCD00130867
Formula	Polypeptide Hormone (191 Amino Acids)
Molecular Weight	22125.8 Da
Form	White Lyophilized Powder
Quality Release Date	29 FEB 2026

Test Results

Test	Specification (Biopharmaceutical Grade)	Result	Unit	Test Method
Appearance	White to off-white lyophilized powder	White lyophilized powder	-	Visual Inspection
Purity (HPLC)	≥ 99.0%	99.7%	%	High Performance Liquid Chromatography
Biological Activity	≥ 3.0 IU/mg	3.2 IU/mg	IU/mg	Rat Weight Gain Bioassay
pH Value (1mg/mL in PBS, 25°C)	6.5-8.5	7.4	-	Digital pH Meter
Moisture Content	≤ 5.0%	1.8%	%	Karl Fischer Titration
Bacterial Endotoxin	≤ 0.5 EU/mg	0.1 EU/mg	EU/mg	Limulus Amebocyte Lysate Test
Sterility	Negative	Negative	-	Membrane Filtration Method
Heavy Metals (Pb)	≤ 5 ppm	0.3 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Protein Content	≥ 95.0%	98.9%	%	Lowry Method
Aggregation (SEC -HPLC)	≤ 1.0%	0.2%	%	Size Exclusion Chromatography
Amino Acid Sequence	Conforms to human GH sequence	Conforms	-	Mass Spectrometry/Edman Degradation
Identity (ELISA)	Positive	Positive	-	Enzyme-Linked Immunosorbent Assay

Certification

This batch of Somatropin has been tested in accordance with USP/EP/ICH biopharmaceutical standards and meets all specified requirements for purity, biological activity and quality control limits. It is qualified for biopharmaceutical R&D, in vitro diagnostics and human growth hormone drug development.

Issue Date: 29 FEB 2026