



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Product Information

Item	Details
Product Name	Insulin Glargine
Product Number	INS-20260216
Batch Number	INS-SH2026021601
Brand	SIGALD
CAS Number	113102-64-0
MDL Number	MFCD00801615
Formula	Long-Acting Recombinant Insulin Analogue (51 Amino Acids)
Molecular Weight	6063.9 Da
Form	White Lyophilized Powder
Quality Release Date	16 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%	99.8%	%	High Performance Liquid Chromatography
Biological Activity	≥ 27.5 IU/mg	28.2 IU/mg	IU/mg	In Vivo Bioassay (Mouse Blood Glucose Assay)
pH Value (1mg/mL in PBS, 25°C)	7.0-8.0	7.5	-	Digital pH Meter
Moisture Content (Karl Fischer)	≤ 3.0%	1.3%	%	Karl Fischer Titration
Bacterial Endotoxin	≤ 0.5 EU/mg	0.2 EU/mg	EU/mg	Limulus Amebocyte Lysate Test
Sterility	Negative	Negative	-	Membrane Filtration Method
Heavy Metals (Pb)	≤ 5 ppm	0.4 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Protein Content	≥ 98.0%	99.5%	%	Lowry Method
Amino Acid Sequence	Conforms to insulin glargine sequence	Conforms	-	Mass Spectrometry/Edman Degradation
Aggregation (SEC-HPLC)	≤ 0.5%	0.2%	%	Size Exclusion Chromatography

Certification

This batch of Insulin Glargine 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 long-acting diabetes drug development applications.

Issue Date: 16 FEB 2026