



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (COA)

### Product Information

Item	Details
Product Name	Insulin (Recombinant Human Insulin)
Product Number	INS-20260221
Batch Number	INS-SH2026022101
Brand	SIGALD
CAS Number	11061-68-0
MDL Number	MFCD00801610
Formula	Recombinant Human Insulin (51 Amino Acids)
Molecular Weight	5807.6 Da
Form	White Lyophilized Powder
Quality Release Date	21 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)	≥ 98.5%	99.6%	%	High Performance Liquid Chromatography
Biological Activity	≥ 27.0 IU/mg	27.8 IU/mg	IU/mg	In Vivo Bioassay (Mouse Blood Glucose Assay)
pH Value (1mg/mL in PBS, 25°C)	6.5-7.5	7.2	-	Digital pH Meter
Moisture Content	≤ 3.0%	1.4%	%	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	≥ 97.0%	99.2%	%	Lowry Method
Amino Acid Sequence	Conforms to human insulin sequence	Conforms	-	Mass Spectrometry/Edman Degradation
Aggregation (SEC-HPLC)	≤ 0.8%	0.3%	%	Size Exclusion Chromatography

### Certification

This batch of Insulin has been tested in accordance with USP/EP/ICH biopharmaceutical industry 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 diabetes drug development applications.

**Issue Date: 21 FEB 2026**