



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Quality Release Date: 15 FEB 2026 Issue Date: 15 FEB 2026

Product Information

Product Name Porcine Insulin
Product Number PI-20260215
Batch Number PI-SH2026021501
Brand SIGALD
CAS Number 12584-58-6
MDL Number MFCD00082057
Formula $C_{257}H_{383}N_{65}O_{77}S_6$
Formula Weight 5778.69 g/mol
Molecular Form Polypeptide Hormone

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)	≥ 26.0 IU/mg	26.8 IU/mg	IU/mg	Biological Assay (Mouse Blood Glucose Method)
Peptide Purity (Main Peak)	$\geq 99.0\%$	99.5%	%	Reverse-Phase High Performance Liquid Chromatography (RP-HPLC)
Loss on Drying	$\leq 1.0\%$	0.32%	%	Gravimetric Method (60°C, 4h, vacuum)
Residue on Ignition	$\leq 0.1\%$	0.01%	%	Ignition at 600°C \pm 50°C
Heavy Metals (Pb)	≤ 2 ppm	0.4 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 0.5 ppm	0.07 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Peptides	$\leq 1.0\%$	0.25%	%	RP-HPLC
Water Content (Karl Fischer)	$\leq 1.0\%$	0.39%	%	Karl Fischer Titration
Bacterial Endotoxins	≤ 0.1 EU/ μ g	0.03 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Total Aerobic Count	≤ 10 CFU/g	4 CFU/g	CFU/g	Plate Count Method
E. coli/Staphylococcus aureus	Negative	Negative	-	Microbiological Detection
Insulin Monomer/Dimer	$\leq 5.0\%$	2.1%	%	Size-Exclusion Chromatography (SEC)
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 Porcine Insulin and meets all specified requirements. It is qualified for pharmaceutical GMP grade use.