



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Product Information

Item	Details
Product Name	Follicle-Stimulating Hormone (FSH)
Product Number	FSH-20260225
Batch Number	FSH-SH2026022501
Brand	SIGALD
CAS Number	9002-68-0
MDL Number	MFCD00131051
Formula	Glycoprotein Hormone (α/β Subunits)
Molecular Weight	32000-38000 Da (glycosylation variable)
Form	Lyophilized Powder
Quality Release Date	25 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 (SDS-PAGE)	$\geq 95.0\%$	98.2%	%	Sodium Dodecyl Sulfate -PAGE
Biological Activity	≥ 1500 IU/mg	1620 IU/mg	IU/mg	In Vivo Bioassay (Rat Ovary Weight Method)
pH Value (100 μ g/mL in PBS, 25 $^{\circ}$ C)	6.0-8.0	7.1	-	Digital pH Meter
Moisture Content (Karl Fischer)	$\leq 5.0\%$	1.8%	%	Karl Fischer Titration
Bacterial Endotoxin	≤ 2 EU/mg	0.9 EU/mg	EU/mg	Limulus Amebocyte Lysate Test
Sterility	Negative	Negative	-	Membrane Filtration Method
Heavy Metals (Pb)	≤ 5 ppm	0.7 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Protein Content	$\geq 90.0\%$	95.6%	%	Bradford Method
Glycosylation Content	25-35%	30.5%	%	HPLC Carbohydrate Analysis
Aggregation (SEC-HPLC)	$\leq 2.0\%$	0.8%	%	Size Exclusion Chromatography

Certification

This batch of Follicle-Stimulating Hormone (FSH) has been tested in accordance with the established biopharmaceutical industry standards and meets all specified requirements for purity, biological activity and quality control limits. It is qualified for use in biopharmaceutical R&D, in vitro diagnostics and reproductive biology research.

Issue Date: 25 FEB 2026