



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Certificate of Analysis (COA)

### Product Information

Item	Details
Product Name	Insulin Aspart
Product Number	IAS-20260220
Batch Number	IAS-SH2026022001
Brand	SIGALD
CAS Number	133107-64-9
MDL Number	MFCD00801622
Formula	Fast-Acting Recombinant Insulin Analogue (51 Amino Acids)
Molecular Weight	5825.8 Da
Form	White Lyophilized Powder
Quality Release Date	20 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%	99.9%	%	High Performance Liquid Chromatography
Biological Activity	≥ 28.0 IU/mg	28.7 IU/mg	IU/mg	In Vivo Bioassay (Mouse Blood Glucose Assay)
pH Value (1mg/mL in PBS, 25°C)	6.5-7.5	7.1	-	Digital pH Meter
Moisture Content	≤ 3.0%	1.2%	%	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	≥ 98.0%	99.6%	%	Lowry Method
Amino Acid Sequence	Conforms to insulin aspart sequence	Conforms	-	Mass Spectrometry/Edman Degradation
Aggregation (SEC-HPLC)	≤ 0.5%	0.1%	%	Size Exclusion Chromatography

### Certification

This batch of Insulin Aspart 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 fast-acting diabetes drug development applications.

**Issue Date: 20 FEB 2026**