

CERTIFICATE OF ANALYSIS

Product:SS-31 (10mg/vial)

Peptide Name	SS-31 / Elamipretide	Molecular Formula	C ₃₂ H ₄₉ N ₉ O ₅
Molecular Weight	639.8	CAS No.	736992-21-5
Lot Number	SS10-20260809	Specifications	10mg/vial
Manufacturing Date	2026/8/9	Report Date	2026/8/23
Re-test Date	2028/8/8	Storage Condition	-25°C to -5°C (Protect from light)
Tests	Specifications	Results	
Appearance	White powder,No visible foreign bodies	Conforms	
Solubility	Soluble in sterile water / 0.1% acetic acid	Conforms	
Assay (per vial, HPLC)	9.50 mg ~ 10.50 mg	10.23mg	
Purity (HPLC)	≥99.0%	99.27%	
Water Content (Karl Fischer)	≤3.0%	2.45%	
pH	4.5-6.5	5.9	
Related Substance (By HPLC)	Total Impurities (%) ≤2.0%	0.73%	
	Largest Single Impurity (%) ≤1.0%	0.49%	
Residual Solvents	Methanol: ≤0.3%	0.18%	
	Acetonitrile: ≤0.041%	0.026%	
	Ethyl Acetate: ≤0.5%	0.35%	
Heavy Metals	≤10ppm (Pb、As、Cd、Hg)	Conforms	
Sterility Test	Sterile (No microbial growth)	Conforms	
Bacterial Endotoxin	<5EU/mg	Conforms	
Content Uniformity	shall comply with regulations	Conforms	
Result(of inspection)	This product was tested according to corporate quality standards, with results conforming to regulations.		
Analyst: <i>Li hua</i>	Reviewed by: <i>Zhang Lin</i>		Authorized by: <i>Wenbin</i>
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