

CERTIFICATE OF ANALYSIS

Peptide Raw Material Analytical Assessment



Product Name: **TESAMORELIN**
Batch/Lot No: **TESA-0315-06**
Form: **PEPTIDE API MATERIAL**
Quantity: **ANALYTICAL TESTING SAMPLE**
Manufacturing Date: **01 / 31 / 2026**
Expiration Date: **01 / 31 / 2029**
Storage Condition: **20°C - 30°C (Room Temperature, Dry, Protected from Light)**



HELIX PHARMACOKINETICS & PHARMACODYNAMICS

Parameter	Method	Specification	Result	Status
Appearance	Visual Inspection	White Amorphous Powder	CONFORMS	PASS
Identity (Peptide Match)	HPLC vs Ref Std	± 0.2 min match	11.46	PASS
Purity	RP-HPLC	≥ 98.0 %	99.22%	PASS
Molecular Weight	MALDI-TOF-MS	5135 ± 5 Da	5134.8	PASS
Solubility	Visual Dissolution Asmnt	Freely Soluble in Water	CONFORMS	PASS
Water Content	Karl Fischer (AOAC 984.20)	≤ 5.0 % moisture	2.40%	PASS
Residual Solvents	GC-MS	NMT 0.5 %	ND (0.00%)	PASS
Assay	HPLC	≥ 95.0%	98.71%	PASS
Acetate Content	Ion Chromatography	≤ 15.0%	7.60%	PASS
Residual TFA	Ion Chromatography	≤ 0.10% (1000ppm)	153ppm	PASS
Loss on Drying	Gravimetric	≤ 5.0%	2.10%	PASS

Analyst: Dr. Amanda R. Voss, Ph.D. - Director of Analyt Date: 03 / 29 / 2026
Approved By: Michael Tran, M.Sc. - Quality Assurance Manage Date: 03 / 31 / 2026

Analytical Verification of Peptide Quality & Stability Validation

Analytical evaluation confirms the peptide meets stringent purity specifications, with no measurable impurities or byproducts detected. Stability testing supports preservation of molecular integrity, with no observable degradation across validated conditions. These findings verify consistency in composition and support reliable performance in controlled applications.

FINAL PERFORMANCE ASSESSMENT

Based on the analytical data presented, the sample meets all specified quality criteria. Testing confirms high purity, accurate molecular identity, and compliance with established specifications for composition and performance. No impurities, residual solvents, endotoxins, or microbial contamination were detected beyond acceptable limits. Stability parameters and physicochemical properties fall within validated ranges, indicating no evidence of degradation.

