

Certificate of Analysis

FULL QUALITY CONTROL PANEL · COMPOUND ANALYTICAL REPORT

CERTIFICATE NO.

COA-2026-9503

Issued 09/11/2026 · Page 1 of 4

CLIENT	PREPARED FOR	SAMPLE & ACCESSION	ACC - 2026 - 9603	SAMPLE PHOTOGRAPH	AS RECEIVED
PeptaraLabs PeptaraLabs.io Client reference: on file Distribution: client confidential		ANALYTE / IDENTITY SS-31 LABELED CONTENT 10 mg MANUFACTURED 06/02/2026 DATE RECEIVED 08/28/2026	CAS NUMBER 736992-21-2 SAMPLE MATRIX Lyophilized RETEST / EXPIRY 06/2028 DATE ANALYZED 09/10/2026	LOT NUMBER SS31-20260602-09 APPEARANCE Conforms / White Cake STORAGE -20 C, dark DISPOSITION RELEASED	 Photographic documentation withheld at the client's request. Identity and integrity confirmed by the analytical methods herein

CHROMATOGRAPHIC PURITY 98.42% Spec ≥ 95.0% ✓ PASS	IDENTITY SS-31 HPLC-RTM + LC-MS ✓ PASS	NET CONTENT 10.42 mg measured · label 10 mg REPORTED	BACTERIAL ENDOTOXIN 0.67 EU/mL · limit NMT 5 ✓ PASS	DISPOSITION RELEASED Full QC Panel complete
---	--	--	---	---

1 RELEASE STATEMENT Authorized Disposition

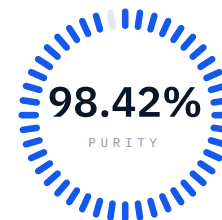
The submitted SS-31 (elamipretide) sample was evaluated under the Full Quality Control Panel covering identity, purity, net peptide content, composition, sterility, bacterial endotoxin, elemental impurities, and targeted adulterant screening. Identity was confirmed by HPLC retention-time matching with a corroborating LC-MS base peak at m/z 640.38 [M+H]⁺, and chromatographic purity of 98.42 percent comfortably exceeded the not less than 95.0 percent release criterion. Sterility returned No Growth, bacterial endotoxin measured 0.67 EU/mL against the not more than 5 EU/mL limit, and arsenic, cadmium, chromium, mercury, and lead were each within their per-element specifications, with fentanyl Not Detected at the screening cutoff. On the basis that all tested attributes meet their respective specifications, the laboratory supports a disposition of RELEASED for the material as received.

IDENTITY Confirmed ✓ PASS	PURITY 98.42% ✓ PASS	NET CONTENT 10.42 mg ✓ PASS	MOISTURE 3.1% w/w ✓ PASS	STERILITY No Growth ✓ PASS	ENDOTOXIN 0.67 EU/mL ✓ PASS	HEAVY METALS Conforms ✓ PASS
--	---	--	---	---	--	---

2 PURITY, QUANTITATION & IDENTITY HPLC / HPLC-RTM

ANALYTE	SPECIFICATION	RESULT	UNIT	STATUS
Chromatographic Purity (HPLC)	≥ 95.0%	98.42	%	✓ PASS
Net Content	Report only	10.42	mg	REPORTED
Identity (HPLC-RTM)	SS-31	Confirmed	—	✓ PASS
Adulterant / Fentanyl Screen	Immunoassay, 50 ng/mL	Not Detected	—	✓ PASS

Interpretation. The measured chromatographic purity of 98.42 percent exceeds the not less than 95.0 percent release criterion by a wide margin, indicating a homogeneous principal peak and a low related-substance burden for the tetrapeptide. Net peptide content of 10.42 mg is the measured peptide mass recovered from the unit and is reported against a nominal 10 mg label claim, confirming the vial delivers at least the labeled mass of active peptide.



Specification ≥ 95.0% PASS
HPLC area %

Figure 1. Purity composition of the released dedicated unit by HPLC area normalization. Target compound 98.42%, total related substances 1.58%.

3 REPRESENTATIVE CHROMATOGRAM

Reversed-phase HPLC-UV

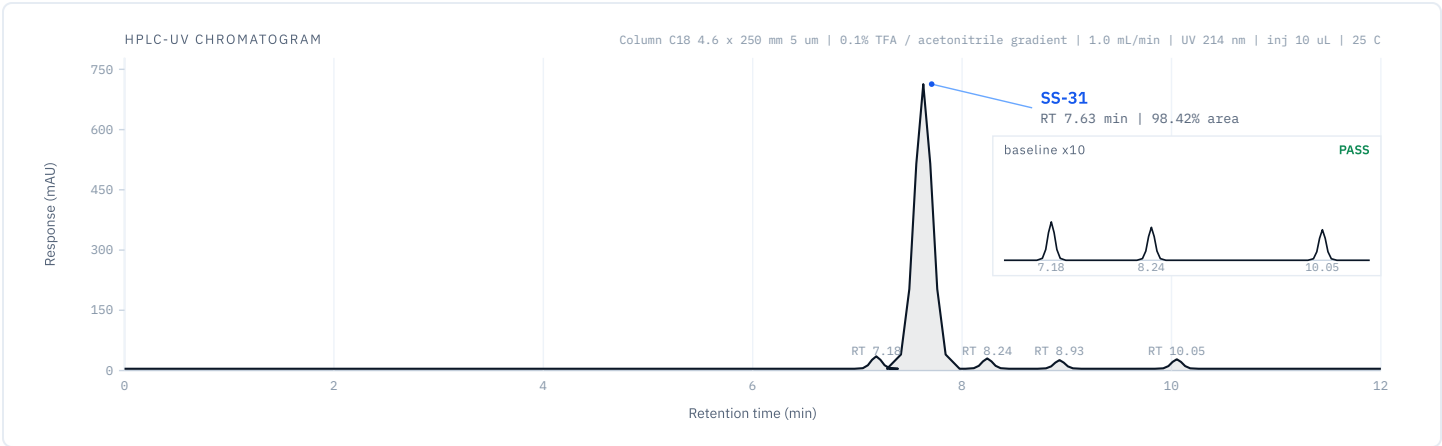


Figure 2. Representative reversed-phase HPLC-UV chromatogram (Conformity unit V1, near the batch mean). Trace related substances are shown magnified 10x in the inset. A sharp, symmetric principal peak with a low related-substance burden is consistent with high chromatographic purity.

PEAK	RT (MIN)	AREA (MAU·S)	AREA %	PLATES (N)	TAILING
SS-31 (principal)	7.63	4,921,000	98.42	8,600	1.05
Des-Arg1 impurity (RRT 0.94)	7.180	32,000	0.64	7,200	1.10
D-Phe isomer (RRT 1.08)	8.240	20,500	0.41	6,900	1.12
Acetylated adduct (RRT 1.17)	8.930	11,000	0.22	6,600	1.14
Unspecified impurity (RRT 1.32)	10.050	15,500	0.31	6,400	1.11
Total		5,000,000	100.00		

4 MASS CONFIRMATION

LC-MS, ESI positive

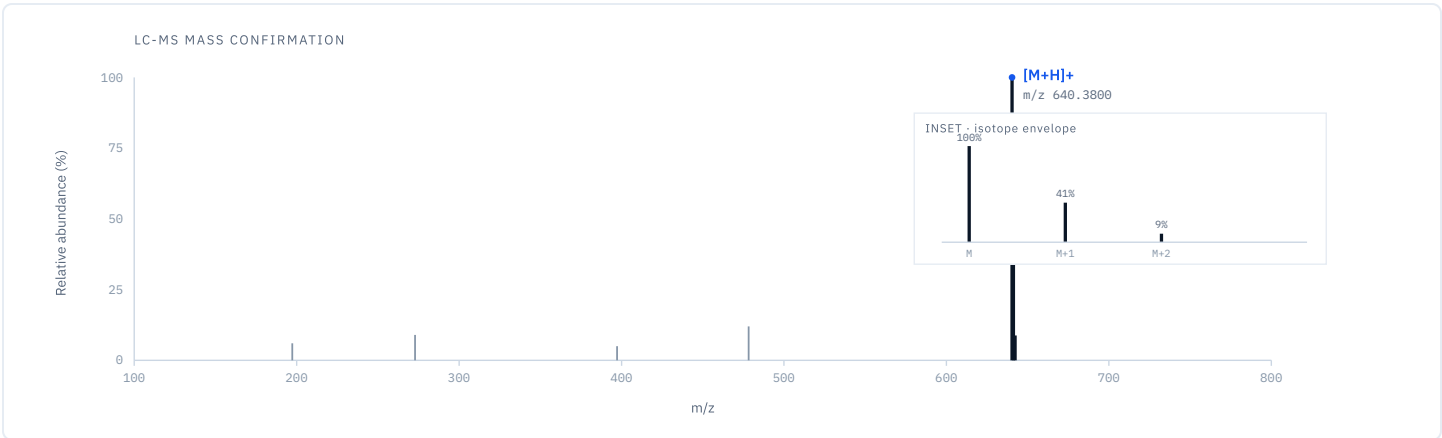


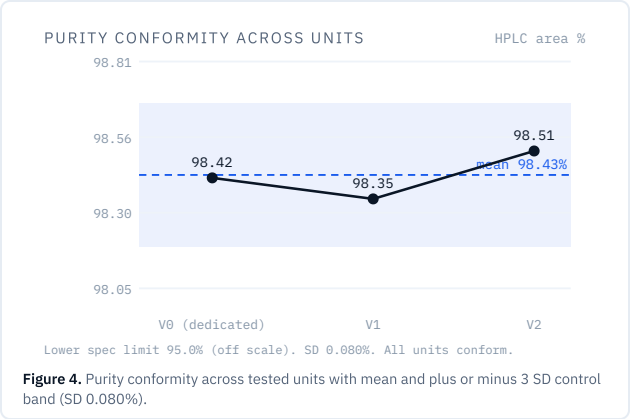
Figure 3. LC-MS mass confirmation (electrospray positive mode). Base peak [M+H]⁺ at m/z 640.3800 matches SS-31 (sequence D-Arg-Dmt-Lys-Phe-NH₂, MW 639.80 Da); the isotopic envelope [M+1] (41.2%) and [M+2] (8.8%) confirms identity.

5 CONFORMITY TESTING

3 units · HPLC

SAMPLE	PURITY	NC (MG)	IDENTITY	RESULT
V0 (dedicated)	98.42%	10.42	Confirmed	✓ PASS
V1	98.35%	10.38	Confirmed	✓ PASS
V2	98.51%	10.46	Confirmed	✓ PASS
Mean	98.43%	10.42	—	—
Std Dev	0.080%	0.04	—	—

Interpretation. Across three independently tested units the purity standard deviation was 0.08 percent and net content standard deviation 0.04 mg, a very low dispersion consistent with a homogeneous, well-controlled batch.



6 COMPOSITION, MOISTURE & COUNTERION

KF · IC · USP <467>

PARAMETER	METHOD	SPECIFICATION	RESULT	STATUS
Net Content	HPLC / AAA	Report only	10.42 mg	REPORTED
Water (Karl Fischer)	USP <921>	NMT 8.0% w/w	3.1%	✓ PASS
Counterion (acetate)	Ion chromatography	Report only	8.4% w/w	REPORTED
Residual Solvents	USP <467>	Not Detected	Not Detected	✓ PASS
Gross Fill Weight	Gravimetric	Report only	85.2 mg	REPORTED

Interpretation. Karl Fischer titration returned 3.1 percent residual water and the acetate counterion accounts for 8.4 percent by weight, both typical for a freeze-dried peptide salt. The 85.2 mg gross fill reconciles peptide, counterion, water, and lyophilization excipient fill.

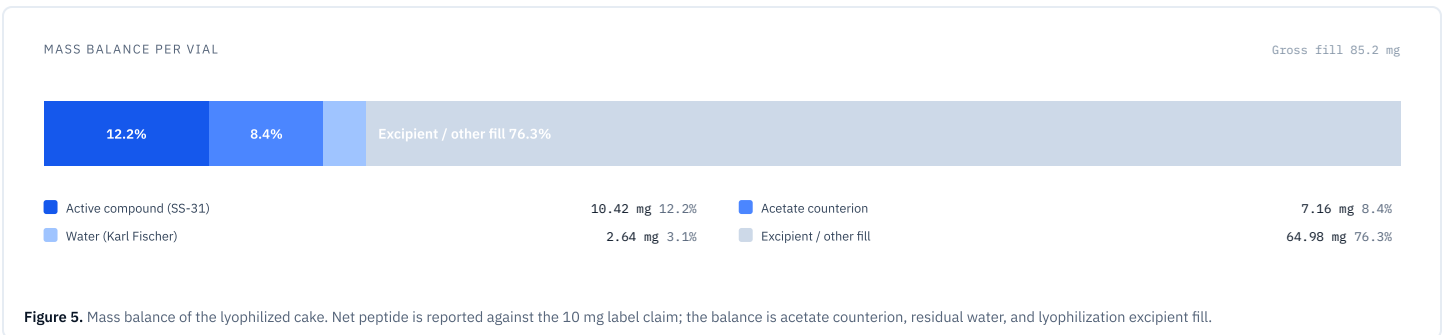


Figure 5. Mass balance of the lyophilized cake. Net peptide is reported against the 10 mg label claim; the balance is acetate counterion, residual water, and lyophilization excipient fill.

7 SAFETY & CONTAMINATION CONTROLS

ICP-MS · USP <71> · <85>

TEST	METHOD	SPECIFICATION	RESULT	STATUS
Arsenic (As)	ICP-MS	NMT 1.5 ppm	0.062 ppm	✓ PASS
Cadmium (Cd)	ICP-MS	NMT 0.5 ppm	0.142 ppm	✓ PASS
Chromium (Cr)	ICP-MS	NMT 10 ppm	0.814 ppm	✓ PASS
Mercury (Hg)	ICP-MS	NMT 1.5 ppm	0.218 ppm	✓ PASS
Lead (Pb)	ICP-MS	NMT 1 ppm	0.057 ppm	✓ PASS
Sterility	USP <71>	No Growth	No Growth	✓ PASS
Bioburden	USP <61>	Report / Low	< 10 CFU/g	✓ PASS
Bacterial Endotoxin	USP <85>	NMT 5 EU/mL	0.67 EU/mL	✓ PASS

Interpretation. By ICP-MS, arsenic, cadmium, chromium, mercury, and lead were each measured well below their specification thresholds. Sterility by membrane filtration returned No Growth with bioburden below the reporting limit, and bacterial endotoxin measured 0.67 EU/mL, within the not more than 5 EU/mL release limit.



Figure 6. Elemental impurity headroom by ICP-MS. All regulated elements measured below specification.



Figure 7. Bacterial endotoxin safety margin (USP <85>). Result 0.67 EU/mL against the NMT 5 EU/mL pass limit.

8 FOR THE RECIPIENT

Plain-language summary

- ✓ **Purity 98.42 percent.** Almost everything measured is SS-31. Only 1.58 percent is trace related peptides, comfortably past the 95 percent release bar.
- ✓ **You get at least the labeled amount.** Measured net peptide content is 10.42 mg, at or above the 10 mg on the label.
- ✓ **It is genuinely SS-31.** HPLC retention time plus an LC-MS base peak at m/z 640.38 confirm the identity, so this is not a substitute or a mislabel.
- ✓ **Sterility and endotoxin within specification.** Sterility shows No Growth and bacterial endotoxin is 0.67 EU/mL, roughly 13 percent of the limit.
- ✓ **Screened for contamination.** Arsenic, cadmium, chromium, mercury, and lead were all below limits, and the fentanyl adulterant screen was Not Detected.
- ✓ **Water and salt are normal.** The small amounts of water (3.1 percent) and acetate (8.4 percent) are expected for a freeze-dried peptide and are already accounted for in the net peptide figure.

Purity (HPLC)

Percent of the main compound peak relative to all detected peaks.

Net content

Measured mass of the actual compound, separate from water and salt.

NMT

Not more than; an upper acceptance limit.

Not Detected

Below the method limit of quantitation (LOQ).

EU/mL

Endotoxin units per milliliter, a measure of bacterial toxin.

RRT

Relative retention time; an impurity position versus the main peak.

Counterion

The salt partner of the compound.

w/w

By weight, as a percent of total mass.

USP <71> / <85>

Standard chapters for sterility and bacterial endotoxin.

Karl Fischer

Titration method for measuring residual water (USP <921>).

Storage. Store the sealed lyophilized vial at -20 C, protected from light. Reconstituted solution is stable at 2 to 8 C; use within 30 days. **Reconstitution.** Add 2 mL bacteriostatic or sterile water down the vial wall, swirl gently, do not shake. **Handling.** Research use only; not for human or veterinary use.

9 ANALYTICAL METHODS & NOTES

Method principles

HPLC Purity and Net Content

Reversed-phase HPLC with UV detection separates the principal compound from related substances; purity is percent main-peak area and content is quantified against a calibrated reference. Acceptance: not less than the stated release limit.

LC-MS Mass Confirmation

Electrospray positive-mode mass spectrometry resolves the molecular ion and isotope or charge-state signature of the analyte.

Counterion by Ion Chromatography

Ion chromatography determines the counterion content by weight, characterizing the salt form.

Heavy Metals by ICP-MS

Inductively coupled plasma mass spectrometry quantifies elemental impurities against per-element limits.

Bioburden by USP <61>

Total aerobic microbial and yeast or mold counts establish microbial load prior to release.

Identity by HPLC Retention-Time Matching

Sample retention time is compared to a qualified reference standard under identical conditions; identity is confirmed on co-elution within the established window.

Water Content by Karl Fischer

Coulometric Karl Fischer titration per USP <921> quantifies residual moisture in the lyophilized cake. Acceptance: not more than 8.0 percent w/w.

Residual Solvents

Headspace GC per USP <467> screens process solvents against a not-detected threshold.

Sterility by USP <71>

Membrane filtration sterility test; No Growth is reported when no microbial recovery is observed across the incubation period.

Bacterial Endotoxin by USP <85>

Kinetic bacterial endotoxin test; acceptance is not more than 5 EU/mL per client specification.

DocuSigned by:



10010000 00011010 00011001 11101000

Finn C.

Laboratory Director

Date of authorization: 09/11/2026



DocuSigned by:



01100111 10110001 10110001 00100000

Brennan C.

Quality Assurance

Reviewed against acceptance criteria: 09/11/2026



Authenticate this certificate

Scan the code or verify online at titreonanalytical.com/verify

Verification ID: TLA-9503-SS31-C0AD



Scope and disclaimer. These results relate only to the item tested as received and do not extend to any other unit, lot, or batch; this certificate shall not be reproduced except in full without the prior written approval of the laboratory. The graphical exhibits shown, including the chromatogram, mass spectrum, composition, conformity, headroom, mass-balance, and margin panels, are rendered representations generated from the reported analytical results for illustrative clarity, with primary instrument data files retained on record. Information herein is confidential to the named client, and liability is limited to the value of the analytical service performed. Research use only; not for human or veterinary use. Titreon is an independent analytical laboratory and does not manufacture, sell, or endorse any product it tests.

Not for use in diagnosing, treating, or curing any disease. Research purposes only.