

Certificate of Analysis

FULL QUALITY CONTROL PANEL · PEPTIDE ANALYTICAL REPORT

CERTIFICATE NO.

COA-2026-6071

Issued 06/13/2026 · Page 1 of 4

CLIENT PREPARED FOR PeptaraLabs PeptaraLabs.io Client reference: on file Distribution: client confidential		SAMPLE & ACCESSION ACC - 2026 - 3387			SAMPLE PHOTOGRAPH AS RECEIVED	
		ANALYTE / IDENTITY Semax	CAS NUMBER 80714-61-0	LOT NUMBER SMX-260407-A		
		LABELED CONTENT 10 mg	SAMPLE MATRIX Lyophilized	APPEARANCE Conforms		
		MANUFACTURED 04/07/2026	RETEST / EXPIRY 04/2028	STORAGE -20 C, dark		
		DATE RECEIVED 06/11/2026	DATE ANALYZED 06/13/2026	DISPOSITION RELEASED		



Semax · 10 mg · Lyophilized

PEPTIDE PURITY ✓ PASS 99.05% Spec ≥ 95.0%	IDENTITY ✓ PASS Semax HPLC-RTM + LC-MS	NET PEPTIDE CONTENT REPORTED 10.16 mg measured · label 10 mg	BACTERIAL ENDOTOXIN ✓ PASS ≤0.05 EU/mL · limit NMT 5	DISPOSITION RELEASED Full QC Panel complete
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1 RELEASE STATEMENT Authorized Disposition

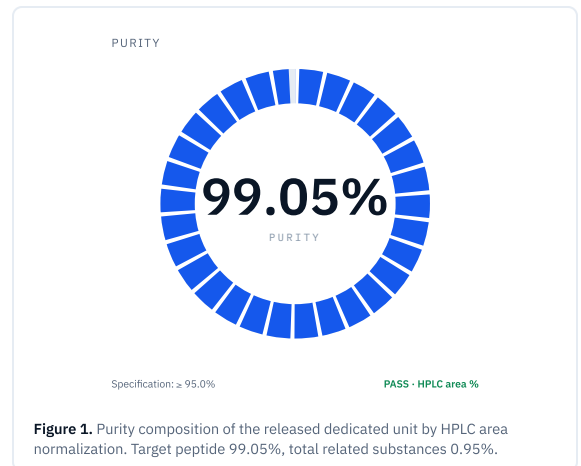
The submitted Semax sample was evaluated under the Full Quality Control Panel covering identity, purity, net peptide content, composition, sterility, bacterial endotoxin, elemental impurities, and targeted adulterant screening. Identity was confirmed by HPLC retention-time matching with an LC-MS [M+H]⁺ ion at m/z 814.94 (neutral mass 813.9 Da). Chromatographic purity of 99.05 percent comfortably exceeded the not less than 95.0 percent release criterion. Sterility returned No Growth, bacterial endotoxin was well within the applicable limit, and arsenic, cadmium, chromium, mercury, and lead were each Not Detected, 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 99.05% ✓ PASS	NET CONTENT 10.16 mg ✓ PASS	MOISTURE 5.05% w/w ✓ PASS	STERILITY No Growth ✓ PASS	ENDOTOXIN ≤0.05 EU/mL ✓ PASS	HEAVY METALS Not Detected ✓ PASS
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2 PURITY, QUANTITATION & IDENTITY HPLC / HPLC-RTM

ANALYTE	SPECIFICATION	RESULT	UNIT	STATUS
Peptide Purity (HPLC)	≥ 95.0%	99.05	%	✓ PASS
Net Peptide Content	Report only	10.16	mg	REPORTED
Identity (HPLC-RTM)	Semax	Confirmed	—	✓ PASS
Fentanyl Screen	Immunoassay, 50 ng/mL	Not Detected	—	✓ PASS

Interpretation. The measured chromatographic purity of 99.05 percent exceeds the not less than 95.0 percent release criterion, indicating a homogeneous principal peak with a low related-substance burden. Net peptide content of 10.16 mg is the measured 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.



3 REPRESENTATIVE CHROMATOGRAM

Reversed-phase HPLC-UV

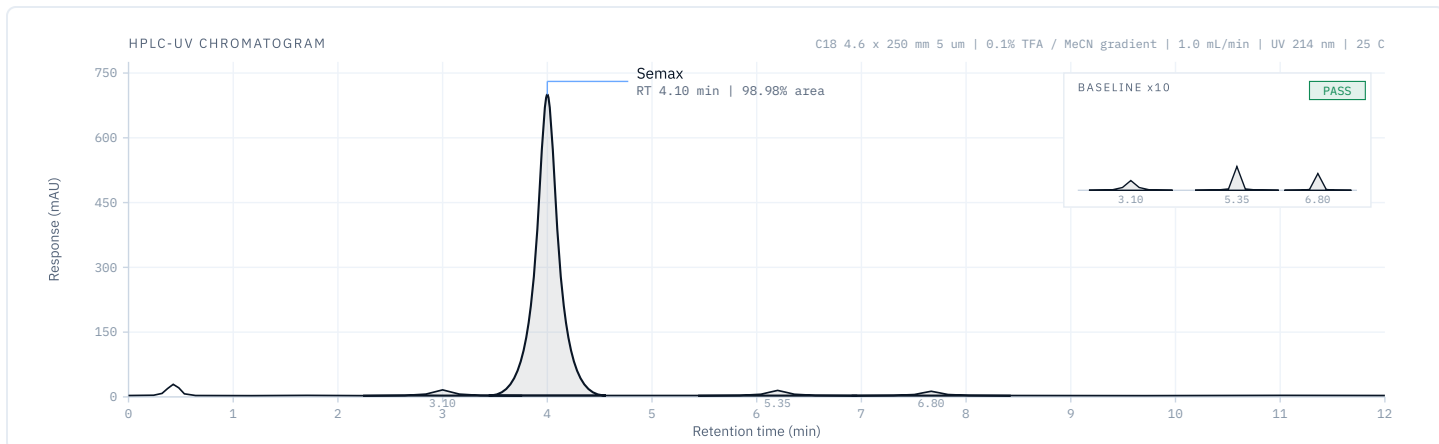


Figure 2. Representative reversed-phase HPLC-UV chromatogram (Conformity unit V1, 98.98% main-peak area, near the batch mean of 99.02%). Trace related substances are shown magnified 10x in the inset. A sharp, symmetric principal peak with a low related-substance burden is consistent with high chromatographic purity.

PEAK	RT (MIN)	AREA (MAU·S)	AREA %	PLATES (N)	TAILING
Semax (principal)	4.10	4,949,000	98.98	11,020	1.04
Related substance 1 (RRT 0.76)	3.10	22,500	0.45	7,140	1.10
Related substance 2 (RRT 1.30)	5.35	16,500	0.33	6,760	1.08
Related substance 3 (RRT 1.66)	6.80	12,000	0.24	6,390	1.12
Total		5,000,000	100.00		

4 MASS CONFIRMATION

LC-MS, ESI positive

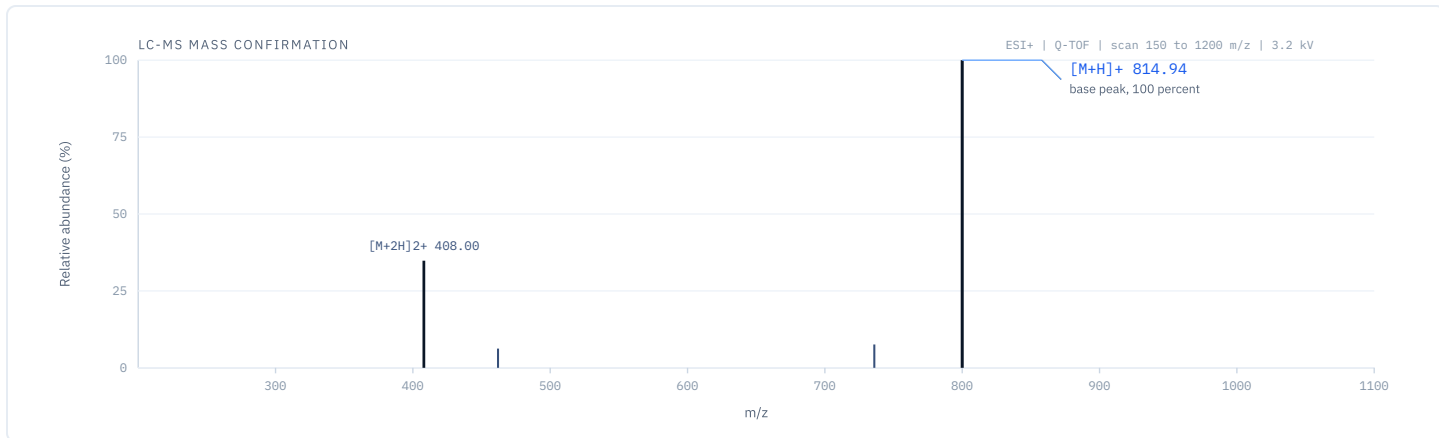


Figure 3. LC-MS mass confirmation (electrospray positive mode). Base peak [M+H]⁺ at m/z 814.94 with [M+2H]²⁺ at 408.00, consistent with the 813.9 Da mass of Semax and confirming identity.

5 CONFORMITY TESTING

3 units · HPLC

SAMPLE	PURITY	NPC (MG)	IDENTITY	RESULT
V0 (dedicated)	99.05%	10.16	Confirmed	✓ PASS
V1	98.98%	10.10	Confirmed	✓ PASS
V2	99.02%	10.23	Confirmed	✓ PASS
Mean	99.02%	10.16	—	—
Std Dev	0.035%	0.0651	—	—

Interpretation. Across three independently tested units the purity standard deviation was 0.035 percent and content standard deviation 0.0651 mg, a low dispersion consistent with a homogeneous, well-controlled batch.



Figure 4. Purity conformity across tested units with mean and plus or minus 3 SD control band (SD 0.035%).

6 COMPOSITION, MOISTURE & COUNTERION

KF · IC · USP <467>

PARAMETER	METHOD	SPECIFICATION	RESULT	STATUS
Net Peptide Content	HPLC / AAA	Report only	10.16 mg	REPORTED
Water (Karl Fischer)	USP <921>	NMT 8.0% w/w	5.05%	✓ PASS
Counterion (acetate)	Ion chromatography	Report only	8.30% w/w	REPORTED
Residual Solvents (TFA)	USP <467>	Not Detected	Not Detected	✓ PASS
Gross Fill Weight	Gravimetric	Report only	11.81 mg	REPORTED

Interpretation. Karl Fischer titration returned 5.05 percent residual water and the acetate counterion accounts for 8.30 percent by weight, both typical for a freeze-dried peptide salt. The 11.81 mg gross fill reconciles peptide, counterion, water, and trace related substances.

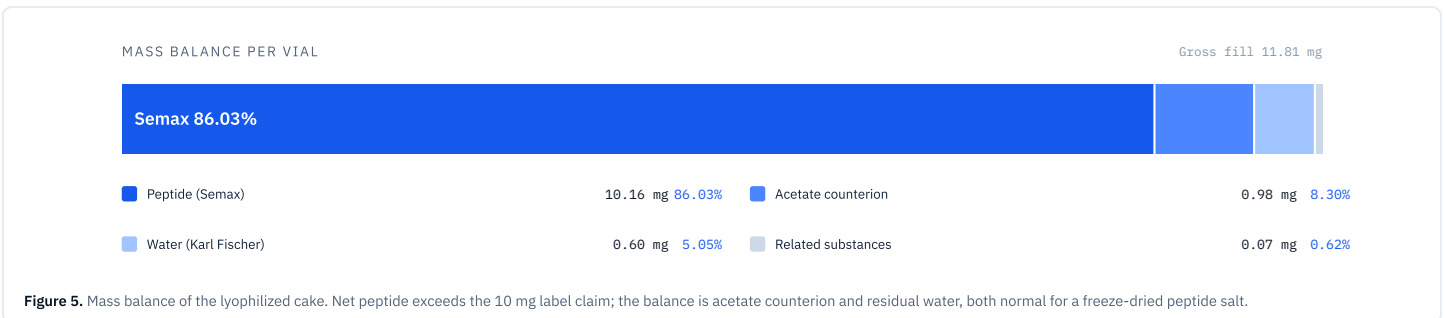


Figure 5. Mass balance of the lyophilized cake. Net peptide exceeds the 10 mg label claim; the balance is acetate counterion and residual water, both normal for a freeze-dried peptide salt.

7 SAFETY & CONTAMINATION CONTROLS

ICP-MS · USP <71> · <85>

TEST	METHOD	SPECIFICATION	RESULT	STATUS
Arsenic (As)	ICP-MS	NMT 1.5 ppm	Not Detected	✓ PASS
Cadmium (Cd)	ICP-MS	NMT 0.5 ppm	Not Detected	✓ PASS
Chromium (Cr)	ICP-MS	NMT 10 ppm	Not Detected	✓ PASS
Mercury (Hg)	ICP-MS	NMT 1.5 ppm	Not Detected	✓ PASS
Lead (Pb)	ICP-MS	NMT 1 ppm	Not Detected	✓ PASS
Sterility	USP <71>	No Growth	No Growth	✓ PASS
Bioburden	USP <61>	< 10 CFU/mL	< 1 CFU/mL	✓ PASS
Bacterial Endotoxin	USP <85>	NMT 5 EU/mL	NMT 0.05 EU/mL	✓ PASS

Interpretation. By ICP-MS, arsenic, cadmium, chromium, mercury, and lead were each Not Detected below their specification thresholds. Sterility by membrane filtration returned No Growth with bioburden below the reporting limit, and bacterial endotoxin was at or below 0.05 EU/mL, approximately one percent of the 5 EU/mL limit, indicating a substantial margin of compliance.

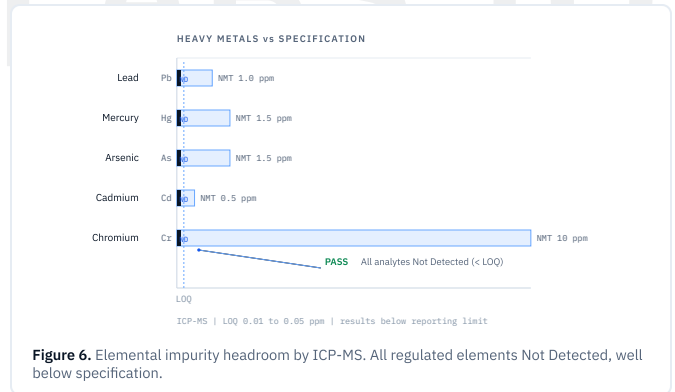


Figure 6. Elemental impurity headroom by ICP-MS. All regulated elements Not Detected, well below specification.



Figure 7. Bacterial endotoxin safety margin (USP <85>). Result at or below 0.05 EU/mL against a 5 EU/mL limit.

8 FOR THE RECIPIENT

Plain-language summary

- ✓ **Purity 99.05 percent.** Almost everything in the vial is Semax. Only 0.95 percent is trace related substances, comfortably past the 95 percent release bar.
- ✓ **You get at least the labeled amount.** Measured net peptide content is 10.16 mg, at or above the 10 mg on the label, so the vial delivers a full labeled dose of active peptide.
- ✓ **It is genuinely Semax.** HPLC retention time plus an LC-MS [M+H]⁺ ion at m/z 814.94 (neutral mass 813.9 Da) confirm the identity, so this is not a substitute or a mislabel.
- ✓ **Injectable-grade safety checks pass.** Sterility shows No Growth and bacterial endotoxin is at or below 0.05 EU/mL, roughly one percent of the limit.
- ✓ **Screened for contamination.** Arsenic, cadmium, chromium, mercury, and lead were Not Detected, and the fentanyl adulterant screen was Not Detected.
- ✓ **Water and salt are normal.** The small amounts of water (5.05 percent) and acetate (8.30 percent) are expected for a freeze-dried peptide and are already accounted for in the net peptide figure.

Purity (HPLC)

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

Net peptide content

Measured mass of actual peptide, 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 peptide.

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 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 Peptide Content

Reversed-phase HPLC with UV detection separates the principal peptide 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 peptide salt form.

Heavy Metals by ICP-MS

Inductively coupled plasma mass spectrometry quantifies elemental impurities against per-element limits, with results below detection reported as Not Detected.

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; trifluoroacetic acid is assessed 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:



01010100 00011000 01000000 10100010

DS



DocuSigned by:



01000101 11001001 00110000 00000010

DS



Finn C.

Laboratory Director

Date of authorization: 06/12/2026

Brennan C.

Quality Assurance

Reviewed against acceptance criteria: 06/13/2026

Authenticate this certificate

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

 Verification ID: **TLA-6071-SEMAX-9E33**


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