TITREON
ANALYTICAL
Peptide Identity, Purity and Safety Analytics

Titreon Analytical
Analytical Chemistry | Mass Spectrometry | Microbiology
Quality system aligned to ISO/IEC 17025:2017
reports@titreonanalytical.com · titreonanalytical.com

Certificate of Analysis

FULL QUALITY CONTROL PANEL · PEPTIDE ANALYTICAL REPORT

CERTIFICATE NO.
COA-2026-2087
Issued 06/13/2026 · Page 1 of 4

CLIENT — PREPARED FOR

PeptaraLabs

PeptaraLabs.io

Client reference: on file
Distribution: client confidential

SAMPLE & ACCESSION — ACC-2026-6650

ANALYTE / IDENTITY	CAS NUMBER	LOT NUMBER
TB-500	77591-33-4	TB5-260415-A
LABELED CONTENT	**SAMPLE MATRIX**	**APPEARANCE**
10 mg	Lyophilized	Conforms
MANUFACTURED	**RETEST / EXPIRY**	**STORAGE**
04/15/2026	04/2028	-20 C, dark
DATE RECEIVED	**DATE ANALYZED**	**DISPOSITION**
06/11/2026	06/13/2026	RELEASED

SAMPLE PHOTOGRAPH — AS RECEIVED



TB-500 · 10 mg · Lyophilized

PEPTARA LABS

PEPTIDE PURITY	IDENTITY	NET PEPTIDE CONTENT	BACTERIAL ENDOTOXIN	DISPOSITION
98.86% ✓ PASS	TB-500 ✓ PASS	10.22 REPORTED	≤0.05 ✓ PASS	RELEASED
Spec ≥ 95.0%	HPLC-RTM + LC-MS	mg measured · label 10 mg	EU/mL · limit NMT 5 EU/mL	Full QC Panel complete

1 RELEASE STATEMENT

Authorized Disposition

The submitted TB-500 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 deconvoluted neutral mass of 4963.4 Da. Chromatographic purity of 98.86 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	PURITY	NET CONTENT	MOISTURE	STERILITY	ENDOTOXIN	HEAVY METALS
Confirmed	98.86%	10.22 mg	4.95% w/w	No Growth	≤0.05 EU/mL	Not Detected
✓ PASS	✓ PASS	✓ PASS	✓ PASS	✓ PASS	✓ PASS	✓ PASS

2 PURITY, QUANTITATION & IDENTITY

HPLC / HPLC-RTM

ANALYTE	SPECIFICATION	RESULT	UNIT	STATUS
Peptide Purity (HPLC)	≥ 95.0%	**98.86**	%	✓ PASS
Net Peptide Content	Report only	**10.22**	mg	REPORTED
Identity (HPLC-RTM)	TB-500	**Confirmed**	—	✓ PASS
Fentanyl Screen	Immunoassay, 50 ng/mL	**Not Detected**	—	✓ PASS

Interpretation. The measured chromatographic purity of 98.86 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 10.22 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.

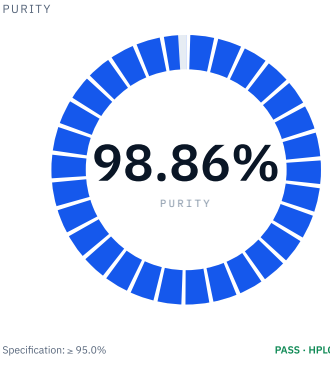


Figure 1. Purity composition of the released dedicated unit by HPLC area normalization. Target peptide 98.86%, total related substances 1.14%.

3 REPRESENTATIVE CHROMATOGRAM

Reversed-phase HPLC-UV

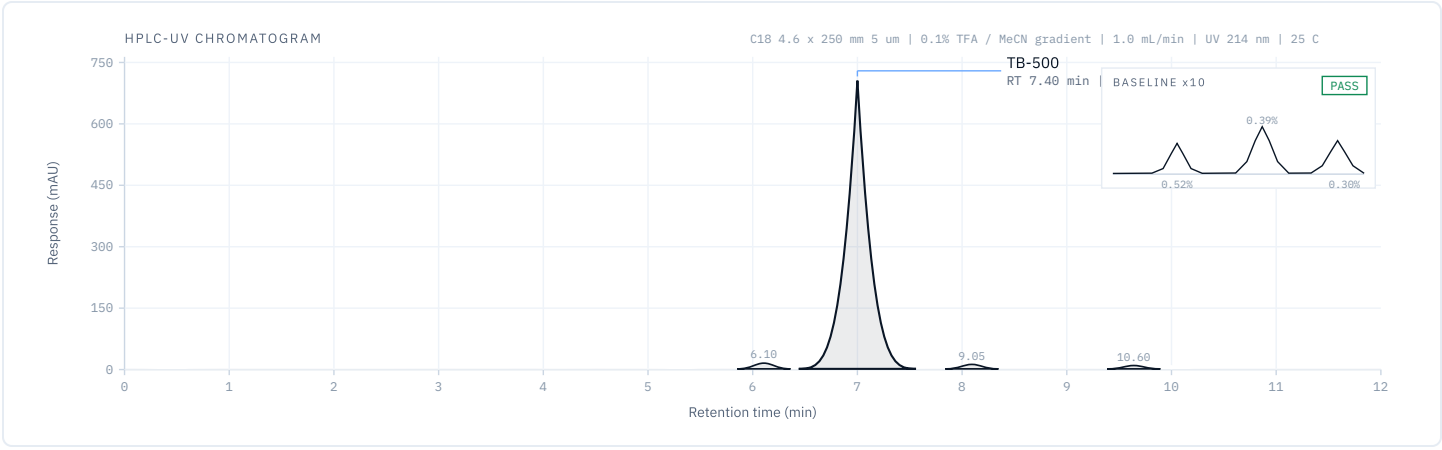


Figure 2. Representative reversed-phase HPLC-UV chromatogram (Conformity unit V1, 98.79% main-peak area, near the batch mean of 98.83%). Trace related substances are shown magnified 10x in the inset. A sharp, symmetric principal peak with a low related-substance burden is consistent with high chromatographic purity.

PEAK	RT (MIN)	AREA (MAU·S)	AREA %	PLATES (N)	TAILING
TB-500 (principal)	7.40	4,939,500	**98.79**	8,050	1.07
Related substance 1 (RRT 0.82)	6.10	26,000	0.52	6,720	1.12
Related substance 2 (RRT 1.22)	9.05	19,500	0.39	6,380	1.10
Related substance 3 (RRT 1.43)	10.60	15,000	0.30	6,010	1.14
Total		**5,000,000**	**100.00**		

4 MASS CONFIRMATION

LC-MS, ESI positive



Figure 3. LC-MS mass confirmation (electrospray positive mode). The multiply-charged ion envelope from [M+3H]3+ to [M+6H]6+ deconvolutes to a neutral mass of 4963.4 Da, matching the theoretical mass of thymosin beta-4 (TB-500) and confirming identity.

5 CONFORMITY TESTING

3 units · HPLC

SAMPLE	PURITY	NPC (MG)	IDENTITY	RESULT
V0 (dedicated)	98.86%	10.22	Confirmed	✓ PASS
V1	98.79%	10.16	Confirmed	✓ PASS
V2	98.83%	10.29	Confirmed	✓ PASS
Mean	**98.83%**	**10.22**	–	–
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	**10.22 mg**	REPORTED
Water (Karl Fischer)	USP <921>	NMT 8.0% w/w	**4.95%**	✓ PASS
Counterion (acetate)	Ion chromatography	Report only	**8.20% w/w**	REPORTED
Residual Solvents (TFA)	USP <467>	Not Detected	**Not Detected**	✓ PASS
Gross Fill Weight	Gravimetric	Report only	**11.88 mg**	REPORTED

Interpretation. Karl Fischer titration returned 4.95 percent residual water and the acetate counterion accounts for 8.20 percent by weight, both typical for a freeze-dried peptide salt. The 11.88 mg gross fill reconciles peptide, counterion, water, and trace related substances.

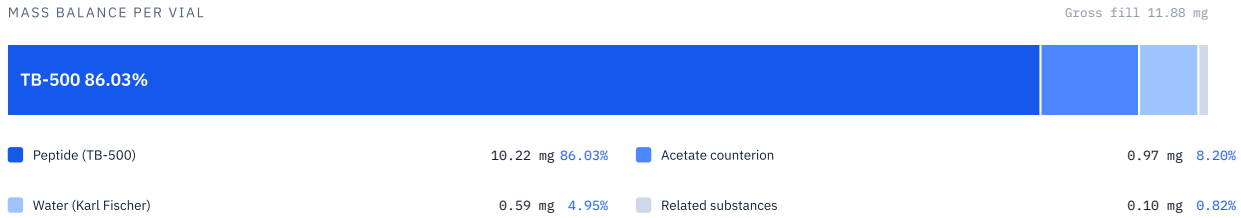


Figure 5. Mass balance of the lyophilized cake. Net peptide exceeds the 10 mg label claim; the balance is acetate counterion and residual water, both normal for a freeze-dried peptide salt.

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	**≤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.

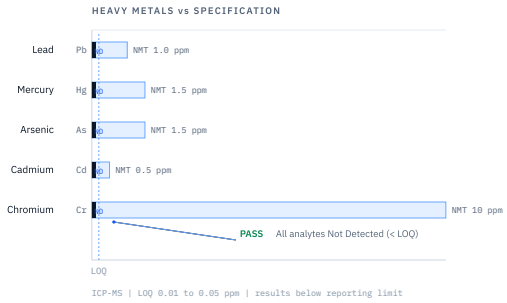


Figure 6. Elemental impurity headroom by ICP-MS. All regulated elements Not Detected, well below specification.



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

8 FOR THE RECIPIENT

Plain-language summary

- ✓ **Purity 98.86 percent.** Almost everything in the vial is TB-500. Only 1.14 percent is trace related substances, comfortably past the 95 percent release bar.
- ✓ **You get at least the labeled amount.** Measured net peptide content is 10.22 mg, at or above the 10 mg on the label, so the vial delivers a full labeled dose of active peptide.
- ✓ **It is genuinely TB-500.** HPLC retention time plus an LC-MS deconvoluted neutral mass of 4963.4 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 (4.95 percent) and acetate (8.20 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>).

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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:
10101000 00111011 10111011 01101111
DS FC

Finn C.
Laboratory Director
Date of authorization: 06/12/2026

DocuSigned by:
11110101 10101110 10110011 01001001
DS BC

Brennan C.
Quality Assurance
Reviewed against acceptance criteria: 06/13/2026

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