LAB CENTRO
ANALYTICAL TESTING LABORATORY

CERTIFICATE OF ANALYSIS

Tirzepatide 20mg Injection Pen

Lab Centro · Analytical Chemistry | Mass Spectrometry | Microbiology
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PREPARED FOR	CLIENT WEBSITE	DISTRIBUTION
H&J Pharma	vietnam-peptides.com	Client confidential

1 SAMPLE & ACCESSION

ANALYTE / IDENTITY	CAS NUMBER	MOLECULAR FORMULA	MOLECULAR MASS (DA)
Tirzepatide 20mg Injection Pen	2023788-19-2	C225H348N48O68	4813.53
SUBSTANCE CLASS	**REFERENCE-DATA CONFIDENCE**	**LOT NUMBER**	**LABELED CONTENT**
Lipidated peptide, 39-mer	High	TIRZPEN-2026-0808-7361	20 mg / 2 mL
ACCESSION NO.	**SAMPLE MATRIX**	**APPEARANCE**	**STORAGE**
ACC-2026-0825-TIRZPEN-4072	Pre-filled Injection Pen	Conforms	-20 °C, protected from light
MANUFACTURED	**RETEST / EXPIRY**	**DATE RECEIVED**	**DATE ANALYZED**
08/08/2026	08/08/2028	08/18/2026	08/19/2026
FILL VOLUME	**DISPOSITION**		
1.99 mL	RELEASED		



PURITY	IDENTITY	NET PEPTIDE	MOISTURE
99.43% PASS	Confirmed PASS	20.11 mg REPORTED	N/A REPORTED

STERILITY	ENDOTOXIN	HEAVY METALS
No Growth PASS	0.065 PASS	ND PASS

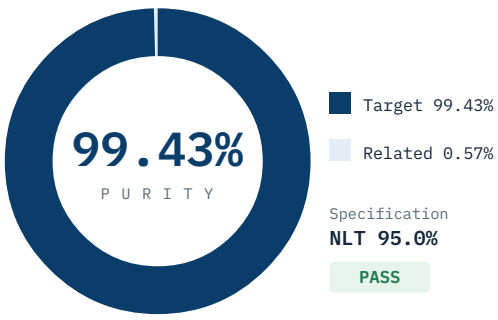
2 PURITY, QUANTITATION & IDENTITY

HPLC · HPLC-RTM · LC-MS

PARAMETER	METHOD	SPECIFICATION	RESULT	UNIT	STATUS
Peptide purity (HPLC)	RP-HPLC-UV 214 nm	NLT 95.0%	99.43	%	PASS
Net peptide content	HPLC / AAA	Report only	20.11	mg	REPORTED
Identity (HPLC-RTM)	Retention-time match	Co-elution	Confirmed	—	PASS
Fentanyl screen	Immunoassay 50 ng/mL	Not Detected	Not Detected	—	PASS

Chromatographic purity of 99.43% is measured against a not-less-than 95.0% release criterion. Net peptide content of 20.11 mg is reported against a nominal 20 mg / 2 mL label claim.

FIGURE 1 · PURITY



HPLC area normalization. Target 99.43%, related substances 0.57%.

3 REPRESENTATIVE CHROMATOGRAM

RP-HPLC-UV

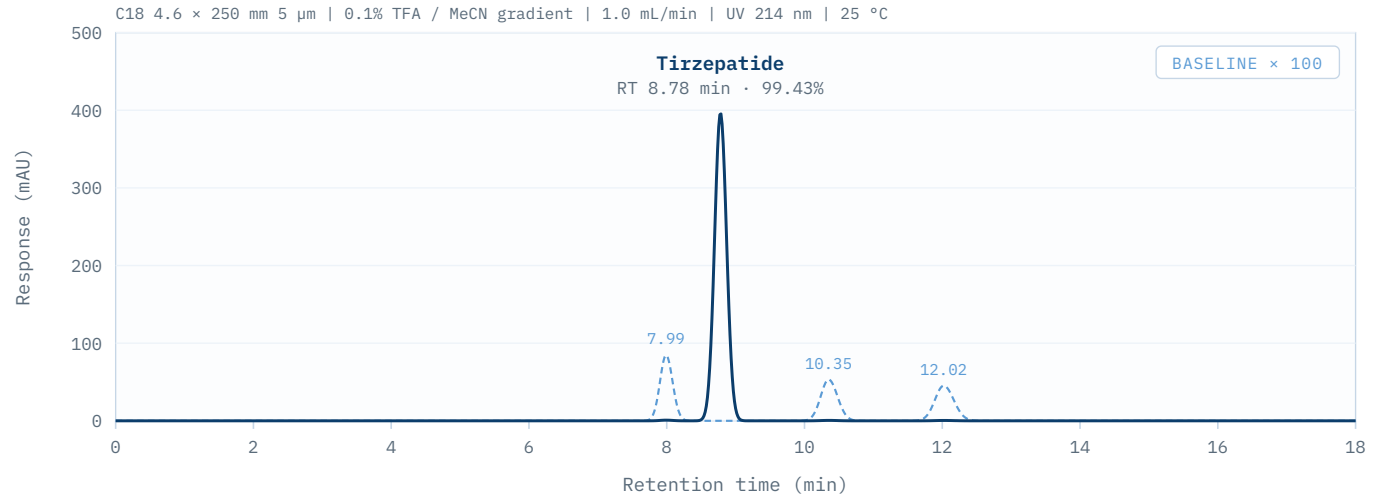


Figure 2. Chromatogram exported from the HPLC data system. — retention time, area, plate count and tailing factor define each peak envelope ($\sigma = t_R/\sqrt{N}$). Related substances shown magnified as the dashed trace, at the factor marked on the plot.

PEAK	RT (MIN)	AREA (µAU·S)	AREA %	PLATES (N)	TAILING
Tirzepatide (principal)	8.78	4,971,500	99.43	11,103	1.04
Related substance 1 (RRT 0.88)	7.99	11,000	0.22	8,552	1.08
Related substance 2 (RRT 1.17)	10.35	9,000	0.18	8,459	1.12
Related substance 3 (RRT 1.37)	12.02	8,500	0.17	9,267	1.15
Total	–	**5,000,000**	**100.00**	–	–

4 MASS CONFIRMATION

LC-MS, ESI positive

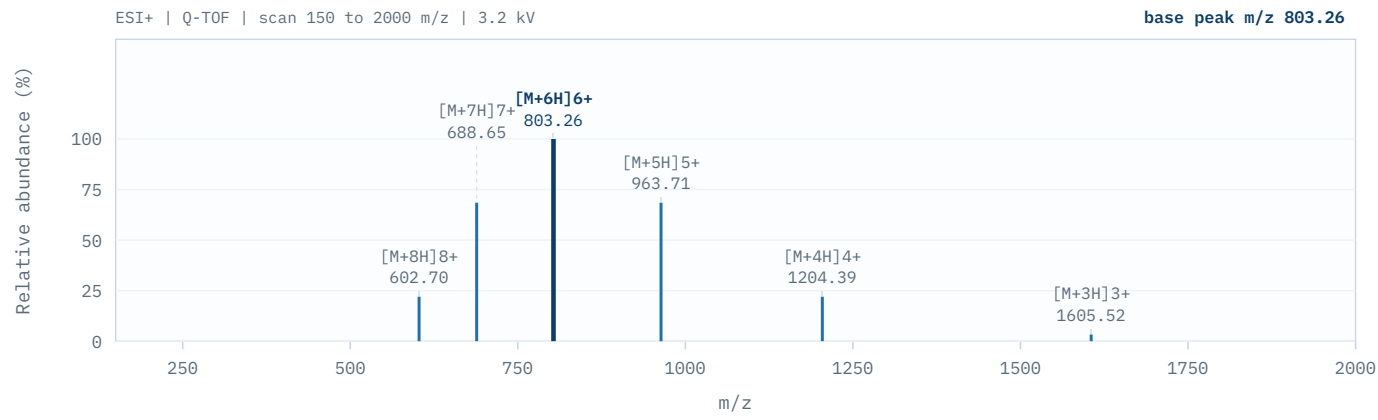


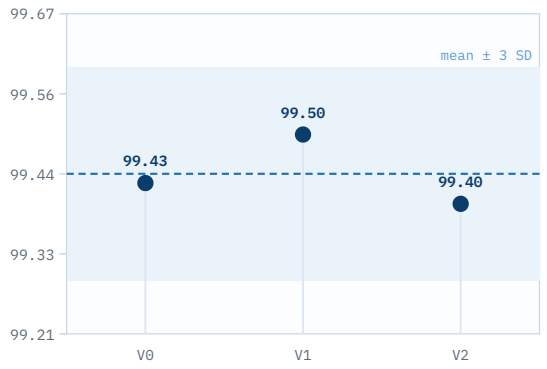
Figure 3. Acquired ESI(+) mass spectrum of the analyzed sample.

5 BATCH CONFORMITY

three independently sampled units

UNIT	PURITY (%)	NET CONTENT (MG)	IDENTITY	STATUS
V0 (dedicated)	99.43	20.11	Confirmed	PASS
V1	99.50	20.07	Confirmed	PASS
V2	99.40	20.06	Confirmed	PASS

FIGURE 4 · CONFORMITY



Mean 99.44% · SD 0.051%
Lower spec limit 95.0% (off scale)

6 COMPOSITION & FILL CHARACTERIZATION

content · volume · concentration

PARAMETER	METHOD	SPECIFICATION	RESULT	UNIT	STATUS
Net peptide content	HPLC / AAA	Report only	20.11	mg	REPORTED
Fill volume	Gravimetric / volumetric	Report only	1.99	mL	REPORTED
Calculated concentration	Content / fill volume	Report only	10.106	mg/mL	REPORTED
Formulation matrix / vehicle	Gravimetric balance	Report only	1978.36	mg	REPORTED
Counterion (acetate)	Ion chromatography	Report only	6.52	% w/w	REPORTED
Residual solvents (TFA)	USP <467> headspace GC	Not Detected	ND	—	PASS

7 CONTENT & FILL CONSISTENCY

pre-filled liquid presentation

PARAMETER	RESULT	UNIT
Labeled content	20 mg / 2 mL	—
Measured net peptide content	20.11	mg
Fill volume	1.99	mL
Calculated concentration	10.106	mg/mL
HPLC purity	99.43	%

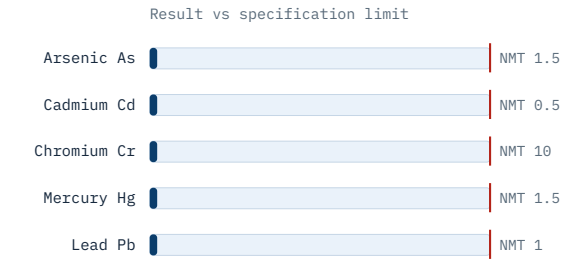
Figure 5. Pre-filled pen content and fill-volume consistency. No reconstitution step or lyophilized-cake mass balance is applicable to this presentation.

8 SAFETY & CONTAMINATION CONTROLS

ICP-MS · USP <71> <61> <85>

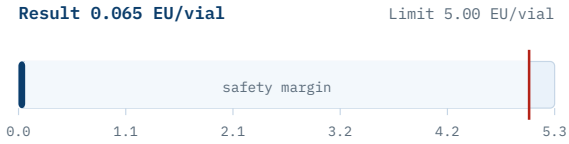
PARAMETER	SPECIFICATION	RESULT	STATUS
Arsenic (As)	NMT 1.5 ppm	Not Detected	PASS
Cadmium (Cd)	NMT 0.5 ppm	Not Detected	PASS
Chromium (Cr)	NMT 10 ppm	Not Detected	PASS
Mercury (Hg)	NMT 1.5 ppm	Not Detected	PASS
Lead (Pb)	NMT 1 ppm	Not Detected	PASS
Sterility	No Growth (USP <71>)	No Growth	PASS
Bioburden	< 10 CFU/mL (USP <61>)	< 1	PASS
Bacterial endotoxin	NMT 5.00 EU/vial	0.065	PASS

FIGURE 6 · ELEMENTAL HEADROOM



ND = below LOQ (0.01 – 0.05 ppm)
red rule = specification limit

FIGURE 7 · ENDOTOXIN MARGIN



Result is 1% of the limit · ~76.9× margin

9 FOR THE RECIPIENT

plain-language summary

Purity (HPLC)	Percent of the main peak relative to all detected peaks.	**Net peptide content**	Measured mass of active, separate from water and salt.
NMT / NLT	Not more than / not less than — an acceptance limit.	**Not Detected**	Below the method limit of quantitation (LOQ).
EU/vial	Endotoxin units per vial; acceptance limit is 5.00 EU/vial.	**RRT**	Relative retention time; an impurity position versus the main peak.
Counterion	The salt partner of the peptide.	**Karl Fischer**	Titration for residual water (USP <921>).

Storage. Store the sealed pre-filled injection pen according to the product storage specification. Do not reconstitute. **Handling.** Research use only; not for human or veterinary use.

11 AUTHORIZATION

Laboratory Director
Name: Alejandro Navarro
Date: 08/22/2026

Quality Assurance
Name: Oliver Bennett
Date: 08/23/2026

AUTHENTICATE THIS CERTIFICATE

Scan the code or verify at https://labcentro.com/coa-verification/?cert=COA-2026-0825-TIRZPEN-4072&code=QRZHXHRV
Verification ID: QRZHXHRV

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