



ELLSWORTH LABS

Certificate of Analysis

PHOENIX, ARIZONA, UNITED STATES

REPORT **EL785-26-CBQ9NN** REVISION **1** ISSUED **2026-08-10**

Client and sample

CLIENT	SAMPLE ID		DECLARED IDENTITY
peptidosliofilizados.mx	ELVW7KF2N7VQ		Tirzepatide
DECLARED LOT / BATCH	DECLARED STRENGTH	DECLARED FORM	RECEIVED
PL-TZ100-260804-E	100.0 mg per vial	Lyophilized powder	2026-08-04
QUANTITY RECEIVED	CONDITION ON RECEIPT		
3 vials	Intact, sealed		

Analytical results

TEST	RESULT	SPECIFICATION	STATUS	METHOD
Appearance	White lyophilized cake, intact and free of visible foreign matter	Conforms to specification	PASS	EL-PH-804 rev 5 Appearance and visual description
Accurate-mass agreement — Tirzepatide	+2.0 ppm 4810.5345 Da observed · 4810.5249 Da theoretical	Within ± 5 ppm of theoretical	PASS	EL-ID-102 rev 3 Peptide accurate-mass characterization and agreement assessment
Chromatographic purity	99.66 % area	NLT 98.0 % area	PASS	EL-PU-201 rev 5 Chromatographic purity and related substances
Total related substances	0.34 % area	NMT 2.0 % area	PASS	EL-PU-201 rev 5 Chromatographic purity and related substances
Net peptide content	100.22 mg/vial	95 – 105 mg/vial	PASS	EL-CT-301 rev 2 Specific peptide assay against reference standard

TEST	RESULT	SPECIFICATION	STATUS	METHOD
Water content	2.9 % w/w	NMT 5.0 % w/w	PASS	EL-CO-404 rev 5 Water determination by coulometric titration
Counterion content	10.2 % w/w	NMT 20.0 % w/w	PASS	EL-CO-403 rev 3 Counterion determination
Residual solvents	174 ppm	NMT 5000 ppm	PASS	EL-GC-504 rev 2 Residual solvent determination by headspace GC-MS
Elemental impurities	2.0 µg/g	NMT 5.0 µg/g	PASS	EL-EI-603 rev 1 Elemental impurities by tandem mass spectrometry
Bacterial endotoxins	< 0.05 EU/mg	NMT 1.0 EU/mg	PASS	EL-MB-701 rev 3 Bacterial endotoxins: kinetic chromogenic assay
Sterility	No growth in either medium at 14 days	No growth in either medium at 14 days	PASS	EL-MB-708 rev 3 Sterility test by membrane filtration

Conclusion

PASS The submitted sample met the specifications tested.

Review, release and verification

ANALYST

D. Howard

QUALITY RELEASE

J. Brown



VERIFY AT
ellsworthlabs.com/v
VERIFICATION KEY
R08Y-6BBC-SV8J

RECORD DIGEST · SHA-256

9227 8A46 F90B F6CE 49AB 17C7 5847 7C4F
1046 7B84 43AC 787E 2DFB 3DD8 FFF3 680A

Digest of this certificate's canonical record. The verification page recomputes it from the stored record and displays it for comparison; if a single character of the content above were altered, this value would not match.

Determinations were performed under Ellsworth Labs internal procedures following the United States Pharmacopeia chapters cited against each result, under cGMP-aligned documentation practice.