GENESIS BIOLABS

255 S Orange Avenue, Suite 104, Orlando, FL 32801
contact@genesisbiolabs.org | www.genesisbiolabs.org

COA # **1553922**

PASS

Certificate of Analysis

Date:	5/24/2026	Date Tested:	5/10/2026
Customer:	Peptides Optimized LLC	Testing material:	Tirzepatide
Batch #:	TR40-260510	BT Sample ID:	005000198191344
Labeled Peptide Content/Potency:	40 mg	Storage:	R.T.
Visual Description:	Small clear vial: white lyophilized powder, silver crimp, green plastic cap.		
Labeled as:	Tirzepatide	Manufacturer:	N/A
Testing Purpose:	FTIR and HPLC analysis for the identification, purity, potency and composition of a peptide product. It additionally reports elemental impurities (heavy metals), bacterial endotoxins and sterility as recorded in this certificate. It does not provide information on particulate matter.		



Test	Method	Specification	Result	Status
General Appearance	Visual	White to off-white powder	white powder	PASS
HPLC Purity of Peptide Assay	USP <621>	NLT 98.0 % (area normalisation)	99.62 %	PASS
HPLC Potency Assay	USP <621>	40 mg (net peptide), 90.0 - 110.0 %	40.11 mg (100.3 %)	PASS
Identity by Mass Spectrometry	LC-MS (ESI)	Observed mass within 1 Da of theoretical	Conforms; observed mass matches Tirzepatide reference standard.	PASS
FTIR Identification and Composition Analysis	USP <197A>	Sample spectrum consistent with the reference standard	FTIR spectrum consistent with the Tirzepatide reference standard.	PASS
Heavy Metals (Elemental Impurities)	USP <233> (ICP-MS)	Class 1 (Pb, Cd, As, Hg): NMT USP <232>/ICH Q3D limits	Complies (< LOQ)	PASS

The results of the CoA relate only to the item(s) tested and applied to the sample as received.

COA # 1553922 ACCESS CODE **VHZNJ2WBEQ45** VERIFY AT www.genesisbiolabs.org/verify

Kenji Sato

Kenji Sato, AS
Laboratory Director
Genesis Biolabs
Signed 5/24/2026

Min-Jun Park

Min-Jun Park, AS
QA Approver
Genesis Biolabs
Signed 5/24/2026

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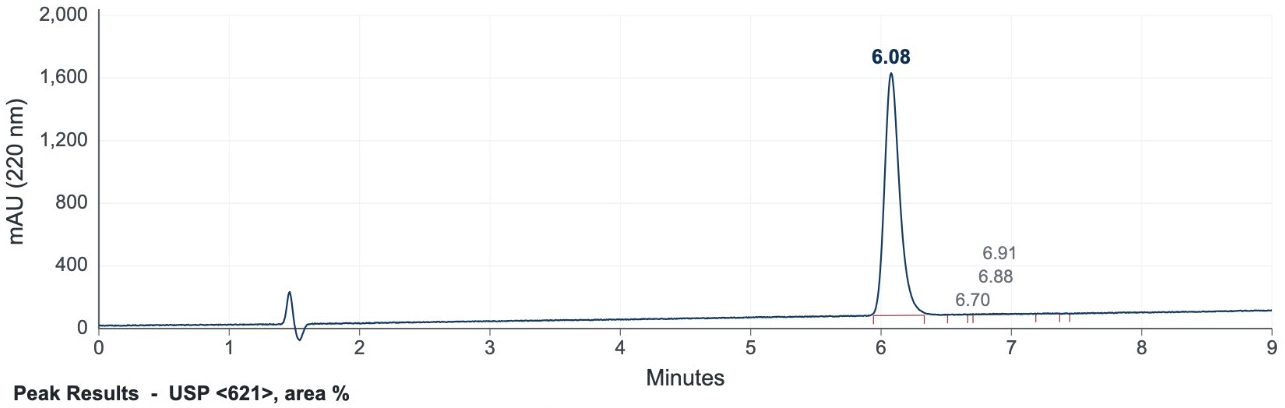
Certificate of Analysis

Product: Tirzepatide **Batch #:** TR40-260510 **Content:** 40 mg **Tested:** 5/10/2026

HPLC Purity Chromatogram @ 220 nm: Tirzepatide Lot TR40-260510

Sample Name: Tirzepatide 40mg
Sample ID / Lot: TR40-260510
Method: PEP_TFA_220_GRAD.M
Column: XBridge BEH C18, 4.6 x 150 mm, 3.5 um
Signal: VWD1 A, 220 nm
Mobile Phase: A 0.1% TFA/H2O, B 0.1% TFA/MeCN (gradient)

Injection Volume: 10.0 uL
Acquired: 5/10/2026 12:50
Vial: 15 Injection: 1
Operator: K. Sato
Flow: 1.0 mL/min Column Temp: 30 C
System: HPLC-05



Peak Results - USP <621>, area %

Pk	RT (min)	Area (mAU*s)	Height (mAU)	Area %	USP Res.	USP Tailing	USP Plates
1	**6.08**	**12,543**	**1,549**	**99.62**	**-**	**1.30**	**14,115**
2	6.70	12	1.0	0.10	-	-	-
3	6.88	9	0.6	0.07	-	-	-
4	6.91	27	1.9	0.21	-	-	-
Total		**12,590**		**100.00**			

OpenLab CDS | Processing method: USP_PURITY_AREAPCT | Result: main peak 99.6 % (area) | Page 1 of 1

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Certificate of Analysis

Product: Tirzepatide **Batch #:** TR40-260510 **Content:** 40 mg **Tested:** 5/10/2026

Heavy Metals Analysis (ICP-MS, USP <233>)

Element	Specification	Result	Status
Arsenic (As)	NMT 1.5 ppm	Not Detected	PASS
Cadmium (Cd)	NMT 0.5 ppm	Not Detected	PASS
Mercury (Hg)	NMT 1.5 ppm	Not Detected	PASS
Lead (Pb)	NMT 1 ppm	Not Detected	PASS
Chromium (Cr)	NMT 10 ppm	Not Detected	PASS

Elemental impurities determined by ICP-MS. Limits are laboratory screening limits for research-use material, derived from ICH Q3D permitted daily exposures for the parenteral route.

Test	Method	Specification	Result	Status
Bacterial Endotoxins Test	USP <85>	NMT 40 EU/vial reconstituted	PASS	PASS

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Bacterial Endotoxins Test Tirzepatide Lot TR40-260510

Sample ID	Description	Volume (mL)	Endotoxin Limit (EU/vial)	Lysate Sensitivity (λ, EU/mL)	Result
TR40-260510	Tirzepatide	3	40 EU/vial	0.25	0.07 EU/vial

The sample passed a valid gel clot endotoxin test based on the type, mode of administration and dosage.

Sterility Test

Test	Method	Specification	Result	Status
Sterility	USP <71> (membrane filtration)	No microbial growth	PASS	PASS

Medium	Incubation Temp.	Duration	Units Tested	Observation
Fluid Thioglycollate Medium (FTM)	30 – 35 °C	14 days	2	No growth
Soybean–Casein Digest Medium (SCDM)	20 – 25 °C	14 days	2	No growth

No microbial growth was observed. The sample meets the requirements of the sterility test (USP <71>).

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Certificate of Analysis

Product: Tirzepatide **Batch #:** TR40-260510 **Content:** 40 mg **Tested:** 5/10/2026

Notes & Methodology

1. Peptide purity determined by RP-HPLC area normalisation at 220 nm. The value represents the percentage of the target peptide relative to all peptide-related peaks. Non-peptide process-related impurities, where detected, are excluded from the calculation.
2. Net peptide content (potency) calculated as assay content corrected for water (Karl Fischer) and counterion content, expressed as a percentage of the labelled claim.
3. Identity confirmed by FTIR against a reference standard (USP <197A>) and by chromatographic retention time comparison.
4. Elemental impurities screened by ICP-MS per USP <233> methodology. Acceptance criteria are laboratory screening limits for research-use material and do not constitute evaluation against a specific pharmacopoeial monograph.
5. Bacterial endotoxins determined by gel-clot method per USP <85>. Sterility per USP <71>.
6. The chromatogram reproduced in this certificate is representative of the batch tested.

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