



## Certificate of Analysis (CoA)

Date: 9/18/2026 Date Tested: 9/2/2026  
Customer: Peptides Optimized LLC Testing material: Tirzepatide  
Batch #: TR20-L01 BT Sample ID: 605188807411041  
Labeled Peptide 20 mg Storage: R.T.  
Content/Potency:  
Visual Description: Small clear vial: white lyophilized powder, research-use label, silver crimp, purple flip 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                                                      | <b>PASS</b> |
| HPLC Purity of Peptide Assay                 | USP <621>          | NLT 98.0 % (area normalisation)                                                | 99.55%                                                            | <b>PASS</b> |
| HPLC Potency Assay                           | USP <621>          | 20 mg (net peptide), 90.0 - 110.0 %                                            | 20.32 mg (101.6 %)                                                | <b>PASS</b> |
| Identity by Mass Spectrometry                | LC-MS (ESI)        | Observed mass within 1 Da of theoretical                                       | Conforms; observed mass matches Tirzepatide reference standard.   | <b>PASS</b> |
| FTIR Identification and Composition Analysis | USP <197A>         | Sample spectrum should confirm the content of peptide via characteristic bands | FTIR spectrum consistent with the Tirzepatide reference standard. | <b>PASS</b> |
| Heavy Metals (Elemental Impurities)          | USP <233> (ICP-MS) | Class 1 (Pb, Cd, As, Hg): meets USP <232>/ICH Q3D                              | Complies (< LOQ)                                                  | <b>PASS</b> |

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

COA # 5938339

ACCESS CODE **MPF07RCE5A4R**

VERIFY AT [www.genesisbiolabs.org/verify](http://www.genesisbiolabs.org/verify)

*Kenji Sato*

Kenji Sato, AS  
Laboratory Director  
Genesis Biolabs  
Signed 9/18/2026

*Min-Jun Park*

Min-Jun Park, AS  
QA Approver  
Genesis Biolabs  
Signed 9/18/2026

**GB-QSA-TR001**  
Rev 1.0 July 2026



# Certificate of Analysis (CoA)

**Product:** Tirzepatide **Batch #:** TR20-L01 **Content:** 20 mg **Tested:** 9/2/2026

## HPLC Purity Chromatogram @ 220 nm: Tirzepatide Lot TR20-L01

**Sample Name:** Tirzepatide 20 mg

**Sample ID / Lot:** TR20-L01

**Method:** PEP\_TFA\_220\_GRAD.M

**Column:** Zorbax SB-C18, 4.6 x 150 mm, 5 um

**Signal:** VWD1 A, 220 nm

**Mobile Phase:** A 0.1% TFA/H<sub>2</sub>O, B 0.1% TFA/MeCN (gradient)

**Injection Volume:** 10.0 uL

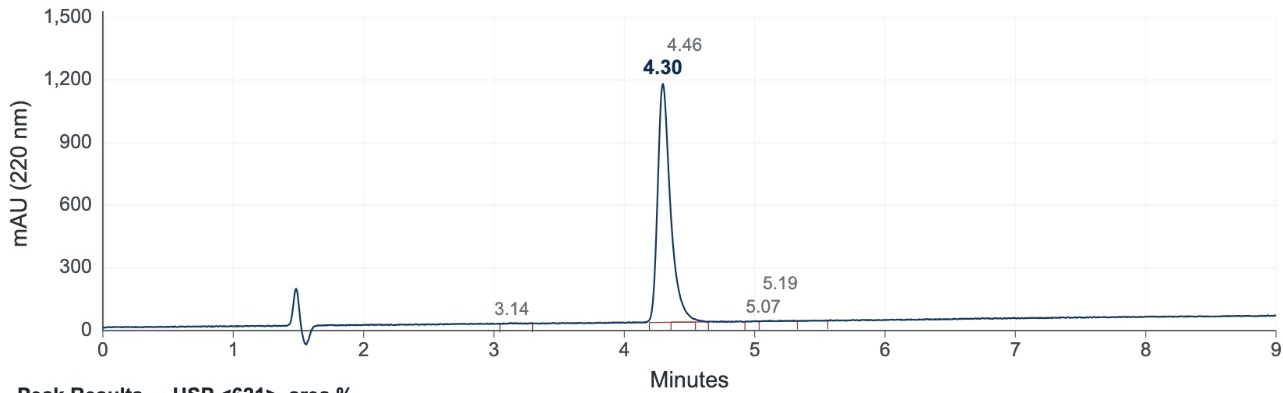
**Acquired:** 9/2/2026 16:08

**Vial:** 24 **Injection:** 1

**Operator:** K. Sato

**Flow:** 1.0 mL/min **Column Temp:** 30 C

**System:** HPLC-04



### Peak Results - USP <621>, area %

| Pk           | RT (min) | Area (mAU*s) | Height (mAU) | Area %        | USP Res. | USP Tailing | USP Plates |
|--------------|----------|--------------|--------------|---------------|----------|-------------|------------|
| 1            | 3.14     | 7            | 1.4          | 0.09          | -        | -           | -          |
| 2            | 4.30     | 7,816        | 1,144        | 99.55         | 7.63     | 1.51        | 10,366     |
| 3            | 4.46     | 10           | 1.6          | 0.12          | -        | -           | -          |
| 4            | 5.07     | 10           | 1.2          | 0.13          | -        | -           | -          |
| 5            | 5.19     | 8            | 0.8          | 0.11          | -        | -           | -          |
| <b>Total</b> |          | <b>7,851</b> |              | <b>100.00</b> |          |             |            |

OpenLab CDS | Processing method: USP\_PURITY\_AREAPCT | Result: main peak 99.5 % (area) | Page 1 of 1



# Certificate of Analysis (CoA)

**Product:** Tirzepatide **Batch #:** TR20-L01 **Content:** 20 mg **Tested:** 9/2/2026

## 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   |

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

## Bacterial Endotoxins Test Tirzepatide Lot TR20-L01

| Sample ID | Description | Volume (mL) | Endotoxin Limit (EU/vial) | Lysate Sensitivity ( $\lambda$ , EU/mL) | Result       |
|-----------|-------------|-------------|---------------------------|-----------------------------------------|--------------|
| TR20-L01  | Tirzepatide | 3           | 40 EU/vial                | 0.25                                    | 0.06 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> | 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>).

## Certificate of Analysis (CoA)

**Product:** Tirzepatide    **Batch #:** TR20-L01    **Content:** 20 mg    **Tested:** 9/2/2026

### 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.