PrymaLab
PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY
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CERTIFICATE NO.
PL-26-00116
VERIFICATION KEY
AHAAXPHE
Scan or enter both at prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE

Tirzepatide 80 mg

Lot **PL-2609-116** · Lyophilized powder · Label claim **80 mg/vial**

TESTED IN-HOUSE BY PRYMALAB
In-house analytical result, not an independent third-party test

LOT / BATCH NUMBER	DATE MADE	DATE OF ANALYSIS	DATE ISSUED
PL-2609-116	2026-09-18	2026-09-19	2026-10-03
RETEST / EXPIRY	**UNITS IN LOT / SAMPLED**	**STORAGE**	**CERTIFICATE TYPE**
2028-09-18	150 / 2	−20 °C, desiccated, dark	Lot COA, 2 pages

COMPOUND	CAS NUMBER	MOLECULAR FORMULA	THEORETICAL MASS (AVG.)
Tirzepatide LY3298176; GIP/GLP-1 receptor dual agonist	2023788-19-2	$C_{225}H_{348}N_{48}O_{68}$	4813.5 Da

SEQUENCE

H-Y-Aib-EGTFTSDYSI-Aib-LDKIAQK(2×AEEA-γGlu-C20 diacid)AFVQWLIAGGPSSGAPPPS-NH_2 (39 residues; Aib2 and Aib13; Lys20 acylated with eicosanedioic acid via γ-Glu and two AEEA spacers; C-terminal amide)

PURITY · RP-HPLC, AREA %
99.21%
Specification 99.0% • main peak at 8.89 min

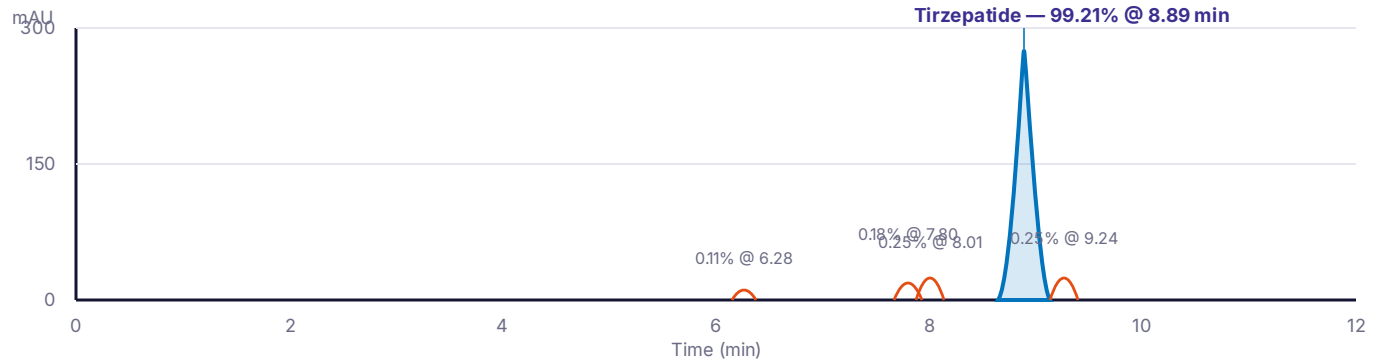
IDENTITY · OBSERVED MASS
4813.3 Da
Theoretical 4813.5 Da • −0.2 Da (−42 ppm)

OVERALL CONCLUSION
PASS
Meets every specification for the tests performed

TEST	METHOD	SPECIFICATION	RESULT	CONCLUSION
Appearance	Visual inspection	White to off-white lyophilized powder	White lyophilized powder	PASS
Identity (mass)	LC-MS, ESI positive	Theoretical ± 1.0 Da	4813.3 Da	PASS
Purity	RP-HPLC, UV 214 nm, area%	99.0%	99.21%	PASS
Largest impurity	RP-HPLC, area%	1.0%	0.25% at 8.01 min (Trp 25 oxidation)	PASS
Water content	Karl Fischer	5.0%	1.9%	PASS
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.06 EU/mg	PASS
Sterility / bioburden	USP <71>, membrane filtration	No growth after 14 days	No growth; conforms	PASS

1 HPLC CHROMATOGRAM

Data file: TZP_PL-2609-116_20260919_01 · Column C18 150 × 4.6 mm · UV 214 nm



Baseline uncropped; main peak and impurities labeled with retention times. Peak table on page 2.

For laboratory research use only. Not for human or veterinary use.

2 HPLC METHOD · TZP_PL-2609-116_20260919_01

INSTRUMENT Waters Alliance e2695, SN E2695B742	DATA SYSTEM Empower 3, Build 3471	DETECTOR Waters 2998 PDA
DETECTION WAVELENGTH 214 nm	COLUMN C18, 150 × 4.6 mm, 3.5 µm	COLUMN PART / SERIAL 186003326 / USHX20000
MOBILE PHASE A 0.1% TFA in water	MOBILE PHASE B 0.1% TFA in MeCN	FLOW RATE 1.0 mL/min
COLUMN TEMPERATURE 40 °C	INJECTION VOLUME 20 µL	RUN TIME 12 min
SAMPLE DILUENT 0.1% TFA in 30% MeCN	SAMPLE CONCENTRATION 0.5 mg/mL	BLANK INJECTED Yes
REFERENCE STANDARD In-house Tirzepatide reference, lot PL-RS-TZP-01, RT 8.86 min		

3 GRADIENT PROGRAM

TIME (MIN)	% A	% B
0.0	65	35
2.0	65	35
9.0	25	75
10.0	15	85
11.0	15	85
12.0	65	35

4 PEAK TABLE

PEAK	RT (MIN)	AREA	AREA %
1	6.28	5,295	0.11
2 (deamid.)	7.80	8,664	0.18
3 (Trp-ox)	8.01	12,033	0.25
4	**8.89**	**4,775,275**	**99.21**
5	9.24	12,033	0.25
Total		4,813,300	100.00

Threshold 0.05% area · Blank subtracted: Y · Purity = main peak area ÷ total integrated area × 100, to two decimals; main peak shaded.

5 IDENTITY BY MASS SPECTROMETRY

INSTRUMENT Waters Acquity SQD	IONIZATION / MODE ESI, positive	OBSERVED M/Z (CHARGE) 963.7 (5+ [M+5H]) · 803.2 (6+ [M+6H])
DECONVOLUTED MASS 4813.3 Da	THEORETICAL MASS 4813.5 Da	DIFFERENCE −0.2 Da (−42 ppm)
DATA FILE TZP_PL-2609-116_MS_20260919_01	ACCEPTANCE Within ± 1.0 Da	

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Water content	PrymaLab	2026-09-19	RPT-KF-PL-2609-116
Endotoxin	PrymaLab	2026-09-19	RPT-ET-PL-2609-116
Sterility	PrymaLab	2026-09-19	RPT-ST-PL-2609-116

A test with no row here was not performed on this lot. Outside-laboratory reports, when used, are attached and named below.

7 REVIEW AND APPROVAL

D. Reynolds
Analyst · performed the testing
Date: 2026-09-19

S. Calloway
Reviewer · checked against raw data
Date: 2026-10-02

M. Phelps
Lab Director · approved for release
Date: 2026-10-03

Raw data retained at: Empower 3 (Build 3471), project PL-2609, archive PL-ARC-2026; 7 years. Outside laboratory reports attached: None

This certificate applies only to the lot named above and describes the units sampled from it; it is not a guarantee for any other lot. Results were obtained by PrymaLab LLC's own laboratory (PrymaLab Analytical) and are not an independent third-party test unless an outside report is attached. Reference values (CAS, formula, theoretical mass, sequence) are literature values for the named compound. Authenticity: scan the QR code or enter certificate number PL-26-00116 and key AHAAXPHE at prymalab.net/testing/verify; any copy that does not match the record shown there is not a PrymaLab certificate. PrymaLab LLC products are supplied for laboratory research use only and not for human or veterinary use.