Keystone

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CERTIFICATE NO.
PL–26–00329

VERIFICATION KEY
2YUTLN4M

Scan or enter both at prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE · ISSUED FOR KEYSTONE

Tirzepatide 10 mg

Lot **PL-2610-216** · Lyophilized powder · Label claim **10 mg per vial** · Distributed as **GIP2-TZ 10 mg**

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–2610–216	2026-10-07	2026-10-08	2026-10-22

RETEST / EXPIRY	UNITS IN LOT / SAMPLED	STORAGE	CERTIFICATE TYPE
2028-10-07	282 / 2	−20 °C, desiccated, dark	Lot COA, 2 pages

COMPOUND	CAS NUMBER	MOLECULAR FORMULA	THEORETICAL MASS (AVG.)
Tirzepatide	2023788-19-2	$C_{225}H_{348}N_{48}O_{68}$	4,813.45 Da

SEQUENCE
acylated GIP/GLP–1 dual agonist

PURITY · RP-HPLC, AREA %
99.30%
Specification ≥ 99.0% • main peak at 11.90 min

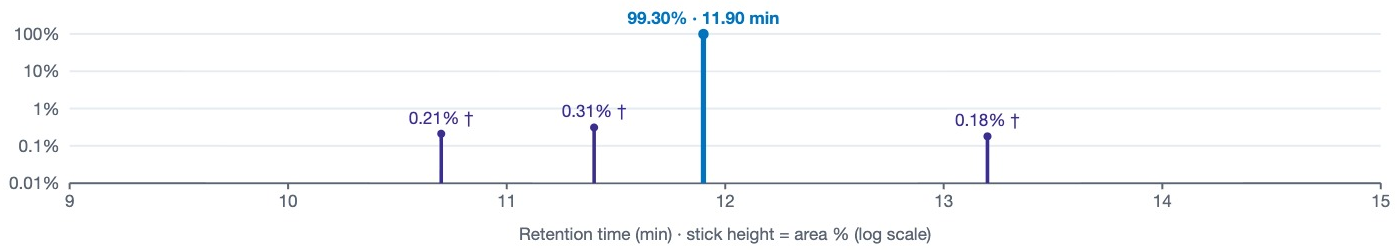
IDENTITY · OBSERVED MASS
4,813.44 Da
Theoretical 4,813.45 Da • −0.01 Da (2 ppm)

OVERALL CONCLUSION
PASS
Meets every specification for the tests performed

TEST	METHOD	SPECIFICATION	RESULT	CONCLUSION
Identity (mass)	LC-MS, ESI positive	Theoretical ± 1.0 Da	4,813.44 Da	**PASS**
Purity	RP-HPLC, UV 214 nm, area%	≥ 99.0%	99.30%	**PASS**
Largest impurity	RP-HPLC, area%	≤ 1.0%	0.31% (RT 11.40)	**PASS**
Water content	Karl Fischer	≤ 5.0%	1.99%	**PASS**
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.178 EU/mg	**PASS**
Sterility	USP <71>, 14-day	No growth	No growth	**PASS**

1 HPLC CHROMATOGRAM

Data file: PL-2610-216-HPLC.raw · Column C18, 150 × 4.6 mm · UV 214 nm



Peak plot drawn from the integrated peak table (area %, log scale); it is not the instrument trace, which is retained in PL-2610-216-HPLC.raw. † Nominal reference retention time for the assigned impurity; the main-peak RT is observed in this lot.

2 HPLC METHOD · PL-2610-216-HPLC.RAW

INSTRUMENT
Waters Alliance e2695

DATA SYSTEM
Empower 3

DETECTOR
UV absorbance

DETECTION WAVELENGTH
214 nm

COLUMN
C18, 150 × 4.6 mm, 3.5 µm

MOBILE PHASE A
0.1% TFA in water

MOBILE PHASE B
0.1% TFA in MeCN

GRADIENT
5–95% B over 25 min (linear)

FLOW RATE
1.0 mL/min

COLUMN TEMPERATURE
40 °C

INJECTION VOLUME
10 µL

3 GRADIENT PROGRAM

TIME (MIN)	% A	% B
0.0	95	5
25.0	5	95

4 PEAK TABLE

PEAK	RT (MIN)	AREA	AREA %
1	10.70 †	—	0.21
2	11.40 †	—	0.31
3	**11.90**	**—**	**99.30**
4	13.20 †	—	0.18
Total		—	100.00

Peaks: 1 deamidation product; 2 isoaspartate (isoasp) variant; 3 main peak (Tirzepatide); 4 tryptophan oxidation product · Area % from the integrated peak table (absolute areas are not part of the lot-release export) · † nominal reference RT for the assigned impurity · Purity = main peak area ÷ total integrated area × 100, to two decimals; main peak shaded.

5 IDENTITY BY MASS SPECTROMETRY

INSTRUMENT
Waters SQD

IONIZATION / MODE
ESI, positive

REFERENCE M/Z (CHARGE)
1204.37 (4+) · 963.70 (5+)

DECONVOLUTED MASS
4,813.44 Da

THEORETICAL MASS
4,813.45 Da

DIFFERENCE
−0.01 Da (2 ppm)

DATA FILE
PL-2610-216-MS.d

ACCEPTANCE
Within ± 1.0 Da

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Water content (Karl Fischer)	PrymaLab Analytical	2026-10-08	—
Endotoxin (LAL, kinetic)	PrymaLab Analytical	2026-10-08	—
Sterility (USP <71>, day-14 read-out)	PrymaLab Analytical	2026-10-22	—

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: 2026-10-22

S. Calloway
Reviewer · checked against raw data
Date: 2026-10-22

M. Phelps
Lab Director · approved for release
Date: 2026-10-22

Raw data retained at: Empower 3, project PL-2610, 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. This copy is issued for Keystone, a distributor of the lot; the brand shown does not change the laboratory, the method or the results. Reference values (CAS, formula, theoretical mass, sequence) are literature values for the named compound. Authenticity: scan the QR code or enter certificate number PL-26-00329 and key 2YUTLN4M 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.