Keystone

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CERTIFICATE NO.
PL–26–00316

VERIFICATION KEY
A4JLNJGD

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

CERTIFICATE OF ANALYSIS · LOT RELEASE · ISSUED FOR KEYSTONE

Tesamorelin 10 mg

TESTED IN-HOUSE BY PRYMALAB

In-house analytical result, not an independent third-party test

Lot **PL-2610-202** · Lyophilized powder · Label claim **10 mg per vial** · Distributed as **Tesamorelin 10 mg**

LOT / BATCH NUMBER	DATE MADE	DATE OF ANALYSIS	DATE ISSUED
PL–2610–202	**2026-10-07**	**2026-10-08**	**2026-10-22**
RETEST / EXPIRY	**UNITS IN LOT / SAMPLED**	**STORAGE**	**CERTIFICATE TYPE**
2028-10-07	**335 / 2**	–20 °C, desiccated, dark	Lot COA, 2 pages

COMPOUND
Tesamorelin
Tesamorelin (trans-3-hexenoyl-GHRH(1-44)-NH2)

SEQUENCE
`GHRH(1–44) analog`

CAS NUMBER
218949-48-5

MOLECULAR FORMULA
$C_{221}H_{366}N_{72}O_{67}S$

THEORETICAL MASS (AVG.)
5,135.86 Da

PURITY · RP-HPLC, AREA %
99.32%
Specification ≥ 99.0% • main peak at 11.69 min

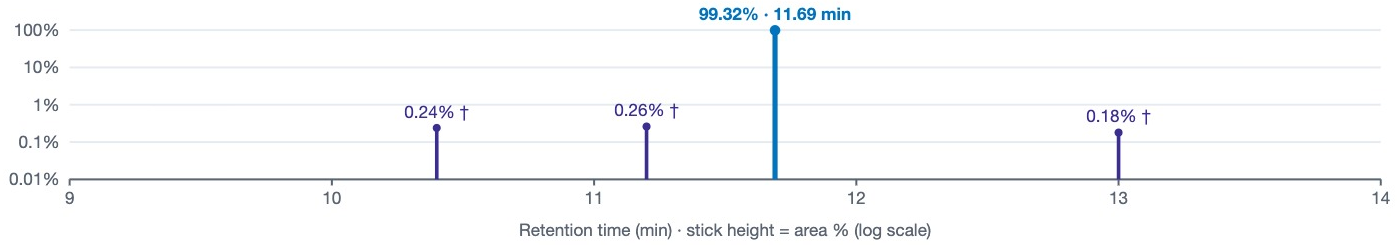
IDENTITY · OBSERVED MASS
5,135.62 Da
Theoretical 5,135.86 Da • −0.24 Da (47 ppm)

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	5,135.62 Da	**PASS**
Purity	RP-HPLC, UV 214 nm, area%	≥ 99.0%	99.32%	**PASS**
Largest impurity	RP-HPLC, area%	≤ 1.0%	0.26% (RT 11.20)	**PASS**
Water content	Karl Fischer	≤ 5.0%	1.55%	**PASS**
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.361 EU/mg	**PASS**
Sterility	USP <71>, 14-day	No growth	No growth	**PASS**

1 HPLC CHROMATOGRAM

Data file: PL-2610-202-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-2610-202-HPLC.raw. † Nominal reference retention time for the assigned impurity; the main-peak RT is observed in this lot.

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2 HPLC METHOD · PL-2610-202-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	10.40 †	—	0.24
2	11.20 †	—	0.26
3	**11.69**	**—**	**99.32**
4	13.00 †	—	0.18
Total		—	100.00

Peaks: 1 deamidation product; 2 isoaspartate (isoasp) variant; 3 main peak (Tesamorelin); 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) 1284.97 (4+) · 1028.18 (5+)
DECONVOLUTED MASS 5,135.62 Da	THEORETICAL MASS 5,135.86 Da	DIFFERENCE −0.24 Da (47 ppm)
DATA FILE PL-2610-202-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-26-00316 and key A4JLNJGD 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.