PrymaLab
PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY
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CERTIFICATE NO.
PL-26-00340
VERIFICATION KEY
H3YH6ETS
Scan or enter both at prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE

Triptorelin 6 mg Pen

Lot **PL-2610-227** · Solution · Label claim **6 mg/mL**

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-2610-227	2026-10-07	2026-10-08	2026-10-22
RETEST / EXPIRY	**UNITS IN LOT / SAMPLED**	**STORAGE**	**CERTIFICATE TYPE**
2028-10-07	357 / 2	—	Lot COA, 2 pages

COMPOUND	CAS NUMBER	MOLECULAR FORMULA	THEORETICAL MASS (AVG.)
Triptorelin [D-Trp6]-GnRH	57773-63-4	$C_{64}H_{82}N_{18}O_{13}$	1,311.45 Da

SEQUENCE
pEHWSY-D-Trp-LRPG-NH2

PURITY · RP-HPLC, AREA %
99.81%
Specification ≥ 99.0 % • main peak at 12.99 min

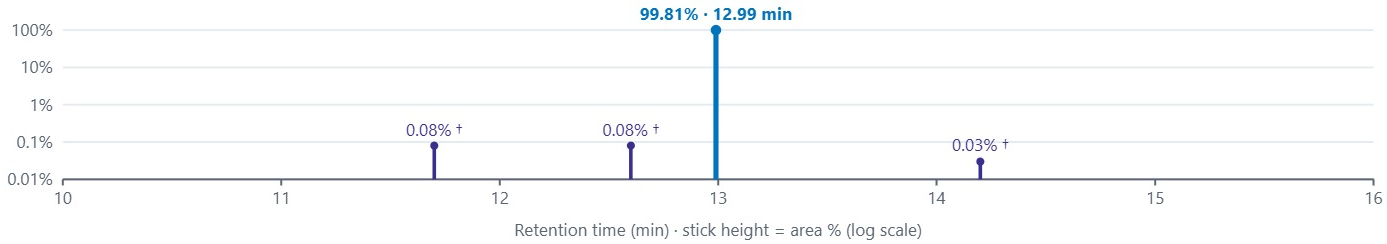
IDENTITY · OBSERVED MASS
1,311.54 Da
Theoretical 1,311.45 Da • +0.09 Da (69 ppm)

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	1,311.54 Da	PASS
Purity	RP-HPLC, UV 214 nm, area %	≥ 99.0 %	99.81 %	PASS
Largest impurity	RP-HPLC, area %	≤ 1.0%	0.08 % (RT 11.70)	PASS
Assay (label claim)	Assay vs label claim	5.7–6.3 mg/mL	5.89 mg/mL	PASS
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.229 EU/mg	PASS
Sterility	USP <71>, 14-day	No growth	No growth	PASS

1 HPLC CHROMATOGRAM

Data file: PL-2610-227-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-2610-227-HPLC.raw. † Nominal reference retention time for the assigned impurity; the main-peak RT is observed in this lot.

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

2 HPLC METHOD · PL-2610-227-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	11.70 †	—	0.08
2	12.60 †	—	0.08
3	**12.99**	**—**	**99.81**
4	14.20 †	—	0.03
Total		—	100.00

Peaks: 1 tryptophan oxidation product; 2 deamidation product; 3 main peak (Triptorelin); 4 truncated sequence · 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)
656.73 (2+) · 438.16 (3+)

DECONVOLUTED MASS
1,311.54 Da

THEORETICAL MASS
1,311.45 Da

DIFFERENCE
+0.09 Da (69 ppm)

DATA FILE
PL-2610-227-MS.d

ACCEPTANCE
Within ± 1.0 Da

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Assay vs label claim	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. Reference values (CAS, formula, theoretical mass, sequence) are literature values for the named compound. Authenticity: scan the QR code or enter certificate number PL-26-00340 and key H3YH6ETS 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.