



PrymaLab

PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY

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CERTIFICATE NO.
PL-26-00050

VERIFICATION KEY
FH5H6QV5

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

CERTIFICATE OF ANALYSIS · LOT RELEASE

HMG 75 IU

Lot PL-2609-050 · Lyophilized powder · Label claim 75 IU/vial (75 IU FSH + 75 IU LH activity)

TESTED IN-HOUSE BY PRYMALAB

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

LOT / BATCH NUMBER PL-2609-050	DATE MADE 2026-09-18	DATE OF ANALYSIS 2026-09-19	DATE ISSUED 2026-10-03
RETEST / EXPIRY 2028-09-18	UNITS IN LOT / SAMPLED 250 / 2	STORAGE 2-8 °C, dark	CERTIFICATE TYPE Lot COA, 2 pages
COMPOUND HMG (Menotropins) Human menopausal gonadotropin: urinary FSH and LH; potency assigned in IU by bioassay	CAS NUMBER 61489-71-2	MOLECULAR FORMULA Not applicable (glycoprotein mixture)	THEORETICAL MASS (AVG.) FSH about 30 kDa and LH about 28.5 kDa glycoform averages
STRUCTURE Co-purified glycoprotein heterodimers: FSH = common α -subunit (92 aa) + FSH β (111 aa); LH = common α -subunit (92 aa) + LH β (121 aa); cystine-k not fold; N-glycosylated.			

PURITY · RP-HPLC, AREA %

98.6%

Specification $\geq$ 95.0% (SDS-PAGE corroboration) •
FSH/LH component peaks at 6.92 / 7.34 min

IDENTITY · OBSERVED MASS

2 / 2

Both gonadotropin components confirmed by LC-MS within glycoform envelopes: FSH ~30 kDa · LH ~28.5 kDa

OVERALL CONCLUSION

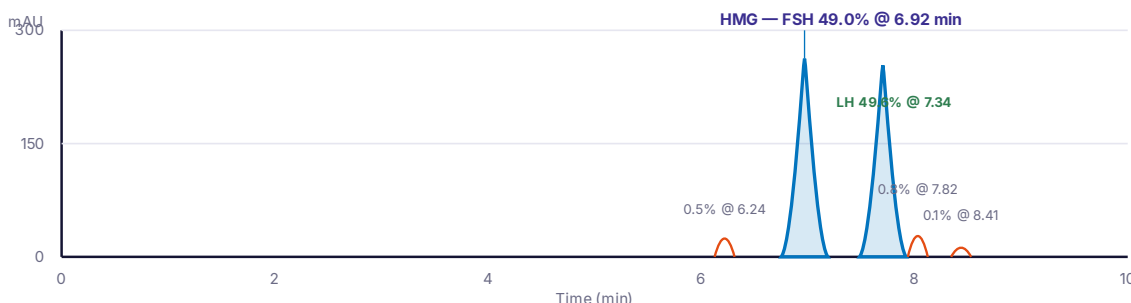
PASS

Meets every specification for the tests performed

TEST	METHOD	SPECIFICATION	RESULT	CONCLUSION
Appearance	Visual inspection	White to off-white lyophilized powder or cake	White lyophilized cake	PASS
Identity	LC-MS, ESI positive	FSH/LH within glycoform envelopes	FSH 30,084 Da · LH 28,577 Da centroids	PASS
	Purity	RP-HPLC, UV 214 nm, area%	$\geq$ 95.0%	98.6%
Largest impurity	RP-HPLC, area%	$\leq$ 5.0%	0.8% at 7.82 min	PASS
Water content	Karl Fischer	5.0%	1.8%	PASS
Bacterial endotoxin	LAL, kinetic	$\leq$ 5.0 EU/mg	0.23 EU/mg	PASS
Sterility / bioburden	USP <71>, membrane filtration	No growth after 14 days	No growth; conforms	PASS

1 HPLC CHROMATOGRAM

Data file: HMG_PL-2609-050_20260919_01 · Column C18 150 × 4.6 mm · UV 214 nm



Baseline uncropped; FSH and LH component peaks (both shaded) and impurities labeled with retention times. Peak table on page 2.

**2 HPLC METHOD · HMG_PL-2609-050_20260919_01**

INSTRUMENT

Waters Alliance e2695, SN E2695B742

DETECTION WAVELENGTH

214 nm

MOBILE PHASE A

0.1% TFA in water

COLUMN TEMPERATURE

30 °C

SAMPLE DILUENT

Water, 0.1% TFA

REFERENCE STANDARD

In-house HMG reference, lot PL-RS-HMG-01, component RTs 6.90 / 7.32 min

DATA SYSTEM

Empower 3, Build 3471

COLUMN

C18, 150 × 4.6 mm, 3.5 µm

MOBILE PHASE B

0.1% TFA in MeCN

INJECTION VOLUME

20 µL

SAMPLE CONCENTRATION

0.2 mg/mL (pooled composite)

DETECTOR

Waters 2998 PDA

COLUMN PART / SERIAL

186003326 / USHX18211

FLOW RATE

1.0 mL/min

RUN TIME

10 min

BLANK INJECTED

Yes

3 GRADIENT PROGRAM

TIME (MIN)	% A	% B
0.0	95	5
3.0	95	5
7.0	55	45
8.0	20	80
9.0	20	80
10.0	95	5

4 PEAK TABLE

PEAK	RT (MIN)	AREA	AREA %
1	6.24	21,500	0.5
2 (FSH)	6.92	2,107,000	49.0
3 (LH)	7.34	2,132,800	49.6
4	7.82	34,400	0.8
5	8.41	4,300	0.1
Total		4,300,000	100.0

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)

1505.2 (20+ [M+20H], FSH) · 1144.6 (25+ [M+25H], LH)

DECONVOLUTED MASS

FSH 30,084 Da · LH 28,577 Da (glycoform centroids)

THEORETICAL MASS

FSH ~30,000 Da · LH ~28,500 Da (average glycoforms)

DIFFERENCE

Within CHO-derived (urinary) glycoform envelopes

DATA FILE

HMG_PL-2609-050_MS_20260919_01

ACCEPTANCE

Within glycoform envelopes, each component

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Water content	PrymaLab	2026-09-20	RPT-KF-PL-2609-050
Endotoxin	PrymaLab	2026-09-21	RPT-ET-PL-2609-050
Sterility	PrymaLab	2026-10-02	RPT-ST-PL-2609-050

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-26-00050 and key FH5H6QV5 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.