CERTIFICATE OF ANALYSIS

HMG 75iu

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0408-H	APX-COA-2026-0408-H	2026-04-08

COMPOUND REFERENCE

Material family
protein or glycoprotein

Material form
lyophilized solid in vial

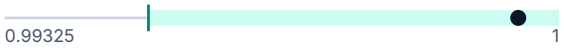
MATERIAL & COMPOSITION

Nominal component amounts
FSH activity: 75 IU; LH activity: 75 IU

Recorded storage
-20 +/-5 C, protected from light; sealed dry vial

Reference fingerprint similarity

Reference fingerprint similarity
0.9995 similarity (0-1)



Criterion: >= 0.995

Criterion uses the result unit. Independent expanded scales.

Measured biological activity

FSH
75.072 IU/vial

Criterion: 71.25 to 78.75

LH
75.13 IU/vial

Criterion: 71.25 to 78.75
Criterion uses the result unit. Independent expanded scales.

71 recorded endpoints across 21 test groups. Results apply to this configuration and lot. For research use only; not for human or animal use.

APPROVED BY

K. Norwood
COA issued 2026-04-08

ONLINE REPORT
Scan to view this record and download the PDF.

Contamination & microbiology

All applicable tested criteria met

32 applicable endpoints reviewed against their stated specifications.

ELEMENTAL IMPURITIES

Lead	✓ PASS
Cadmium	✓ PASS
Arsenic	✓ PASS
Mercury	✓ PASS
Cobalt	✓ PASS
Vanadium	✓ PASS
Nickel	✓ PASS
Palladium	✓ PASS
Platinum	✓ PASS
Rhodium	✓ PASS
Ruthenium	✓ PASS
Iridium	✓ PASS

RESIDUAL SOLVENTS

Methanol	✓ PASS
Acetonitrile	✓ PASS
Dichloromethane	✓ PASS
N, N-dimethylformamide	✓ PASS
Ethanol	✓ PASS
Acetone	✓ PASS
Ethyl acetate	✓ PASS
Toluene	✓ PASS
n-Hexane	✓ PASS
Benzene	✓ PASS

MICROBIOLOGY & ENDOTOXINS

Sterility: FTM	✓ PASS
Sterility: SCDM	✓ PASS
Bacterial endotoxins	✓ PASS
TAMC	✓ PASS
TYMC	✓ PASS
Escherichia coli	✓ PASS
Staphylococcus aureus	✓ PASS
Pseudomonas aeruginosa	✓ PASS
Salmonella species	✓ PASS
Candida albicans	✓ PASS

PASS indicates that the recorded result meets its stated criterion for the tested sample. Exact values, detection limits, sampling scope and methods follow in the complete results. For research use only.

Complete assay results

Reported values, units and acceptance outcomes are reproduced separately for each endpoint. Method keys link to the method reference section.

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T01 / Identity and structure			
01 / Orthogonal identity against specified reference	Conforms to the assigned reference; see identity basis Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M01 PASS C01
02 / Orthogonal fingerprint similarity	= 0.9994 similarity (0-1) Basis B01	>= 0.995 Unit: similarity (0-1)	M01 PASS C02
T02 / Chromatographic purity			
03 / Multipeak fingerprint similarity to defined reference	= 0.9995 similarity (0-1) Basis B02	>= 0.995 Unit: similarity (0-1)	M02 PASS C02
T03 / Active content and assay			
05 / FSH activity per vial	= 75.072 IU/vial Basis B04	71.25 to 78.75 Unit: IU/vial	M04 PASS C02
11 / LH activity per vial	= 75.13 IU/vial Basis B04	71.25 to 78.75 Unit: IU/vial	M04 PASS C02
T04 / Blend composition			
06 / FSH activity component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
07 / FSH activity component content	= 75.072 IU/vial Basis B05	71.25 to 78.75 Unit: IU/vial	M05 PASS C02
12 / LH activity component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
13 / LH activity component content	= 75.13 IU/vial Basis B05	71.25 to 78.75 Unit: IU/vial	M05 PASS C02
T05 / Related substances and degradants			
04 / New unexplained chromatographic signal outside defined fingerprint	= 0.035 % total fingerprint response Basis B03	<= 0.1 Unit: % total fingerprint response	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T06 / Water content			
17 / Residual water	= 0.547 % w/w finished fill Basis B10	<= 2 Unit: % w/w finished fill	M07 PASS C02
T07 / Counterions and associated species			
18 / Applicability decision	Not applicable — No fixed counterion salt is assigned in this formulation; vehicle ions and intentional metal complexes are treated by their component specifications. Unit: qualitative Basis B06	Same as reported result Unit: qualitative Basis B07	M08 N/A — justified C05
T08 / Residual solvents			
19 / Methanol	= 20.085 ug/g finished fill Basis B11	<= 3000 Unit: ug/g finished fill	M09 PASS C06
20 / Acetonitrile	= 8.75 ug/g finished fill Basis B11	<= 410 Unit: ug/g finished fill	M09 PASS C07
21 / Dichloromethane	= 3.366 ug/g finished fill Basis B11	<= 600 Unit: ug/g finished fill	M09 PASS C08
22 / N, N-dimethylformamide	= 4.209 ug/g finished fill Basis B11	<= 880 Unit: ug/g finished fill	M09 PASS C09
23 / Ethanol	= 35.033 ug/g finished fill Basis B11	<= 5000 Unit: ug/g finished fill	M09 PASS C06
24 / Acetone	= 12.922 ug/g finished fill Basis B11	<= 5000 Unit: ug/g finished fill	M09 PASS C09
25 / Ethyl acetate	= 9.07 ug/g finished fill Basis B11	<= 5000 Unit: ug/g finished fill	M09 PASS C09
26 / Toluene	= 1.621 ug/g finished fill Basis B11	<= 890 Unit: ug/g finished fill	M09 PASS C10
27 / n-Hexane	= 1.159 ug/g finished fill Basis B11	<= 290 Unit: ug/g finished fill	M09 PASS C10
28 / Benzene	= 0.085 ug/g finished fill Basis B11	<= 2 Unit: ug/g finished fill	M09 PASS C11

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T09 / Elemental impurities			
29 / Lead	= 0.0113 ug/g finished fill Basis B12	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
30 / Cadmium	= 0.0074 ug/g finished fill Basis B12	<= 0.2 Unit: ug/g finished fill	M10 PASS C12
31 / Arsenic	= 0.0185 ug/g finished fill Basis B12	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
32 / Mercury	= 0.0056 ug/g finished fill Basis B12	<= 0.1 Unit: ug/g finished fill	M10 PASS C12
33 / Cobalt	= 0.021 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
34 / Vanadium	= 0.024 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
35 / Nickel	= 0.0382 ug/g finished fill Basis B12	<= 2 Unit: ug/g finished fill	M10 PASS C12
36 / Palladium	= 0.0103 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
37 / Platinum	= 0.0091 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
38 / Rhodium	= 0.0071 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
39 / Ruthenium	= 0.0084 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
40 / Iridium	= 0.0056 ug/g finished fill Basis B12	<= 1 Unit: ug/g finished fill	M10 PASS C12
T10 / Sterility test			
45 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B17	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
46 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
47 / Bacterial endotoxins	<0.025 EU/vial Basis B19	<= 0.1 Unit: EU/vial	M15 PASS C14
T12 / Microbial enumeration			
48 / TAMC	<1 CFU/g finished fill Basis B20	<= 100 Unit: CFU/g finished fill	M16 PASS C15
49 / TYMC	<1 CFU/g finished fill Basis B20	<= 10 Unit: CFU/g finished fill	M16 PASS C15
50 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
51 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
52 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
53 / Salmonella species	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
54 / Candida albicans	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
T13 / pH and analytical solution			
41 / pH of specified buffered analytical solution	= 4.79 pH Basis B13	4.1 to 5.5 Unit: pH	M11 PASS C02
T14 / Excipients and preservatives			
42 / Trehalose excipient	= 5.004 mg/vial Basis B14	4.75 to 5.25 Unit: mg/vial	M12 PASS C02
T15 / Unit uniformity			
08 / FSH activity individual-unit mean	= 100.096 % label claim Basis B06	98 to 102 Unit: % label claim Basis B07	M06 PASS C04

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
09 / FSH activity acceptance value (n=10)	= 0.8458 % label claim Basis B08	<= 15 Unit: % label claim	M06 PASS C04
10 / FSH activity individual-unit RSD	= 0.3521 % Basis B09	<= 2 Unit: %	M06 PASS C04
14 / LH activity individual-unit mean	= 100.173 % label claim Basis B06	98 to 102 Unit: % label claim Basis B07	M06 PASS C04
15 / LH activity acceptance value (n=10)	= 0.8458 % label claim Basis B08	<= 15 Unit: % label claim	M06 PASS C04
16 / LH activity individual-unit RSD	= 0.3518 % Basis B09	<= 2 Unit: %	M06 PASS C04
T16 / Biological activity			
55 / FSHR relative potency	= 100.096 % reference response potency Basis B22	90 to 110 Unit: % reference response potency	M17 PASS C02
56 / LHCGR relative potency	= 100.173 % reference response potency Basis B22	90 to 110 Unit: % reference response potency	M17 PASS C02
T17 / Protein and conjugate characterization			
57 / Size-exclusion main defined population	= 99.91 % SEC response Basis B23	99.7 to 100 Unit: % SEC response	M18 PASS C02
58 / High molecular weight aggregate fraction	= 0.045 % SEC response Basis B06	<= 0.1 Unit: % SEC response Basis B07	M18 PASS C02
59 / Low molecular weight non-reference fraction	= 0.045 % SEC response Basis B06	<= 0.1 Unit: % SEC response Basis B07	M18 PASS C02
60 / Orthogonal construct/fingerprint mapping	Conforms to explicit reference specification Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M18 PASS C01
63 / Released N-glycan composition-profile cosine similarity	= 1 similarity0-1 Numeric value: 0.9999997294317454 Basis B27	0.995 to 1 Unit: similarity0-1	M20 PASS C02
64 / hCG-fraction O-glycan composition-profile recovery	= 100 % assigned reference fractions Basis B28	98 to 102 Unit: % assigned reference fractions	M21 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
65 / Nonreducing CE-SDS intended chain-population fraction	= 99.85 % integrated CE-SDS area Basis B29	99.7 to 100 Unit: % integrated CE-SDS area	M22 PASS C02
66 / Reducing CE-SDS intended chain-population fraction	= 99.85 % integrated CE-SDS area Basis B29	99.7 to 100 Unit: % integrated CE-SDS area	M22 PASS C02
T18 / Process impurities			
61 / Residual source-process protein impurities	= 2.1 ng/vial Basis B25	<= 100 Unit: ng/vial	M19 PASS C17
62 / Residual source DNA	= 0.012 ng/vial Basis B26	<= 1 Unit: ng/vial	M19 PASS C18
T19 / Particles and container closure			
67 / Subvisible particles >= 10um	= 21 particles/container Basis B30	<= 6000 Unit: particles/container	M23 PASS C19
68 / Subvisible particles >= 25um	= 2 particles/container Basis B30	<= 600 Unit: particles/container	M23 PASS C19
69 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B31	Conforms to the specified acceptance criterion Unit: qualitative	M23 PASS C20
T20 / Stability observations			
70 / Reported 6 month assay retention	= 99.9101 % of initial assay Basis B32	98 to 102 Unit: % of initial assay	M24 PASS C02
71 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B32	Conforms to the specified acceptance criterion Unit: qualitative	M24 PASS C01
T21 / Appearance and physical inspection			
43 / Appearance	white to off-white; uniform lyophilized cake Unit: qualitative Basis B15	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
44 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B16	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01

Method reference

The keys below identify the methods referenced in the result tables.

Key / method ID	Method	Technique
M01 M-T01-DEFAULT	Orthogonal chemical/structural identity	LC-HRMS/MS plus sequence/connectivity-sensitive reference comparison
M02 M-T02-DEFAULT	Chromatographic purity	RP-UPLC DAD; SEC for protein size species; HILIC/CAD for nonchromophoric analytes
M03 M-T05-DEFAULT	Related substances	Stability-indicating LC integration; orthogonal size/charge separation for biologics
M04 M-T03-BIOACTIVITY	Gonadotropin activity content against an IU-assigned reference	Receptor-specific relative biological-potency calibration and IU accounting
M05 M-T04-DEFAULT	Component-resolved blend assay	Separate calibrated selective assay for every declared component
M06 M-T15-DEFAULT	Individual-unit uniformity	Ten separate unit preparations and fill measurements
M07 M-T06-KF	Residual formulation water on a defined mass basis	Coulometric Karl Fischer with oven transfer
M08 M-T07-DEFAULT	Counterion composition	Ion chromatography and stoichiometric accounting
M09 M-T08-DEFAULT	Residual solvent panel	headspace GC-MS
M10 M-T09-DEFAULT	Elemental impurity panel	ICP-MS
M11 M-T13-DEFAULT	pH and solution state	Calibrated potentiometry
M12 M-T14-DEFAULT	Excipients/preservatives	Component-specific quantitative LC/CAD or formulation identity
M13 M-T21-DEFAULT	Appearance	Controlled visual examination
M14 M-T10-DEFAULT	Sterility observations in two media with matrix-specific preparation	Membrane filtration/rinsing or neutralized direct inoculation for Lemon dispersion
M15 M-T11-DEFAULT	Bacterial endotoxins	Recombinant factor C fluorometric assay
M16 M-T12-DEFAULT	Microbial enumeration/organisms	Membrane filtration enumeration and enrichment
M17 M-T16-DEFAULT	Functional biological activity	Reference-relative concentration-response assay
M18 M-T17-DEFAULT	Protein/conjugate characterization	SEC-MALS, CE-SDS, peptide mapping, glycan/PEG profiling

Key / method ID	Method	Technique
M19 M-T18-DEFAULT	Biological process impurity panel	Host/process-specific ELISA and qPCR
M20 M-T17-GLYCAN-COMPOSITION-PROFILE	Released N-glycan composition-profile comparison	PNGase-F release with composition-resolved, response-calibrated LC-MS
M21 M-T17-HCG-O-GLYCAN-PROFILE	hCG beta-contributing O-glycan composition profile	C-terminal hCG beta glycopeptide LC-MS/MS with desialylation controls
M22 M-T17-PROTEIN-CHAIN-PROFILE	Reference-defined reduced/nonreducing protein-chain populations	CE-SDS with independent chain-reference migration and subunit identity comparison
M23 M-T19-DEFAULT	Particles and package integrity	Light obscuration plus vacuum decay
M24 M-T20-DEFAULT	Stability observation	Time-zero/1/3/6-month trend

Analytical detail appendix

Basis keys preserve the exact analytical scope of each result. Detection limits and sampling context are reported separately from measured values. N/A limits are not numerical detection limits and are omitted from the context key.

Result and criterion bases

Key	Basis
B01	spectrum/peptide-map comparison; score is not proof of stereochemistry
B02	Fingerprint similarity, not chemical purity percentage
B03	Aggregate non-reference signal; not mass fraction or component purity
B04	Assigned against a activity reference; IU is not converted to milligrams
B05	Same independent component assay as T03, not a second independent test
B06	specified sample/form only
B07	material-specific limit
B08	AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5
B09	Precision criterion for the listed specification, independently of AV
B10	Water as percentage of total net formulation, not peptide area purity
B11	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B12	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B13	1.000 mg active/mL in 25mM acetate buffer, pH4.80,25.0C; buffer-solution compatibility is not the pH of dry material
B14	Explicit stabilizer amount; biological protein mass remains independent of IU
B15	Three containers under diffuse white illumination
B16	Visual observation only; subvisible particles reported separately
B17	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B18	SCDM20-25C; tested units only; no sterility assurance level assigned
B19	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B20	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B21	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B22	Relative to the specified reference response; activity units and mass units are evaluated separately. Method validation is not asserted by this report.
B23	Same primary SEC population result as T02 for proteins; orthogonal size separation for PEG/mixtures. Includes expected biological heterogeneity.
B24	Identity Reference defines construct, termini, and mixture caveats; no raw mass spectrum or gel image exists
B25	urinary-source gonadotropin process; source-specific assay. For hydrolysates, intact source proteins outside the target digest are measured by selective separation; intended peptides are not HCP impurities.
B26	Source-specific qPCR in process; extraction recovery demonstrated only
B27	Cosine similarity of complete response-corrected fraction vectors to explicit reference; no site/linkage assignment
B28	Separate35:65 mono-/disialylated Hex1HexNAc1 composition profile; independent of N-glycan table

Key	Basis
B29	Protein-specific reference profile; hCG/HMG expected alpha/beta subunits are intended species, not degraded monomer
B30	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B31	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B32	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.

Sampling and detection context

Key	Reported context
C01	Analytical replicates: 2; Statistic type: individual/qualitative observation; Units sampled: 3; Units type: finished containers
C02	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers
C03	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.002 % total fingerprint response; LOQ: 0.005 % total fingerprint response
C04	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 10; Units type: finished containers
C05	Analytical replicates: 0; Statistic type: individual/qualitative observation; Units sampled: 0; Units type: finished containers
C06	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 ug/g finished fill; LOQ: 3 ug/g finished fill
C07	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.3 ug/g finished fill; LOQ: 1 ug/g finished fill
C08	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.2 ug/g finished fill; LOQ: 0.6 ug/g finished fill
C09	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.5 ug/g finished fill; LOQ: 1.5 ug/g finished fill
C10	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.1 ug/g finished fill; LOQ: 0.3 ug/g finished fill
C11	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 ug/g finished fill; LOQ: 0.03 ug/g finished fill
C12	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.0005 ug/g finished fill; LOQ: 0.002 ug/g finished fill
C13	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 20; Units type: finished containers
C14	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 EU/vial; LOQ: 0.025 EU/vial
C15	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 CFU/g finished fill; LOQ: 1 CFU/g finished fill
C16	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 1; Units type: finished containers
C17	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.2 ng/vial; LOQ: 0.6 ng/vial
C18	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.001 ng/vial; LOQ: 0.003 ng/vial
C19	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers

Key	Reported context
C20	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 10; Units type: finished containers

Supporting analytical details

01 / Orthogonal identity against specified reference

Field	Reported value	Unit / note
neutral average mass	Not assigned: construct/distribution or no supported unique species	Da or explicit reason
neutral monoisotopic mass	Not assigned — see component-specific HRMS records; a reference mass is not a measured neutral mass	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
observed mz	Not assigned — heterogeneous construct or no defined ion; orthogonal identity documented instead	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
mass tolerance	+/-5 ppm for an explicitly defined monoisotopic ion; not 5 Da.	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
reduced deglycosylated or intact	Intact specified parent for defined compounds; glycoproteins and PEG retain the specified population heterogeneity. No single exact intact glycoprotein mass is invented.	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
stereochemistry method	Component-specific chiral amino acid analysis or orthogonal structure comparison, where applicable; HRMS cannot distinguish stereoisomers.	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
identity standard traceability	RS-2630; internal standard, not a purchased certified reference material	text

08 / FSH activity individual-unit mean

Field	Reported value	Unit / note
physical unit count	1	Explicit context; see value Method and sample context; reference facts are in Identity Reference.

17 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.005500085467507	factor For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor.

47 / Bacterial endotoxins

Field	Reported value	Unit / note
dilution factor	5	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
maximum valid dilution if used	20	Explicit context; see value Method and sample context; reference facts are in Identity Reference.

55 / FSHR relative potency

Field	Reported value	Unit / note
biological replicates	3	Explicit context; see value Method and sample context; reference facts are in Identity Reference.

67 / Subvisible particles >= 10um

Field	Reported value	Unit / note
packaging sample count	10	Explicit context; see value Method and sample context; reference facts are in Identity Reference.

END OF REPORT

Apex Laboratory | APX-COA-2026-0408-H | APX-2026-0408-H