



CERTIFICATE OF ANALYSIS

IGF-1 LR3

1 mg

LOT NUMBER

APX-2026-0520-I

REPORT NUMBER

APX-COA-2026-0520-I

COA ISSUE DATE

2026-05-20

COMPOUND REFERENCE

Material family
protein or glycoprotein

Reference formula

$C_{400}H_{619}N_{111}O_{115}S_9$

Average mass

9111.554 Da

Monoisotopic mass

9105.34873126 Da

MATERIAL & COMPOSITION

Nominal component amounts

IGF-1 LR3: 1 mg

Recorded storage

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

Formula and neutral masses describe the stated reference species. Counterions, solvates, formulation and measured ions retain their own reporting basis.

RECORDED RESULTS

IGF-1 LR3

Purity

% integrated detector area

99.917%

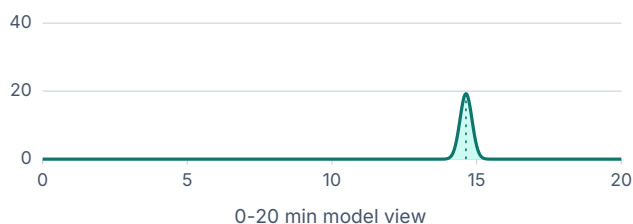
Active content

0.99947 mg/vial

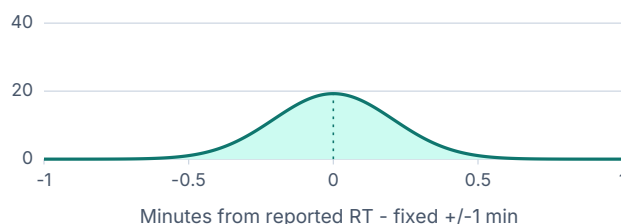
ESTIMATED PEAK PROFILE

Reported RT: 14.631 min

Modeled area density (10⁶ counts/min)



Reported integrated area: 9,991,700 counts



Gaussian model; N = 5,000 assumed. Width and height estimated; not detector measurements.

69 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 2026-05-20

ONLINE REPORT

Scan to view this record
and download the PDF.



02 Contamination & microbiology

Metals, solvents and microbial results

03+ Complete assay results

Methods, specifications and analytical context

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
59 / IGF-1 LR3: Leu D fraction	= 0.02 mol% of selected amino acid Basis B29	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C19
60 / IGF-1 LR3 Native disulfide-oxidized HRMS mass error	= 0.75 ppm Basis B30	-5 to 5 Unit: ppm	M21 PASS C02
61 / IGF-1 LR3 Fully reduced six thiols HRMS mass error	= 0.75 ppm Basis B30	-5 to 5 Unit: ppm	M21 PASS C02
62 / IGF-1 LR3 Fully reduced plus six carbamidomethyl cysteines HRMS mass error	= 0.75 ppm Basis B30	-5 to 5 Unit: ppm	M21 PASS C02
T02 / Chromatographic purity			
03 / IGF-1 LR3 chromatographic purity	= 99.917 % integrated detector area Basis B02	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
08 / IGF-1 LR3 active content	= 0.99947 mg/vial Basis B05	0.98 to 1.02 Unit: mg/vial	M04 PASS C02
09 / IGF-1 LR3 label claim assay	= 99.947 % label claim Basis B06	98 to 102 Unit: % label claim	M04 PASS C02
T04 / Blend composition			
13 / Applicability decision	Not applicable — One declared active or a water/preservative reagent. Preservative is separately quantified under T14; there is no multi-active blend ratio. Unit: qualitative Basis B07	Same as reported result Unit: qualitative Basis B08	M06 N/A — justified C05

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T05 / Related substances and degradants			
04 / IGF-1 LR3 Unknown U1	= 0.042 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
05 / IGF-1 LR3 Unknown U2	= 0.025 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
06 / IGF-1 LR3 Unknown U3	= 0.016 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / IGF-1 LR3 total related peaks	= 0.083 % integrated detector area Basis B04	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
14 / Residual water	= 0.72 % w/w finished fill Basis B11	<= 2 Unit: % w/w finished fill	M07 PASS C02
T07 / Counterions and associated species			
15 / Acetate content relative to parent active mass	= 1.5 % acetate/parent mass Basis B12	0.5 to 3 Unit: % acetate/parent mass	M08 PASS C02
T08 / Residual solvents			
16 / Methanol	= 21.876 ug/g finished fill Basis B13	<= 3000 Unit: ug/g finished fill	M09 PASS C06
17 / Acetonitrile	= 7.825 ug/g finished fill Basis B13	<= 410 Unit: ug/g finished fill	M09 PASS C07
18 / Dichloromethane	= 3.506 ug/g finished fill Basis B13	<= 600 Unit: ug/g finished fill	M09 PASS C08
19 / N, N-dimethylformamide	= 3.813 ug/g finished fill Basis B13	<= 880 Unit: ug/g finished fill	M09 PASS C09
20 / Ethanol	= 40.306 ug/g finished fill Basis B13	<= 5000 Unit: ug/g finished fill	M09 PASS C06
21 / Acetone	= 12.316 ug/g finished fill Basis B13	<= 5000 Unit: ug/g finished fill	M09 PASS C09

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
22 / Ethyl acetate	= 9.363 ug/g finished fill Basis B13	<= 5000 Unit: ug/g finished fill	M09 PASS C09
23 / Toluene	= 1.678 ug/g finished fill Basis B13	<= 890 Unit: ug/g finished fill	M09 PASS C10
24 / n-Hexane	= 1.098 ug/g finished fill Basis B13	<= 290 Unit: ug/g finished fill	M09 PASS C10
25 / Benzene	= 0.082 ug/g finished fill Basis B13	<= 2 Unit: ug/g finished fill	M09 PASS C11
T09 / Elemental impurities			
26 / Lead	= 0.0122 ug/g finished fill Basis B14	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
27 / Cadmium	= 0.0074 ug/g finished fill Basis B14	<= 0.2 Unit: ug/g finished fill	M10 PASS C12
28 / Arsenic	= 0.0172 ug/g finished fill Basis B14	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
29 / Mercury	= 0.006 ug/g finished fill Basis B14	<= 0.1 Unit: ug/g finished fill	M10 PASS C12
30 / Cobalt	= 0.0208 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
31 / Vanadium	= 0.0217 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
32 / Nickel	= 0.0328 ug/g finished fill Basis B14	<= 2 Unit: ug/g finished fill	M10 PASS C12
33 / Palladium	= 0.0117 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
34 / Platinum	= 0.0086 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
35 / Rhodium	= 0.0071 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
36 / Ruthenium	= 0.0093 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
37 / Iridium	= 0.0065 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
T10 / Sterility test			
42 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B19	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
43 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B20	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
44 / Bacterial endotoxins	<0.025 EU/mg active-equivalent Basis B21	<= 0.1 Unit: EU/mg active-equivalent	M15 PASS C14
T12 / Microbial enumeration			
45 / TAMC	<1 CFU/g finished fill Basis B22	<= 100 Unit: CFU/g finished fill	M16 PASS C15
46 / TYMC	<1 CFU/g finished fill Basis B22	<= 10 Unit: CFU/g finished fill	M16 PASS C15
47 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
48 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
49 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
50 / Salmonella species	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
51 / Candida albicans	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T13 / pH and analytical solution			
38 / pH of specified buffered analytical solution	= 4.8 pH Basis B15	4.1 to 5.5 Unit: pH	M11 PASS C02
T14 / Excipients and preservatives			
39 / Trehalose content	= 5.004 mg/vial Basis B16	4.75 to 5.25 Unit: mg/vial	M12 PASS C02
T15 / Unit uniformity			
10 / IGF-1 LR3 individual-unit mean	= 99.947 % label claim Basis B07	98 to 102 Unit: % label claim Basis B08	M05 PASS C04
11 / IGF-1 LR3 acceptance value (n=10)	= 0.8458 % label claim Basis B09	<= 15 Unit: % label claim	M05 PASS C04
12 / IGF-1 LR3 individual-unit RSD	= 0.3526 % Basis B10	<= 2 Unit: %	M05 PASS C04
T16 / Biological activity			
52 / IGF1R phosphorylation assay relative potency	= 100.05 % reference response potency Basis B24	90 to 110 Unit: % reference response potency	M17 PASS C02
T17 / Protein and conjugate characterization			
53 / Size-exclusion main defined population	= 99.917 % SEC response Basis B25	99.7 to 100 Unit: % SEC response	M18 PASS C02
54 / High molecular weight aggregate fraction	= 0.041 % SEC response Basis B07	<= 0.1 Unit: % SEC response Basis B08	M18 PASS C02
55 / Low molecular weight non-reference fraction	= 0.042 % SEC response Basis B07	<= 0.1 Unit: % SEC response Basis B08	M18 PASS C02
56 / Orthogonal construct/fingerprint mapping	Conforms to explicit reference specification Unit: qualitative Basis B26	Conforms to the specified acceptance criterion Unit: qualitative	M18 PASS C01
63 / IGF-1 LR3 disulfide connectivity	Cys19-Cys61; Cys31-Cys74; Cys60-Cys65 match in mapping Unit: qualitative Basis B31	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T18 / Process impurities			
57 / Residual source-process protein impurities	= 2.1 ng/mg assigned target material Basis B27	<= 100 Unit: ng/mg assigned target material	M19 PASS C17
58 / Residual source DNA	= 0.012 ng/vial Basis B28	<= 1 Unit: ng/vial	M19 PASS C18
T19 / Particles and container closure			
64 / Subvisible particles >= 10um	= 21 particles/container Basis B32	<= 6000 Unit: particles/container	M23 PASS C19
65 / Subvisible particles >= 25um	= 2 particles/container Basis B32	<= 600 Unit: particles/container	M23 PASS C19
66 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B33	Conforms to the specified acceptance criterion Unit: qualitative	M23 PASS C20
T20 / Stability observations			
67 / Reported 6 month assay retention	= 99.91 % of initial assay Basis B34	98 to 102 Unit: % of initial assay	M24 PASS C02
68 / Reported 6 month minimum component purity	= 99.875 % integrated detector area Basis B35	99.7 to 100 Unit: % integrated detector area	M24 PASS C02
69 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B34	Conforms to the specified acceptance criterion Unit: qualitative	M24 PASS C01
T21 / Appearance and physical inspection			
40 / Appearance	white to off-white; uniform lyophilized cake Unit: qualitative Basis B17	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
41 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B18	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-SEC-UV280	Reference-defined protein size-population response purity	Size-exclusion chromatography with UV detection at 280 nm
M03 M-T05-DEFAULT	Related substances	Stability-indicating LC integration; orthogonal size/charge separation for biologics
M04 M-T03-DEFAULT	Calibrated material content	Independent quantitative LC/CAD, protein assay or bioactivity calibration for IU
M05 M-T15-DEFAULT	Individual-unit uniformity	Ten separate unit preparations and fill measurements
M06 M-T04-DEFAULT	Component-resolved blend assay	Separate calibrated selective assay for every declared component
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-T01-RESIDUE-CHIRAL-LC	Diagnostic amino-acid absolute-configuration/composition check	Marfey-type diastereomeric derivatization LC-MS with authentic L/D references
M21 M-T01-LR3-REDOX-MS	IGF-1 LR3 intact oxidized, reduced and alkylated identity	Independent redox-preparation LC-HRMS, [M+9H] ⁹⁺
M22 M-T17-LR3-DISULFIDE-MAP	IGF-1 LR3 pairwise disulfide connectivity	Disulfide-linked peptide/fragment mapping with reduction and alkylation controls
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	Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation
B03	Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only
B04	Sum of U1+U2+U3; purity plus related areas = 100%
B05	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B06	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B07	specified sample/form only
B08	material-specific limit
B09	AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5
B10	Precision criterion for the listed specification, independently of AV
B11	Water as percentage of total net formulation, not peptide area purity
B12	Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion.
B13	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B14	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B15	1.000 mg active/mL in 25mM acetate buffer, pH4.80,25.0C; buffer-solution compatibility is not the pH of dry material
B16	Separate excipient-specific assay; not label active
B17	Three containers under diffuse white illumination
B18	Visual observation only; subvisible particles reported separately
B19	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B20	SCDM20-25C; tested units only; no sterility assurance level assigned
B21	Sample reporting limit after 1:5 dilution; threshold is and not based on administration route/dose
B22	Zero colonies observed from 1g or 1 mL equivalent filter; report <1, not exact absence
B23	Specified-organism enrichment in explicit 1g/1 mL scope; not a universal pharmacopeial panel
B24	Relative to the specified reference response; activity units and mass units are evaluated separately. Method validation is not asserted by this report.
B25	Same primary SEC population result as T02 for proteins; orthogonal size separation for PEG/mixtures. Includes expected biological heterogeneity.
B26	Identity Reference defines construct, termini, and mixture caveats; no raw mass spectrum or gel image exists
B27	E.coli recombinant expression process; source-specific assay. For hydrolysates, intact source proteins outside the target digest are measured by selective separation; intended peptides are not HCP impurities.

Key	Basis
B28	Source-specific qPCR in process; extraction recovery demonstrated only
B29	Residue-specific target from explicit structure. Mixed D/L ratios are intentional where stated; not total chemical-purity percentage.
B30	Calculated directly from 83-residue sequence and three disulfides; reduced/alkylated preparations independent
B31	LR3 residue numbering; intact mass, full reduction and pairwise localization are separate identity controls
B32	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B33	method vacuum-decay threshold 0.20 kPa/60s; 5 µm positive defect control. No universal leakage-to-sterility equivalence.
B34	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B35	Separate endpoint; no shelf-life claim

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 % integrated detector area; LOQ: 0.005 % integrated detector area
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/mg active-equivalent; LOQ: 0.025 EU/mg active-equivalent
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/mg assigned target material; LOQ: 0.6 ng/mg assigned target material
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	9111.554	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-2686; internal standard, not a purchased certified reference material	text

03 / IGF-1 LR3 chromatographic purity

Field	Reported value	Unit / note
main peak retention time	14.631	min
main peak area	9991700	counts
total integrated area	10000000	counts

08 / IGF-1 LR3 active content

Field	Reported value	Unit / note
sample preparation volume	1	mL
dilution factor	10	fold

10 / IGF-1 LR3 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.

14 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.007252215954875	factor For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor.

15 / Acetate content relative to parent active mass

Field	Reported value	Unit / note
counterion molar ratio	2.31477051012804	mol acetate/mol parent

44 / 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.

52 / IGF1R phosphorylation assay relative potency

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

64 / 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-2026-0520-I | APX-2026-0520-I