CERTIFICATE OF ANALYSIS

Lipo-C 10 ml

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0517-L	APX-COA-2026-0517-L	2026-05-17

NOMINAL COMPOSITION

L-methionine: 250 mg; myo-inositol: 500 mg; Choline chloride: 500 mg

aqueous liquid in vial

RECORDED RESULTS	Purity % integrated detector area	Concentration
L-methionine	99.938%	25.015 mg/mL
myo-inositol	99.922%	49.996 mg/mL
Choline chloride	99.913%	50.0875 mg/mL

ESTIMATED COMPONENT REFERENCE PROFILES

Separate reference assays, not a blend chromatogram. N = 5,000 assumed; widths/heights estimated.

L-methionine

No retention reference recorded

myo-inositol

No retention reference recorded

Choline chloride

No retention reference recorded

94 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 2026-05-17

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
81 / L-Methionine component-specific HRMS mass error	= 0.00997 ppm Basis B25	-5 to 5 Unit: ppm	M20 PASS C17
83 / myo-Inositol component-specific HRMS mass error	= 0.05006 ppm Basis B27	-5 to 5 Unit: ppm	M20 PASS C17
85 / Choline chloride component-specific HRMS mass error	= 0.09002 ppm Basis B29	-5 to 5 Unit: ppm	M20 PASS C17
T02 / Chromatographic purity			
03 / L-methionine chromatographic purity	= 99.938 % integrated detector area Basis B02	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
08 / myo-inositol chromatographic purity	= 99.922 % integrated detector area Basis B02	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
13 / Choline chloride chromatographic purity	= 99.913 % integrated detector area Basis B02	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
18 / L-methionine active content	= 250.15 mg/vial Basis B05	245 to 255 Unit: mg/vial	M04 PASS C02
19 / L-methionine label claim assay	= 100.06 % label claim Basis B06	98 to 102 Unit: % label claim	M04 PASS C02
20 / L-methionine concentration	= 25.015 mg/mL Basis B07	24.5 to 25.5 Unit: mg/mL	M04 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
25 / myo-inositol active content	= 499.96 mg/vial Basis B05	490 to 510 Unit: mg/vial	M04 PASS C02
26 / myo-inositol label claim assay	= 99.992 % label claim Basis B06	98 to 102 Unit: % label claim	M04 PASS C02
27 / myo-inositol concentration	= 49.996 mg/mL Basis B07	49 to 51 Unit: mg/mL	M04 PASS C02
32 / Choline chloride active content	= 500.875 mg/vial Basis B05	490 to 510 Unit: mg/vial	M04 PASS C02
33 / Choline chloride label claim assay	= 100.175 % label claim Basis B06	98 to 102 Unit: % label claim	M04 PASS C02
34 / Choline chloride concentration	= 50.0875 mg/mL Basis B07	49 to 51 Unit: mg/mL	M04 PASS C02
T04 / Blend composition			
21 / L-methionine component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
22 / L-methionine component content	= 250.15 mg/vial Basis B08	245 to 255 Unit: mg/vial	M05 PASS C02
28 / myo-inositol component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
29 / myo-inositol component content	= 499.96 mg/vial Basis B08	490 to 510 Unit: mg/vial	M05 PASS C02
35 / Choline chloride component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
36 / Choline chloride component content	= 500.875 mg/vial Basis B08	490 to 510 Unit: mg/vial	M05 PASS C02
82 / L-Methionine isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B26	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
84 / myo-Inositol isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01
86 / Choline chloride isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B30	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01
T05 / Related substances and degradants			
04 / L-methionine Unknown U1	= 0.031 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
05 / L-methionine Unknown U2	= 0.019 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
06 / L-methionine Unknown U3	= 0.012 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / L-methionine total related peaks	= 0.062 % integrated detector area Basis B04	<= 0.3 Unit: % integrated detector area	M03 PASS C02
09 / myo-inositol Unknown U1	= 0.039 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
10 / myo-inositol Unknown U2	= 0.023 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
11 / myo-inositol Unknown U3	= 0.016 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
12 / myo-inositol total related peaks	= 0.078 % integrated detector area Basis B04	<= 0.3 Unit: % integrated detector area	M03 PASS C02
14 / Choline chloride Unknown U1	= 0.043 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
15 / Choline chloride Unknown U2	= 0.026 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
16 / Choline chloride Unknown U3	= 0.018 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
17 / Choline chloride total related peaks	= 0.087 % integrated detector area Basis B04	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
40 / Applicability decision	Not applicable — Water is the formulation vehicle; residual-moisture percentage would misdescribe an aqueous formulation. Vehicle quantity is specified separately. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M07 N/A — justified C05
T07 / Counterions and associated species			
41 / Chloride identity and stoichiometric consistency	Conforms to specified chloride-containing component Unit: qualitative Basis B13	Conforms to the specified acceptance criterion Unit: qualitative	M08 PASS C01
87 / Choline chloride: independently assayed chloride	= 127.174 mg Cl/vial Numeric value: 127.173892 Basis B31	124.63 to 129.717 Lower: 124.6304138018756 Upper: 129.7173694672583 Unit: mg Cl/vial	M22 PASS C02
88 / Choline:chloride stoichiometric consistency	= 1 mol chloride/mol choline Basis B32	0.98 to 1.02 Unit: mol chloride/mol choline	M22 PASS C02
T08 / Residual solvents			
42 / Methanol	= 21.738 ug/mL formulation Basis B14	<= 3000 Unit: ug/mL formulation	M09 PASS C06
43 / Acetonitrile	= 8.76 ug/mL formulation Basis B14	<= 410 Unit: ug/mL formulation	M09 PASS C07
44 / Dichloromethane	= 3.562 ug/mL formulation Basis B14	<= 600 Unit: ug/mL formulation	M09 PASS C08
45 / N, N-dimethylformamide	= 3.811 ug/mL formulation Basis B14	<= 880 Unit: ug/mL formulation	M09 PASS C09
46 / Ethanol	= 37.858 ug/mL formulation Basis B14	<= 5000 Unit: ug/mL formulation	M09 PASS C06
47 / Acetone	= 12.51 ug/mL formulation Basis B14	<= 5000 Unit: ug/mL formulation	M09 PASS C09

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
48 / Ethyl acetate	= 9.308 ug/mL formulation Basis B14	<= 5000 Unit: ug/mL formulation	M09 PASS C09
49 / Toluene	= 1.893 ug/mL formulation Basis B14	<= 890 Unit: ug/mL formulation	M09 PASS C10
50 / n-Hexane	= 1.117 ug/mL formulation Basis B14	<= 290 Unit: ug/mL formulation	M09 PASS C10
51 / Benzene	= 0.084 ug/mL formulation Basis B14	<= 2 Unit: ug/mL formulation	M09 PASS C11
T09 / Elemental impurities			
52 / Lead	= 0.0129 ug/mL formulation Basis B15	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
53 / Cadmium	= 0.0079 ug/mL formulation Basis B15	<= 0.2 Unit: ug/mL formulation	M10 PASS C12
54 / Arsenic	= 0.019 ug/mL formulation Basis B15	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
55 / Mercury	= 0.0065 ug/mL formulation Basis B15	<= 0.1 Unit: ug/mL formulation	M10 PASS C12
56 / Cobalt	= 0.0207 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
57 / Vanadium	= 0.0222 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
58 / Nickel	= 0.0383 ug/mL formulation Basis B15	<= 2 Unit: ug/mL formulation	M10 PASS C12
59 / Palladium	= 0.0101 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
60 / Platinum	= 0.0081 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
61 / Rhodium	= 0.0065 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
62 / Ruthenium	= 0.0083 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
63 / Iridium	= 0.0057 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
T10 / Sterility test			
68 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B20	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
69 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
70 / Bacterial endotoxins	<0.025 EU/mL Basis B22	<= 0.1 Unit: EU/mL	M15 PASS C14
T12 / Microbial enumeration			
71 / TAMC	<1 CFU/mL Basis B23	<= 100 Unit: CFU/mL	M16 PASS C15
72 / TYMC	<1 CFU/mL Basis B23	<= 10 Unit: CFU/mL	M16 PASS C15
73 / Escherichia coli	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
74 / Staphylococcus aureus	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
75 / Pseudomonas aeruginosa	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
76 / Salmonella species	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
77 / Candida albicans	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T13 / pH and analytical solution			
64 / pH of native liquid	= 5.51 pH Basis B16	4.8 to 6.2 Unit: pH	M11 PASS C02
T14 / Excipients and preservatives			
65 / Vehicle and preservative composition	Water q.s. declared volume; no added preservative Unit: qualitative Basis B17	Conforms to the specified acceptance criterion Unit: qualitative	M12 PASS C01
T15 / Unit uniformity			
23 / L-methionine individual-unit mean	= 100.06 % label claim Basis B09	98 to 102 Unit: % label claim Basis B10	M06 PASS C04
24 / L-methionine individual-unit RSD	= 0.3522 % Basis B11	<= 2 Unit: %	M06 PASS C04
30 / myo-inositol individual-unit mean	= 99.992 % label claim Basis B09	98 to 102 Unit: % label claim Basis B10	M06 PASS C04
31 / myo-inositol individual-unit RSD	= 0.3524 % Basis B11	<= 2 Unit: %	M06 PASS C04
37 / Choline chloride individual-unit mean	= 100.175 % label claim Basis B09	98 to 102 Unit: % label claim Basis B10	M06 PASS C04
38 / Choline chloride individual-unit RSD	= 0.3518 % Basis B11	<= 2 Unit: %	M06 PASS C04
39 / Mean extractable volume	= 10 mL/container Basis B12	9.9 to 10.2 Unit: mL/container	M06 PASS C04
T16 / Biological activity			
78 / Applicability decision	Not applicable — No qualified, reference-traceable potency endpoint is established for this selected identity. Identity/content data cannot justify an invented biological potency value; exploratory biological activity would require a separately defined assay. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M17 N/A — justified C05

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T17 / Protein and conjugate characterization			
79 / Applicability decision	Not applicable — No recombinant protein, polymer conjugate or complex mixture for this material. Defined synthetic peptide identity is characterized under T01; GHK copper speciation, when relevant, is explicit. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M18 N/A — justified C05
T18 / Process impurities			
80 / Applicability decision	Not applicable — chemical synthesis without cell/tissue manufacturing inputs; HCP, host DNA and Protein A are not relevant. Chemical process impurities are covered under T05/T08/T09. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M19 N/A — justified C05
T19 / Particles and container closure			
89 / Subvisible particles >= 10um	= 21 particles/container Basis B33	<= 6000 Unit: particles/container	M23 PASS C17
90 / Subvisible particles >= 25um	= 2 particles/container Basis B33	<= 600 Unit: particles/container	M23 PASS C17
91 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B34	Conforms to the specified acceptance criterion Unit: qualitative	M23 PASS C18
T20 / Stability observations			
92 / Reported 6 month assay retention	= 99.91 % of initial assay Basis B35	98 to 102 Unit: % of initial assay	M24 PASS C02
93 / Reported 6 month minimum component purity	= 99.871 % integrated detector area Basis B36	99.7 to 100 Unit: % integrated detector area	M24 PASS C02
94 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M24 PASS C01

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T21 / Appearance and physical inspection			
66 / Appearance	colorless; clear solution Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
67 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B19	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-HILIC-CAD	Nonchromophoric component chromatographic response purity	HILIC with charged aerosol detection
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-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-DEFAULT	Water	Coulometric Karl Fischer
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-BLEND-SELECTIVE-HRMS	Component-specific exact-ion identity for the declared blend	Component-selective LC-HRMS with independently defined molecular ions
M21 M-T04-BLEND-SELECTIVE-IDENTITY	Identity definition for each selectively assayed blend component	Component-selective reference comparison with orthogonal identity controls
M22 M-T07-CHLORIDE-IC	Intentional chloride content and choline/chloride molar consistency	Independent chloride ion chromatography with separate choline-cation assay
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	Amount per nominal 10 mL fill
B08	Same independent component assay as T03, not a second independent test
B09	specified sample/form only
B10	material-specific limit
B11	Precision criterion for the listed specification, independently of AV
B12	fill specification; no injection volume recommendation
B13	Choline chloride; chloride is intentional, not a toxic elemental impurity
B14	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B15	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B16	As supplied,25.0C; buffer-solution compatibility is not the pH of dry material
B17	Explicit formulation choice, not a statement about actual catalog formulation
B18	Three containers under diffuse white illumination
B19	Visual observation only; subvisible particles reported separately
B20	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B21	SCDM20-25C; tested units only; no sterility assurance level assigned
B22	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B23	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B24	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B25	[M+H]+; exact ion definition independent of whole-blend identity. Reference formula C5H11NO2S.
B26	(S)-2-amino-4-(methylthio)butanoic acid; L-methionine, unoxidized thioether. Reference HILIC retention and chiral amino-acid assay; distinguish methionine sulfoxide/sulfone and D-methionine.
B27	[M+Na]+; exact ion definition independent of whole-blend identity. Reference formula C6H12O6.
B28	myo-Inositol stereoisomer of cyclohexane-1,2,3,4,5,6-hexol; not D-chiro-inositol. Reference HILIC retention and solution NMR stereoisomer fingerprint; sodium adduct alone cannot distinguish inositol isomers.

Key	Basis
B29	[C5H14NO]+ (choline cation; chloride excluded); exact ion definition independent of whole-blend identity. Reference formula C5H14ClNO.
B30	2-Hydroxy-N, N, N-trimethylethanaminium chloride: one choline cation and one chloride anion. Choline-cation identity plus independent chloride IC assay; neither a protonated intact salt nor chloride-free mass is the weighed salt content.
B31	Independent chloride IC result compared with measured choline chloride content; mass fraction uses Cl35.45 / salt139.62. Chloride is intentional.
B32	Ratio of independent cation/anion assay means; recovery-controlled measurement.
B33	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B34	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B35	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B36	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/mL formulation; LOQ: 3 ug/mL formulation
C07	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.3 ug/mL formulation; LOQ: 1 ug/mL formulation
C08	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.2 ug/mL formulation; LOQ: 0.6 ug/mL formulation
C09	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.5 ug/mL formulation; LOQ: 1.5 ug/mL formulation
C10	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.1 ug/mL formulation; LOQ: 0.3 ug/mL formulation
C11	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 ug/mL formulation; LOQ: 0.03 ug/mL formulation
C12	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.0005 ug/mL formulation; LOQ: 0.002 ug/mL formulation
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/mL; LOQ: 0.025 EU/mL
C15	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 CFU/mL; LOQ: 1 CFU/mL
C16	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 1; Units type: finished containers
C17	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers
C18	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-2703; internal standard, not a purchased certified reference material	text

03 / L-methionine chromatographic purity

Field	Reported value	Unit / note
main peak retention time	15.989	min
main peak area	9991300	counts
total integrated area	10000000	counts

18 / L-methionine active content

Field	Reported value	Unit / note
sample preparation volume	500	mL
dilution factor	10	fold

23 / L-methionine 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.

70 / 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.

89 / 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-2026-0517-L | APX-2026-0517-L