CERTIFICATE OF ANALYSIS

MIC Blend (Lipo C + B12) 10 mg

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0503-M	APX-COA-2026-0503-M	2026-05-03

NOMINAL COMPOSITION

L-methionine: 1.98 mg; myo-inositol: 3.96 mg; Choline chloride: 3.96 mg; Cyanocobalamin: 0.1 mg

aqueous liquid in vial

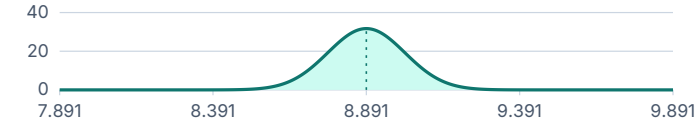
RECORDED RESULTS	Purity % integrated detector area	Concentration
L-methionine	99.871%	1.985188 mg/mL
myo-inositol	99.903%	3.962732 mg/mL
Choline chloride	99.864%	3.958218 mg/mL
Cyanocobalamin	99.918%	0.099939 mg/mL

ESTIMATED COMPONENT REFERENCE PROFILES

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

Cyanocobalamin

RT 8.891 min | 9,994,800 counts | APX-2026-0507-C



Fixed 2 min window; area density (10^6 counts/min).

L-methionine

No retention reference recorded

myo-inositol

No retention reference recorded

Choline chloride

No retention reference recorded

110 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 2026-05-03

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
Vanadium	✓ PASS
Nickel	✓ PASS
Palladium	✓ PASS
Platinum	✓ PASS
Rhodium	✓ PASS
Ruthenium	✓ PASS
Iridium	✓ PASS
Non-cobalamin cobalt fraction	✓ 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
03 / Cyanocobalamin HRMS ion mass error	= -0.973 ppm Basis B02	-5 to 5 Unit: ppm	M01 PASS C02
95 / L-Methionine component-specific HRMS mass error	= 0.00997 ppm Basis B29	-5 to 5 Unit: ppm	M21 PASS C17
97 / myo-Inositol component-specific HRMS mass error	= 0.05006 ppm Basis B31	-5 to 5 Unit: ppm	M21 PASS C17
99 / Choline chloride component-specific HRMS mass error	= 0.09002 ppm Basis B33	-5 to 5 Unit: ppm	M21 PASS C17
101 / Cyanocobalamin component-specific HRMS mass error	= 0.12998 ppm Basis B35	-5 to 5 Unit: ppm	M21 PASS C17
T02 / Chromatographic purity			
04 / L-methionine chromatographic purity	= 99.871 % integrated detector area Basis B03	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
09 / myo-inositol chromatographic purity	= 99.903 % integrated detector area Basis B03	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
14 / Choline chloride chromatographic purity	= 99.864 % integrated detector area Basis B03	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
19 / Cyanocobalamin chromatographic purity	= 99.918 % integrated detector area Basis B03	99.7 to 100 Unit: % integrated detector area	M04 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T03 / Active content and assay			
24 / L-methionine active content	= 1.98519 mg/vial Numeric value: 1.985188 Basis B06	1.9404 to 2.0196 Unit: mg/vial	M05 PASS C02
25 / L-methionine label claim assay	= 100.262 % label claim Basis B07	98 to 102 Unit: % label claim	M05 PASS C02
26 / L-methionine concentration	= 1.98519 mg/mL Numeric value: 1.985188 Basis B08	1.9404 to 2.0196 Unit: mg/mL	M05 PASS C02
31 / myo-inositol active content	= 3.96273 mg/vial Numeric value: 3.962732 Basis B06	3.8808 to 4.0392 Unit: mg/vial	M05 PASS C02
32 / myo-inositol label claim assay	= 100.069 % label claim Basis B07	98 to 102 Unit: % label claim	M05 PASS C02
33 / myo-inositol concentration	= 3.96273 mg/mL Numeric value: 3.962732 Basis B08	3.8808 to 4.0392 Unit: mg/mL	M05 PASS C02
38 / Choline chloride active content	= 3.95822 mg/vial Numeric value: 3.958218 Basis B06	3.8808 to 4.0392 Unit: mg/vial	M05 PASS C02
39 / Choline chloride label claim assay	= 99.955 % label claim Basis B07	98 to 102 Unit: % label claim	M05 PASS C02
40 / Choline chloride concentration	= 3.95822 mg/mL Numeric value: 3.958218 Basis B08	3.8808 to 4.0392 Unit: mg/mL	M05 PASS C02
45 / Cyanocobalamin active content	= 0.099939 mg/vial Basis B06	0.098 to 0.102 Unit: mg/vial	M05 PASS C02
46 / Cyanocobalamin label claim assay	= 99.939 % label claim Basis B07	98 to 102 Unit: % label claim	M05 PASS C02
47 / Cyanocobalamin concentration	= 0.099939 mg/mL Basis B08	0.098 to 0.102 Unit: mg/mL	M05 PASS C02
T04 / Blend composition			
27 / L-methionine component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M06 PASS C01

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
28 / L-methionine component content	= 1.98519 mg/vial Numeric value: 1.985188 Basis B09	1.9404 to 2.0196 Unit: mg/vial	M06 PASS C02
34 / myo-inositol component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M06 PASS C01
35 / myo-inositol component content	= 3.96273 mg/vial Numeric value: 3.962732 Basis B09	3.8808 to 4.0392 Unit: mg/vial	M06 PASS C02
41 / Choline chloride component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M06 PASS C01
42 / Choline chloride component content	= 3.95822 mg/vial Numeric value: 3.958218 Basis B09	3.8808 to 4.0392 Unit: mg/vial	M06 PASS C02
48 / Cyanocobalamin component identity	Conforms to specified component identity Unit: qualitative Basis B13	Conforms to the specified acceptance criterion Unit: qualitative	M06 PASS C01
49 / Cyanocobalamin component content	= 0.099939 mg/vial Basis B09	0.098 to 0.102 Unit: mg/vial	M06 PASS C02
96 / L-Methionine isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B30	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01
98 / myo-Inositol isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B32	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01
100 / Choline chloride isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B34	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01
102 / Cyanocobalamin isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B36	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01
T05 / Related substances and degradants			
05 / L-methionine Unknown U1	= 0.065 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
06 / L-methionine Unknown U2	= 0.039 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / L-methionine Unknown U3	= 0.025 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
08 / L-methionine total related peaks	= 0.129 % integrated detector area Basis B05	<= 0.3 Unit: % integrated detector area	M03 PASS C02
10 / myo-inositol Unknown U1	= 0.049 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
11 / myo-inositol Unknown U2	= 0.029 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
12 / myo-inositol Unknown U3	= 0.019 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
13 / myo-inositol total related peaks	= 0.097 % integrated detector area Basis B05	<= 0.3 Unit: % integrated detector area	M03 PASS C02
15 / Choline chloride Unknown U1	= 0.068 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
16 / Choline chloride Unknown U2	= 0.041 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
17 / Choline chloride Unknown U3	= 0.027 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
18 / Choline chloride total related peaks	= 0.136 % integrated detector area Basis B05	<= 0.3 Unit: % integrated detector area	M03 PASS C02
20 / Cyanocobalamin Unknown U1	= 0.041 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
21 / Cyanocobalamin Unknown U2	= 0.025 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03
22 / Cyanocobalamin Unknown U3	= 0.016 % integrated detector area Basis B04	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
23 / Cyanocobalamin total related peaks	= 0.082 % integrated detector area Basis B05	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
53 / 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 B10	Same as reported result Unit: qualitative Basis B11	M08 N/A — justified C05
T07 / Counterions and associated species			
54 / Chloride identity and stoichiometric consistency	Conforms to specified chloride-containing component Unit: qualitative Basis B15	Conforms to the specified acceptance criterion Unit: qualitative	M09 PASS C01
76 / Intentional cyanocobalamin-bound total cobalt	= 0.0043481 mg Co/vial Basis B18	0.00426116 to 0.00443509 Lower: 0.004261163381216937 Upper: 0.004435088417184975 Unit: mg Co/vial	M09 PASS C02
103 / Choline chloride: independently assayed chloride	= 1.005 mg Cl/vial Numeric value: 1.005005 Basis B37	0.984905 to 1.02511 Lower: 0.9849051105729466 Upper: 1.025105319167761 Unit: mg Cl/vial	M23 PASS C02
104 / Choline:chloride stoichiometric consistency	= 1 mol chloride/mol choline Basis B38	0.98 to 1.02 Unit: mol chloride/mol choline	M23 PASS C02
T08 / Residual solvents			
55 / Methanol	= 20.909 ug/mL formulation Basis B16	<= 3000 Unit: ug/mL formulation	M10 PASS C06
56 / Acetonitrile	= 8.668 ug/mL formulation Basis B16	<= 410 Unit: ug/mL formulation	M10 PASS C07
57 / Dichloromethane	= 3.432 ug/mL formulation Basis B16	<= 600 Unit: ug/mL formulation	M10 PASS C08
58 / N, N-dimethylformamide	= 4.088 ug/mL formulation Basis B16	<= 880 Unit: ug/mL formulation	M10 PASS C09

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
59 / Ethanol	= 35.398 ug/mL formulation Basis B16	<= 5000 Unit: ug/mL formulation	M10 PASS C06
60 / Acetone	= 10.995 ug/mL formulation Basis B16	<= 5000 Unit: ug/mL formulation	M10 PASS C09
61 / Ethyl acetate	= 8.809 ug/mL formulation Basis B16	<= 5000 Unit: ug/mL formulation	M10 PASS C09
62 / Toluene	= 1.915 ug/mL formulation Basis B16	<= 890 Unit: ug/mL formulation	M10 PASS C10
63 / n-Hexane	= 1.03 ug/mL formulation Basis B16	<= 290 Unit: ug/mL formulation	M10 PASS C10
64 / Benzene	= 0.086 ug/mL formulation Basis B16	<= 2 Unit: ug/mL formulation	M10 PASS C11
T09 / Elemental impurities			
65 / Lead	= 0.0129 ug/mL formulation Basis B17	<= 0.5 Unit: ug/mL formulation	M11 PASS C12
66 / Cadmium	= 0.0073 ug/mL formulation Basis B17	<= 0.2 Unit: ug/mL formulation	M11 PASS C12
67 / Arsenic	= 0.0195 ug/mL formulation Basis B17	<= 0.5 Unit: ug/mL formulation	M11 PASS C12
68 / Mercury	= 0.0065 ug/mL formulation Basis B17	<= 0.1 Unit: ug/mL formulation	M11 PASS C12
69 / Vanadium	= 0.0242 ug/mL formulation Basis B17	<= 1 Unit: ug/mL formulation	M11 PASS C12
70 / Nickel	= 0.0377 ug/mL formulation Basis B17	<= 2 Unit: ug/mL formulation	M11 PASS C12
71 / Palladium	= 0.0116 ug/mL formulation Basis B17	<= 1 Unit: ug/mL formulation	M11 PASS C12
72 / Platinum	= 0.0087 ug/mL formulation Basis B17	<= 1 Unit: ug/mL formulation	M11 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
73 / Rhodium	= 0.0066 ug/mL formulation Basis B17	<= 1 Unit: ug/mL formulation	M11 PASS C12
74 / Ruthenium	= 0.0088 ug/mL formulation Basis B17	<= 1 Unit: ug/mL formulation	M11 PASS C12
75 / Iridium	= 0.0065 ug/mL formulation Basis B17	<= 1 Unit: ug/mL formulation	M11 PASS C12
77 / Non-cobalamin cobalt fraction	= 0.025 % of total cobalt Basis B19	<= 0.1 Unit: % of total cobalt	M11 PASS C02
T10 / Sterility test			
82 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M15 PASS C13
83 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M15 PASS C13
T11 / Bacterial endotoxins			
84 / Bacterial endotoxins	<0.025 EU/mL Basis B26	<= 0.1 Unit: EU/mL	M16 PASS C14
T12 / Microbial enumeration			
85 / TAMC	<1 CFU/mL Basis B27	<= 100 Unit: CFU/mL	M17 PASS C15
86 / TYMC	<1 CFU/mL Basis B27	<= 10 Unit: CFU/mL	M17 PASS C15
87 / Escherichia coli	Not detected in 1 mL Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C16
88 / Staphylococcus aureus	Not detected in 1 mL Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C16
89 / Pseudomonas aeruginosa	Not detected in 1 mL Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C16
90 / Salmonella species	Not detected in 1 mL Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C16

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
91 / Candida albicans	Not detected in 1 mL Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C16
T13 / pH and analytical solution			
78 / pH of native liquid	= 5.54 pH Basis B20	4.8 to 6.2 Unit: pH	M12 PASS C02
T14 / Excipients and preservatives			
79 / Vehicle and preservative composition	Water q.s. declared volume; no added preservative Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
T15 / Unit uniformity			
29 / L-methionine individual-unit mean	= 100.262 % label claim Basis B10	98 to 102 Unit: % label claim Basis B11	M07 PASS C04
30 / L-methionine individual-unit RSD	= 0.3515 % Basis B12	<= 2 Unit: %	M07 PASS C04
36 / myo-inositol individual-unit mean	= 100.069 % label claim Basis B10	98 to 102 Unit: % label claim Basis B11	M07 PASS C04
37 / myo-inositol individual-unit RSD	= 0.3522 % Basis B12	<= 2 Unit: %	M07 PASS C04
43 / Choline chloride individual-unit mean	= 99.955 % label claim Basis B10	98 to 102 Unit: % label claim Basis B11	M07 PASS C04
44 / Choline chloride individual-unit RSD	= 0.3526 % Basis B12	<= 2 Unit: %	M07 PASS C04
50 / Cyanocobalamin individual-unit mean	= 99.939 % label claim Basis B10	98 to 102 Unit: % label claim Basis B11	M07 PASS C04
51 / Cyanocobalamin individual-unit RSD	= 0.3526 % Basis B12	<= 2 Unit: %	M07 PASS C04
52 / Mean extractable volume	= 1 mL/container Basis B14	0.99 to 1.02 Unit: mL/container	M07 PASS C04

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T16 / Biological activity			
92 / 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 B10	Same as reported result Unit: qualitative Basis B11	M18 N/A — justified C05
T17 / Protein and conjugate characterization			
93 / 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 B10	Same as reported result Unit: qualitative Basis B11	M19 N/A — justified C05
T18 / Process impurities			
94 / 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 B10	Same as reported result Unit: qualitative Basis B11	M20 N/A — justified C05
T19 / Particles and container closure			
105 / Subvisible particles >= 10um	= 21 particles/container Basis B39	<= 6000 Unit: particles/container	M24 PASS C17
106 / Subvisible particles >= 25um	= 2 particles/container Basis B39	<= 600 Unit: particles/container	M24 PASS C17
107 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B40	Conforms to the specified acceptance criterion Unit: qualitative	M24 PASS C18
T20 / Stability observations			
108 / Reported 6 month assay retention	= 99.9099 % of initial assay Basis B41	98 to 102 Unit: % of initial assay	M25 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
109 / Reported 6 month minimum component purity	= 99.822 % integrated detector area Basis B42	99.7 to 100 Unit: % integrated detector area	M25 PASS C02
110 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B41	Conforms to the specified acceptance criterion Unit: qualitative	M25 PASS C01
T21 / Appearance and physical inspection			
80 / Appearance	red; clear solution Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C01
81 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M14 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-T02-RP-UPLC-DAD	Component-specific reversed-phase chromatographic response purity	RP-UPLC with diode-array detection
M05 M-T03-DEFAULT	Calibrated material content	Independent quantitative LC/CAD, protein assay or bioactivity calibration for IU
M06 M-T04-DEFAULT	Component-resolved blend assay	Separate calibrated selective assay for every declared component
M07 M-T15-DEFAULT	Individual-unit uniformity	Ten separate unit preparations and fill measurements
M08 M-T06-DEFAULT	Water	Coulometric Karl Fischer
M09 M-T07-DEFAULT	Counterion composition	Ion chromatography and stoichiometric accounting
M10 M-T08-DEFAULT	Residual solvent panel	headspace GC-MS
M11 M-T09-DEFAULT	Elemental impurity panel	ICP-MS
M12 M-T13-DEFAULT	pH and solution state	Calibrated potentiometry
M13 M-T14-DEFAULT	Excipients/preservatives	Component-specific quantitative LC/CAD or formulation identity
M14 M-T21-DEFAULT	Appearance	Controlled visual examination
M15 M-T10-DEFAULT	Sterility observations in two media with matrix-specific preparation	Membrane filtration/rinsing or neutralized direct inoculation for Lemon dispersion
M16 M-T11-DEFAULT	Bacterial endotoxins	Recombinant factor C fluorometric assay
M17 M-T12-DEFAULT	Microbial enumeration/organisms	Membrane filtration enumeration and enrichment
M18 M-T16-DEFAULT	Functional biological activity	Reference-relative concentration-response assay

Key / method ID	Method	Technique
M19 M-T17-DEFAULT	Protein/conjugate characterization	SEC-MALS, CE-SDS, peptide mapping, glycan/PEG profiling
M20 M-T18-DEFAULT	Biological process impurity panel	Host/process-specific ELISA and qPCR
M21 M-T01-BLEND-SELECTIVE-HRMS	Component-specific exact-ion identity for the declared blend	Component-selective LC-HRMS with independently defined molecular ions
M22 M-T04-BLEND-SELECTIVE-IDENTITY	Identity definition for each selectively assayed blend component	Component-selective reference comparison with orthogonal identity controls
M23 M-T07-CHLORIDE-IC	Intentional chloride content and choline/chloride molar consistency	Independent chloride ion chromatography with separate choline-cation assay
M24 M-T19-DEFAULT	Particles and package integrity	Light obscuration plus vacuum decay
M25 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	[M+2H]^2+; reference monoisotopic M=1354.567399 Da; molecule excludes associated salt/solvate
B03	Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation
B04	Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only
B05	Sum of U1+U2+U3; purity plus related areas = 100%
B06	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B07	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B08	Amount per nominal 1 mL fill
B09	Same independent component assay as T03, not a second independent test
B10	specified sample/form only
B11	material-specific limit
B12	Precision criterion for the listed specification, independently of AV
B13	Vitamin B12 reference: cyanocobalamin,5,6-dimethylbenzimidazolyl cyanocobamide with native corrin stereochemistry, cobalt-containing cyanide upper axial ligand and dimethylbenzimidazole lower ligand; selected PubChem cyanocobalamin reference. No intentional salt or fixed hydrate.
B14	fill specification; no injection volume recommendation
B15	Choline chloride; chloride is intentional, not a toxic elemental impurity
B16	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B17	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B18	OneCo atom per cyanocobalamin molecule; no generic total-cobalt trace limit is applied
B19	species-resolved separation plus ICP-MS; intentionally bound cobalt excluded from impurity assessment
B20	As supplied,25.0C; buffer-solution compatibility is not the pH of dry material
B21	Explicit formulation choice, not a statement about actual catalog formulation
B22	Three containers under diffuse white illumination
B23	Visual observation only; subvisible particles reported separately
B24	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B25	SCDM20-25C; tested units only; no sterility assurance level assigned
B26	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B27	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B28	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel

Key	Basis
B29	[M+H]+; exact ion definition independent of whole-blend identity. Reference formula C5H11NO2S.
B30	(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.
B31	[M+Na]+; exact ion definition independent of whole-blend identity. Reference formula C6H12O6.
B32	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.
B33	[C5H14NO]+ (choline cation; chloride excluded); exact ion definition independent of whole-blend identity. Reference formula C5H14ClNO.
B34	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.
B35	[M+2H]2+; exact ion definition independent of whole-blend identity. Reference formula C63H88CoN14O14P.
B36	Native cyanocobalamin corrin stereochemistry, cobalt with cyanide upper axial ligand and dimethylbenzimidazole lower ligand. Light-protected LC-DAD reference spectrum and retention; resolve other cobalamin forms and photodegradation products.
B37	Independent chloride IC result compared with measured choline chloride content; mass fraction uses Cl35.45 / salt139.62. Chloride is intentional.
B38	Ratio of independent cation/anion assay means; recovery-controlled measurement.
B39	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B40	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B41	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B42	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	1354.567399	Da Reference, not measured neutral mass
observed mz	678.290316	m/z
charge state	2	integer
adduct	[M+2H]^2+	text
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-2704; internal standard, not a purchased certified reference material	text

04 / L-methionine chromatographic purity

Field	Reported value	Unit / note
main peak retention time	10.969	min
main peak area	9991800	counts
total integrated area	10000000	counts

24 / L-methionine active content

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

29 / 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.

84 / 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.

105 / 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

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