CERTIFICATE OF ANALYSIS

Lemon Bottle 10 ml

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0709-L	APX-COA-2026-0709-L	2026-07-09

COMPOUND REFERENCE

Material family
heterogeneous mixture

Material form
aqueous liquid in vial

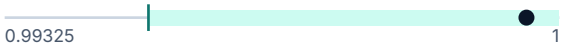
MATERIAL & COMPOSITION

Nominal component amounts
Riboflavin: 5 mg; Lecithin total phospholipids: 100 mg; Bromelain protein fraction: 10 mg

Recorded storage
2-8 C, protected from light

Reference fingerprint similarity

Reference fingerprint similarity
0.9996 similarity (0-1)



Criterion: >= 0.995

Criterion uses the result unit. Independent expanded scales.

Measured concentration

Riboflavin concentration
0.501265 mg/mL

Criterion: 0.49 to 0.51

Lecithin total phospholipids concentration
10.0144 mg/mL

Criterion: 9.8 to 10.2

Bromelain protein fraction concentration
0.99951 mg/mL

Criterion: 0.98 to 1.02

Criterion uses the result unit. Independent expanded scales.

83 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 2026-07-09

ONLINE REPORT
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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
71 / Riboflavin component-specific HRMS mass error	= 0.01007 ppm Basis B27	-5 to 5 Unit: ppm	M19 PASS C19
T02 / Chromatographic purity			
03 / Multipeak fingerprint similarity to defined reference	= 0.9996 similarity (0-1) Basis B02	>= 0.995 Unit: similarity (0-1)	M02 PASS C02
T03 / Active content and assay			
05 / Riboflavin active content	= 5.01265 mg/vial Basis B04	4.9 to 5.1 Unit: mg/vial	M04 PASS C02
06 / Riboflavin label claim assay	= 100.253 % label claim Basis B05	98 to 102 Unit: % label claim	M04 PASS C02
07 / Riboflavin concentration	= 0.501265 mg/mL Basis B06	0.49 to 0.51 Unit: mg/mL	M04 PASS C02
12 / Lecithin total phospholipids active content	= 100.144 mg/vial Basis B04	98 to 102 Unit: mg/vial	M04 PASS C02
13 / Lecithin total phospholipids label claim assay	= 100.144 % label claim Basis B05	98 to 102 Unit: % label claim	M04 PASS C02
14 / Lecithin total phospholipids concentration	= 10.0144 mg/mL Basis B06	9.8 to 10.2 Unit: mg/mL	M04 PASS C02
19 / Bromelain protein fraction active content	= 9.9951 mg/vial Basis B04	9.8 to 10.2 Unit: mg/vial	M04 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
20 / Bromelain protein fraction label claim assay	= 99.951 % label claim Basis B05	98 to 102 Unit: % label claim	M04 PASS C02
21 / Bromelain protein fraction concentration	= 0.99951 mg/mL Basis B06	0.98 to 1.02 Unit: mg/mL	M04 PASS C02
T04 / Blend composition			
08 / Riboflavin component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
09 / Riboflavin component content	= 5.01265 mg/vial Basis B07	4.9 to 5.1 Unit: mg/vial	M05 PASS C02
15 / Lecithin total phospholipids component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
16 / Lecithin total phospholipids component content	= 100.144 mg/vial Basis B07	98 to 102 Unit: mg/vial	M05 PASS C02
22 / Bromelain protein fraction component identity	Conforms to specified component identity Unit: qualitative	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
23 / Bromelain protein fraction component content	= 9.9951 mg/vial Basis B07	9.8 to 10.2 Unit: mg/vial	M05 PASS C02
72 / Riboflavin isolated component identity definition	Conforms to the stated component reference Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M20 PASS C01
73 / Riboflavin total-content extraction suitability	= 99.85 % recovery	98 to 102 Unit: % recovery	M21 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			
27 / 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 B08	Same as reported result Unit: qualitative Basis B09	M07 N/A — justified C05
T07 / Counterions and associated species			
28 / 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 B08	Same as reported result Unit: qualitative Basis B09	M08 N/A — justified C05
T08 / Residual solvents			
29 / Methanol	= 19.31 ug/mL formulation Basis B12	<= 3000 Unit: ug/mL formulation	M09 PASS C06
30 / Acetonitrile	= 8.18 ug/mL formulation Basis B12	<= 410 Unit: ug/mL formulation	M09 PASS C07
31 / Dichloromethane	= 3.398 ug/mL formulation Basis B12	<= 600 Unit: ug/mL formulation	M09 PASS C08
32 / N, N-dimethylformamide	= 4.496 ug/mL formulation Basis B12	<= 880 Unit: ug/mL formulation	M09 PASS C09
33 / Ethanol	= 40.022 ug/mL formulation Basis B12	<= 5000 Unit: ug/mL formulation	M09 PASS C06
34 / Acetone	= 11.64 ug/mL formulation Basis B12	<= 5000 Unit: ug/mL formulation	M09 PASS C09
35 / Ethyl acetate	= 9.78 ug/mL formulation Basis B12	<= 5000 Unit: ug/mL formulation	M09 PASS C09
36 / Toluene	= 1.895 ug/mL formulation Basis B12	<= 890 Unit: ug/mL formulation	M09 PASS C10
37 / n-Hexane	= 1.025 ug/mL formulation Basis B12	<= 290 Unit: ug/mL formulation	M09 PASS C10

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
38 / Benzene	= 0.083 ug/mL formulation Basis B12	<= 2 Unit: ug/mL formulation	M09 PASS C11
T09 / Elemental impurities			
39 / Lead	= 0.0112 ug/mL formulation Basis B13	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
40 / Cadmium	= 0.008 ug/mL formulation Basis B13	<= 0.2 Unit: ug/mL formulation	M10 PASS C12
41 / Arsenic	= 0.0187 ug/mL formulation Basis B13	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
42 / Mercury	= 0.006 ug/mL formulation Basis B13	<= 0.1 Unit: ug/mL formulation	M10 PASS C12
43 / Cobalt	= 0.0229 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
44 / Vanadium	= 0.0228 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
45 / Nickel	= 0.0347 ug/mL formulation Basis B13	<= 2 Unit: ug/mL formulation	M10 PASS C12
46 / Palladium	= 0.0101 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
47 / Platinum	= 0.0092 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
48 / Rhodium	= 0.0063 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
49 / Ruthenium	= 0.009 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
50 / Iridium	= 0.0065 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T10 / Sterility test			
55 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
56 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B19	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
57 / Bacterial endotoxins	<0.025 EU/mL Basis B20	<= 0.1 Unit: EU/mL	M15 PASS C14
T12 / Microbial enumeration			
58 / TAMC	<1 CFU/mL Basis B21	<= 100 Unit: CFU/mL	M16 PASS C15
59 / TYMC	<1 CFU/mL Basis B21	<= 10 Unit: CFU/mL	M16 PASS C15
60 / Escherichia coli	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
61 / Staphylococcus aureus	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
62 / Pseudomonas aeruginosa	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
63 / Salmonella species	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
64 / Candida albicans	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
T13 / pH and analytical solution			
51 / pH of native liquid	= 5.49 pH Basis B14	4.8 to 6.2 Unit: pH	M11 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T14 / Excipients and preservatives			
52 / Vehicle and preservative composition	Water q.s. declared volume; no added preservative Unit: qualitative Basis B15	Conforms to the specified acceptance criterion Unit: qualitative	M12 PASS C01
T15 / Unit uniformity			
10 / Riboflavin individual-unit mean	= 100.253 % label claim Basis B08	98 to 102 Unit: % label claim Basis B09	M06 PASS C04
11 / Riboflavin individual-unit RSD	= 0.3515 % Basis B10	<= 2 Unit: %	M06 PASS C04
17 / Lecithin total phospholipids individual-unit mean	= 100.144 % label claim Basis B08	98 to 102 Unit: % label claim Basis B09	M06 PASS C04
18 / Lecithin total phospholipids individual-unit RSD	= 0.3519 % Basis B10	<= 2 Unit: %	M06 PASS C04
24 / Bromelain protein fraction individual-unit mean	= 99.951 % label claim Basis B08	98 to 102 Unit: % label claim Basis B09	M06 PASS C04
25 / Bromelain protein fraction individual-unit RSD	= 0.3526 % Basis B10	<= 2 Unit: %	M06 PASS C04
26 / Mean extractable volume	= 10 mL/container Basis B11	9.9 to 10.2 Unit: mL/container	M06 PASS C04
T16 / Biological activity			
77 / Bromelain caseinolytic specific activity	= 2.00009 casein U/mg bromelain protein Numeric value: 2.000095 Basis B30	1.9 to 2.1 Unit: casein U/mg bromelain protein	M23 PASS C19
78 / Bromelain caseinolytic activity per vial	= 19.9912 casein U/vial Numeric value: 19.991151 Basis B31	19 to 21 Unit: casein U/vial	M23 PASS C19
79 / Bromelain caseinolytic activity concentration	= 1.99911 casein U/mL formulation Numeric value: 1.999115 Basis B32	1.9 to 2.1 Unit: casein U/mL formulation	M23 PASS C19
80 / Bromelain matrix-spike activity recovery	= 100.8 % activity recovery Basis B33	90 to 110 Unit: % activity recovery	M23 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T17 / Protein and conjugate characterization			
65 / Size-exclusion main defined population	= 99.91 % SEC response Basis B23	99.7 to 100 Unit: % SEC response	M17 PASS C02
66 / High molecular weight aggregate fraction	= 0.045 % SEC response Basis B08	<= 0.1 Unit: % SEC response Basis B09	M17 PASS C02
67 / Low molecular weight non-reference fraction	= 0.045 % SEC response Basis B08	<= 0.1 Unit: % SEC response Basis B09	M17 PASS C02
68 / Orthogonal construct/fingerprint mapping	Conforms to explicit reference specification Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C01
74 / Lecithin Phosphatidylcholine class fraction	= 80.03 % w/w designated phospholipid fraction Basis B29	78 to 82 Unit: % w/w designated phospholipid fraction	M22 PASS C02
75 / Lecithin Phosphatidylethanolamine class fraction	= 14.98 % w/w designated phospholipid fraction Basis B29	13.5 to 16.5 Unit: % w/w designated phospholipid fraction	M22 PASS C02
76 / Lecithin Phosphatidylinositol class fraction	= 4.99 % w/w designated phospholipid fraction Basis B29	4.5 to 5.5 Unit: % w/w designated phospholipid fraction	M22 PASS C02
T18 / Process impurities			
69 / Residual source-process protein impurities	= 2.1 ng/mg assigned target material Basis B25	<= 100 Unit: ng/mg assigned target material	M18 PASS C17
70 / Residual source DNA	= 0.012 ng/vial Basis B26	<= 1 Unit: ng/vial	M18 PASS C18
T19 / Particles and container closure			
81 / Container closure and visible package condition	No damage; closure and seal conform in 10 packages Unit: qualitative Basis B34	Conforms to the specified acceptance criterion Unit: qualitative	M24 PASS C20
T20 / Stability observations			
82 / Reported 6 month assay retention	= 99.91 % of initial assay Basis B35	98 to 102 Unit: % of initial assay	M25 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
83 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M25 PASS C01
T21 / Appearance and physical inspection			
53 / Appearance	yellow opalescent dispersion; uniform dispersion Unit: qualitative Basis B16	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
54 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B17	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-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-T17-DEFAULT	Protein/conjugate characterization	SEC-MALS, CE-SDS, peptide mapping, glycan/PEG profiling
M18 M-T18-DEFAULT	Biological process impurity panel	Host/process-specific ELISA and qPCR

Key / method ID	Method	Technique
M19 M-T01-BLEND-SELECTIVE-HRMS	Component-specific exact-ion identity for the declared blend	Component-selective LC-HRMS with independently defined molecular ions
M20 M-T04-BLEND-SELECTIVE-IDENTITY	Identity definition for each selectively assayed blend component	Component-selective reference comparison with orthogonal identity controls
M21 M-T04-RIBOFLAVIN-EXTRACTION	Riboflavin total-content extraction suitability in Lemon dispersion	Component-selective quantitative extraction and matrix-spike recovery
M22 M-T17-LIPID-CLASS-LC-CAD	Lecithin phospholipid-class mass-fraction fingerprint	Class-calibrated LC-CAD with independent LC-MS class identification
M23 M-T16-BROMELAIN-INITIAL-RATE	Bromelain caseinolytic initial-rate activity and matrix recovery	Time-course casein hydrolysis with TCA separation and tyrosine-calibrated Folin detection
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	Fingerprint similarity, not chemical purity percentage
B03	Aggregate non-reference signal; not mass fraction or component purity
B04	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B05	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B06	Amount per nominal 10 mL fill
B07	Same independent component assay as T03, not a second independent test
B08	specified sample/form only
B09	material-specific limit
B10	Precision criterion for the listed specification, independently of AV
B11	fill specification; no injection volume recommendation
B12	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B13	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B14	As supplied,25.0C; buffer-solution compatibility is not the pH of dry material
B15	Explicit formulation choice, not a statement about actual catalog formulation
B16	Three containers under diffuse white illumination
B17	Visual observation only; subvisible particles reported separately
B18	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B19	SCDM20-25C; tested units only; no sterility assurance level assigned
B20	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B21	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B22	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B23	Isolated bromelain protein fraction only; excludes lecithin and riboflavin
B24	Identity Reference defines construct, termini, and mixture caveats; no raw mass spectrum or gel image exists
B25	pineapple-derived bromelain/plant lecithin 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	[M+H]+; exact ion definition independent of whole-blend identity. Reference formula C17H20N4O6.
B28	Riboflavin with native D-ribityl side-chain stereochemistry; not riboflavin phosphate/FMN. Light-protected LC-DAD retention and absorbance fingerprint; resolve lumichrome, lumiflavin and other degradation products.

Key	Basis
B29	Class-specific mass-calibrated LC-CAD with independent LC-MS class identification. These are intended constituents, not three impurities. Heterogeneous acyl species remain within each class.
B30	1 casein U = 1 micromol tyrosine-equivalent TCA-soluble product released per minute at 37.0C, pH7.00,1.00%w/v casein,50mM sodium phosphate and5mM L-cysteine; tyrosine-calibrated Folin color response after precipitation. Method-defined equivalent units, not GDU. Use a separate native aqueous enzyme preparation; do not expose it to lipid or riboflavin extraction solvents. Dilute the native protein preparation1:10; add0.100 mL to a2.000 mL reaction. Sample at 0,1,2,3,4,5min and quench in equal-volume10%w/v TCA. After removal of precipitate, use a matrix-blank-corrected tyrosine calibration expressed as micromol equivalents per original reaction. Reference and sample matrices matched.
B31	Specific activity x independently measured bromelain protein mg/vial. Target20 caseinU/vial from 10 mg x2caseinU/mg; not GDU.
B32	Relative to the specified reference response; activity units and mass units are evaluated separately. Method validation is not asserted by this report.
B33	Activity-added reference matched for casein, pH, thiol activation and color matrix; separate from total-protein spike recovery.
B34	Nonsterile capsule bottle or intentional dispersion; light-obscuration particulate numbers inappropriate for these matrices
B35	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/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: 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	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-2705; internal standard, not a purchased certified reference material	text

05 / Riboflavin active content

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

10 / Riboflavin 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.

57 / 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.

77 / Bromelain caseinolytic specific activity

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

81 / Container closure and visible package condition

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-2026-0709-L | APX-2026-0709-L