CERTIFICATE OF ANALYSIS

Klow Blend 80 mg

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0806-K	APX-COA-2026-0806-K	2026-08-06

NOMINAL COMPOSITION

GHK-Cu (1:1 complex): 50 mg; BPC-157: 10 mg; TB-500 (Ac-LKKTETQ): 10 mg; KPV: 10 mg

lyophilized solid in vial

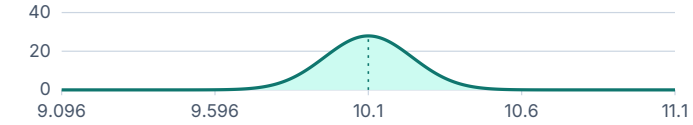
RECORDED RESULTS	Purity % integrated detector area	Active content
GHK-Cu (1:1 complex)	99.95%	50.032 mg/vial
BPC-157	99.904%	10.0038 mg/vial
TB-500 (Ac-LKKTETQ)	99.93%	10.0129 mg/vial
KPV	99.909%	10.0204 mg/vial

ESTIMATED COMPONENT REFERENCE PROFILES

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

GHK-Cu (1:1 complex)

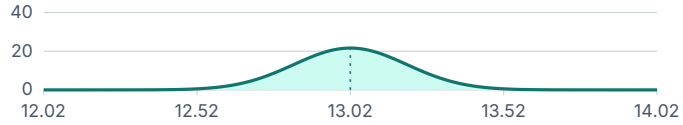
RT 10.096 min | 9,992,000 counts | APX-2026-0625-G



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

BPC-157

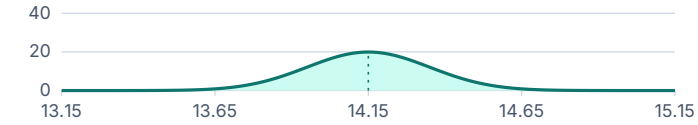
RT 13.024 min | 9,988,400 counts | APX-2026-0725-B



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

TB-500 (Ac-LKKTETQ)

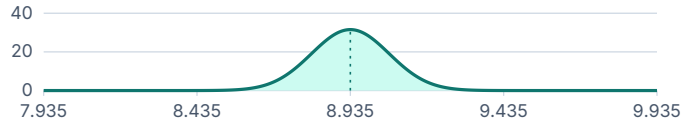
RT 14.146 min | 9,992,300 counts | APX-2026-0614-T



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

KPV

RT 8.935 min | 9,986,800 counts | APX-2026-0515-K



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

106 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 2026-08-06

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
03 / GHK-Cu (1:1 complex) HRMS ion mass error	= 1.0732 ppm Basis B02	-5 to 5 Unit: ppm	M01 PASS C02
04 / BPC-157 HRMS ion mass error	= 1.3263 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
05 / TB-500 (Ac-LKKTETQ) HRMS ion mass error	= 0.9181 ppm Basis B04	-5 to 5 Unit: ppm	M01 PASS C02
06 / KPV HRMS ion mass error	= 1.2618 ppm Basis B05	-5 to 5 Unit: ppm	M01 PASS C02
98 / BPC-157: Pro D fraction	= 0.02 mol% of selected amino acid Basis B36	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C17
99 / TB-500 (Ac-LKKTETQ): Lys D fraction	= 0.02 mol% of selected amino acid Basis B36	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C17
100 / KPV: Val D fraction	= 0.02 mol% of selected amino acid Basis B36	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C17
T02 / Chromatographic purity			
07 / GHK-Cu (1:1 complex) chromatographic purity	= 99.95 % integrated detector area Basis B06	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
12 / BPC-157 chromatographic purity	= 99.904 % integrated detector area Basis B06	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
17 / TB-500 (Ac-LKKTETQ) chromatographic purity	= 99.93 % integrated detector area Basis B06	99.7 to 100 Unit: % integrated detector area	M02 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
22 / KPV chromatographic purity	= 99.909 % integrated detector area Basis B06	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
27 / GHK-Cu (1:1 complex) active content	= 50.032 mg/vial Basis B09	49 to 51 Unit: mg/vial	M04 PASS C02
28 / GHK-Cu (1:1 complex) label claim assay	= 100.064 % label claim Basis B10	98 to 102 Unit: % label claim	M04 PASS C02
34 / BPC-157 active content	= 10.0038 mg/vial Basis B09	9.8 to 10.2 Unit: mg/vial	M04 PASS C02
35 / BPC-157 label claim assay	= 100.038 % label claim Basis B10	98 to 102 Unit: % label claim	M04 PASS C02
41 / TB-500 (Ac-LKKTETQ) active content	= 10.0129 mg/vial Basis B09	9.8 to 10.2 Unit: mg/vial	M04 PASS C02
42 / TB-500 (Ac-LKKTETQ) label claim assay	= 100.129 % label claim Basis B10	98 to 102 Unit: % label claim	M04 PASS C02
48 / KPV active content	= 10.0204 mg/vial Basis B09	9.8 to 10.2 Unit: mg/vial	M04 PASS C02
49 / KPV label claim assay	= 100.204 % label claim Basis B10	98 to 102 Unit: % label claim	M04 PASS C02
58 / Intentional bound-plus-free total copper	= 7.9055 mg Cu/vial Basis B23	7.74739 to 8.06361 Lower: 7.747391206986639 Upper: 8.0636112562514 Unit: mg Cu/vial	M04 PASS C02
T04 / Blend composition			
29 / GHK-Cu (1:1 complex) component identity	Conforms to specified component identity Unit: qualitative Basis B11	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
30 / GHK-Cu (1:1 complex) component content	= 50.032 mg/vial Basis B12	49 to 51 Unit: mg/vial	M05 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
36 / BPC-157 component identity	Conforms to specified component identity Unit: qualitative Basis B17	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
37 / BPC-157 component content	= 10.0038 mg/vial Basis B12	9.8 to 10.2 Unit: mg/vial	M05 PASS C02
43 / TB-500 (Ac-LKKTETQ) component identity	Conforms to specified component identity Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
44 / TB-500 (Ac-LKKTETQ) component content	= 10.0129 mg/vial Basis B12	9.8 to 10.2 Unit: mg/vial	M05 PASS C02
50 / KPV component identity	Conforms to specified component identity Unit: qualitative Basis B19	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
51 / KPV component content	= 10.0204 mg/vial Basis B12	9.8 to 10.2 Unit: mg/vial	M05 PASS C02
T05 / Related substances and degradants			
08 / GHK-Cu (1:1 complex) Unknown U1	= 0.025 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
09 / GHK-Cu (1:1 complex) Unknown U2	= 0.015 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
10 / GHK-Cu (1:1 complex) Unknown U3	= 0.01 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
11 / GHK-Cu (1:1 complex) total related peaks	= 0.05 % integrated detector area Basis B08	<= 0.3 Unit: % integrated detector area	M03 PASS C02
13 / BPC-157 Unknown U1	= 0.048 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
14 / BPC-157 Unknown U2	= 0.029 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
15 / BPC-157 Unknown U3	= 0.019 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
16 / BPC-157 total related peaks	= 0.096 % integrated detector area Basis B08	<= 0.3 Unit: % integrated detector area	M03 PASS C02
18 / TB-500 (Ac-LKKTETQ) Unknown U1	= 0.035 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
19 / TB-500 (Ac-LKKTETQ) Unknown U2	= 0.021 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
20 / TB-500 (Ac-LKKTETQ) Unknown U3	= 0.014 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
21 / TB-500 (Ac-LKKTETQ) total related peaks	= 0.07 % integrated detector area Basis B08	<= 0.3 Unit: % integrated detector area	M03 PASS C02
23 / KPV Unknown U1	= 0.045 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
24 / KPV Unknown U2	= 0.027 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
25 / KPV Unknown U3	= 0.019 % integrated detector area Basis B07	<= 0.1 Unit: % integrated detector area	M03 PASS C03
26 / KPV total related peaks	= 0.091 % integrated detector area Basis B08	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
55 / Residual water	= 0.79 % w/w finished fill Basis B20	<= 2 Unit: % w/w finished fill	M07 PASS C02
T07 / Counterions and associated species			
56 / Acetate content relative to parent active mass	= 1.5 % acetate/parent mass Basis B21	0.5 to 3 Unit: % acetate/parent mass	M08 PASS C02
57 / GHK:Cu complex stoichiometry	= 1 mol Cu/mol GHK Basis B22	0.98 to 1.02 Unit: mol Cu/mol GHK	M08 PASS C02
T08 / Residual solvents			
60 / Methanol	= 21.949 ug/g finished fill Basis B25	<= 3000 Unit: ug/g finished fill	M10 PASS C05

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
61 / Acetonitrile	= 7.778 ug/g finished fill Basis B25	<= 410 Unit: ug/g finished fill	M10 PASS C06
62 / Dichloromethane	= 3.476 ug/g finished fill Basis B25	<= 600 Unit: ug/g finished fill	M10 PASS C07
63 / N, N-dimethylformamide	= 4.337 ug/g finished fill Basis B25	<= 880 Unit: ug/g finished fill	M10 PASS C08
64 / Ethanol	= 35.487 ug/g finished fill Basis B25	<= 5000 Unit: ug/g finished fill	M10 PASS C05
65 / Acetone	= 10.88 ug/g finished fill Basis B25	<= 5000 Unit: ug/g finished fill	M10 PASS C08
66 / Ethyl acetate	= 9.505 ug/g finished fill Basis B25	<= 5000 Unit: ug/g finished fill	M10 PASS C08
67 / Toluene	= 1.678 ug/g finished fill Basis B25	<= 890 Unit: ug/g finished fill	M10 PASS C09
68 / n-Hexane	= 1.192 ug/g finished fill Basis B25	<= 290 Unit: ug/g finished fill	M10 PASS C09
69 / Benzene	= 0.079 ug/g finished fill Basis B25	<= 2 Unit: ug/g finished fill	M10 PASS C10
T09 / Elemental impurities			
70 / Lead	= 0.0125 ug/g finished fill Basis B26	<= 0.5 Unit: ug/g finished fill	M11 PASS C11
71 / Cadmium	= 0.0079 ug/g finished fill Basis B26	<= 0.2 Unit: ug/g finished fill	M11 PASS C11
72 / Arsenic	= 0.0186 ug/g finished fill Basis B26	<= 0.5 Unit: ug/g finished fill	M11 PASS C11
73 / Mercury	= 0.0057 ug/g finished fill Basis B26	<= 0.1 Unit: ug/g finished fill	M11 PASS C11
74 / Cobalt	= 0.0214 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
75 / Vanadium	= 0.0261 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11
76 / Nickel	= 0.032 ug/g finished fill Basis B26	<= 2 Unit: ug/g finished fill	M11 PASS C11
77 / Palladium	= 0.0107 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11
78 / Platinum	= 0.0094 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11
79 / Rhodium	= 0.0071 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11
80 / Ruthenium	= 0.0094 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11
81 / Iridium	= 0.0057 ug/g finished fill Basis B26	<= 1 Unit: ug/g finished fill	M11 PASS C11
T10 / Sterility test			
86 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B31	Conforms to the specified acceptance criterion Unit: qualitative	M15 PASS C12
87 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B32	Conforms to the specified acceptance criterion Unit: qualitative	M15 PASS C12
T11 / Bacterial endotoxins			
88 / Bacterial endotoxins	<0.025 EU/mg active-equivalent Basis B33	<= 0.1 Unit: EU/mg active-equivalent	M16 PASS C13
T12 / Microbial enumeration			
89 / TAMC	<1 CFU/g finished fill Basis B34	<= 100 Unit: CFU/g finished fill	M17 PASS C14
90 / TYMC	<1 CFU/g finished fill Basis B34	<= 10 Unit: CFU/g finished fill	M17 PASS C14
91 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C15

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
92 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C15
93 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C15
94 / Salmonella species	Not detected in 1g Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C15
95 / Candida albicans	Not detected in 1g Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M17 PASS C15
T13 / pH and analytical solution			
82 / pH of specified buffered analytical solution	= 5.98 pH Basis B27	5.3 to 6.7 Unit: pH	M12 PASS C02
T14 / Excipients and preservatives			
83 / Trehalose content	= 5.004 mg/vial Basis B28	4.75 to 5.25 Unit: mg/vial	M13 PASS C02
T15 / Unit uniformity			
31 / GHK-Cu (1:1 complex) individual-unit mean	= 100.064 % label claim Basis B13	98 to 102 Unit: % label claim Basis B14	M06 PASS C04
32 / GHK-Cu (1:1 complex) acceptance value (n=10)	= 0.8458 % label claim Basis B15	<= 15 Unit: % label claim	M06 PASS C04
33 / GHK-Cu (1:1 complex) individual-unit RSD	= 0.3522 % Basis B16	<= 2 Unit: %	M06 PASS C04
38 / BPC-157 individual-unit mean	= 100.038 % label claim Basis B13	98 to 102 Unit: % label claim Basis B14	M06 PASS C04
39 / BPC-157 acceptance value (n=10)	= 0.8458 % label claim Basis B15	<= 15 Unit: % label claim	M06 PASS C04
40 / BPC-157 individual-unit RSD	= 0.3523 % Basis B16	<= 2 Unit: %	M06 PASS C04
45 / TB-500 (Ac-LKKTETQ) individual-unit mean	= 100.129 % label claim Basis B13	98 to 102 Unit: % label claim Basis B14	M06 PASS C04

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
46 / TB-500 (Ac-LKKTETQ) acceptance value (n=10)	= 0.8458 % label claim Basis B15	<= 15 Unit: % label claim	M06 PASS C04
47 / TB-500 (Ac-LKKTETQ) individual-unit RSD	= 0.352 % Basis B16	<= 2 Unit: %	M06 PASS C04
52 / KPV individual-unit mean	= 100.204 % label claim Basis B13	98 to 102 Unit: % label claim Basis B14	M06 PASS C04
53 / KPV acceptance value (n=10)	= 0.8458 % label claim Basis B15	<= 15 Unit: % label claim	M06 PASS C04
54 / KPV individual-unit RSD	= 0.3517 % Basis B16	<= 2 Unit: %	M06 PASS C04
T16 / Biological activity			
96 / 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 B13	Same as reported result Unit: qualitative Basis B14	M18 N/A — justified C16
T17 / Protein and conjugate characterization			
59 / Unbound copper fraction	= 0.03 % of total copper Basis B24	<= 0.1 Unit: % of total copper	M09 PASS C02
T18 / Process impurities			
97 / 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 B13	Same as reported result Unit: qualitative Basis B14	M19 N/A — justified C16
T19 / Particles and container closure			
101 / Subvisible particles >= 10um	= 21 particles/container Basis B37	<= 6000 Unit: particles/container	M21 PASS C17

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
102 / Subvisible particles >= 25um	= 2 particles/container Basis B37	<= 600 Unit: particles/container	M21 PASS C17
103 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B38	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C18
T20 / Stability observations			
104 / Reported 6 month assay retention	= 99.91 % of initial assay Basis B39	98 to 102 Unit: % of initial assay	M22 PASS C02
105 / Reported 6 month minimum component purity	= 99.862 % integrated detector area Basis B40	99.7 to 100 Unit: % integrated detector area	M22 PASS C02
106 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B39	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01
T21 / Appearance and physical inspection			
84 / Appearance	blue; uniform lyophilized cake Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C01
85 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B30	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-RP-UPLC-DAD	Component-specific reversed-phase chromatographic response purity	RP-UPLC with diode-array 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-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-T17-DEFAULT	Protein/conjugate characterization	SEC-MALS, CE-SDS, peptide mapping, glycan/PEG profiling
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-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-T19-DEFAULT	Particles and package integrity	Light obscuration plus vacuum decay
M22 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+1H]^1+; reference monoisotopic M=401.09985 Da; molecule excludes associated salt/solvate
B03	[M+2H]^2+; reference monoisotopic M=1418.70415882 Da; molecule excludes associated salt/solvate
B04	[M+1H]^1+; reference monoisotopic M=888.49164688 Da; molecule excludes associated salt/solvate
B05	[M+1H]^1+; reference monoisotopic M=342.22670545 Da; molecule excludes associated salt/solvate
B06	Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation
B07	Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only
B08	Sum of U1+U2+U3; purity plus related areas = 100%
B09	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B10	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B11	1:1Cu(II):GHK neutral complex of glycyl-L-histidyl-L-lysine; GHK free amino and carboxyl termini, two net ligand protons displaced in bookkeeping formulaC14H22CuN6O4. Aqueous protonation/coordination is pH-dependent.
B12	Same independent component assay as T03, not a second independent test
B13	specified sample/form only
B14	material-specific limit
B15	AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5
B16	Precision criterion for the listed specification, independently of AV
B17	H-GEPPPGKPADDAGLV-OH,15 residues, all-L except glycine, alpha peptide linkages; acetate-associated form with independently quantified acetate.
B18	Explicit TB-500 fragment: Ac-L-Leu-L-Lys-L-Lys-L-Thr-L-Glu-L-Thr-L-Gln-OH (Ac-LKKTETQ-OH),7residues, N-alpha acetyl, free C-terminal acid. Acetate-associated material with variable acetate composition.
B19	H-L-Lys-L-Pro-L-Val-OH; unacetylated N-terminus and free C-terminal acid. This is the free-acid reference represented by PubChem CID125672.
B20	Water as percentage of total net formulation, not peptide area purity
B21	Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion.
B22	neutral1:1 complex; copper is intentional composition, not a trace impurity
B23	Cu fraction63.546/401.91 of named1:1 complex; total ICP-MS alone cannot prove binding
B24	species-resolved separation followed by ICP-MS; independent of total copper assay
B25	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B26	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.

Key	Basis
B27	1.000 mg active/mL in 10mM MES buffer, pH6.00,25.0C; buffer-solution compatibility is not the pH of dry material
B28	Separate excipient-specific assay; not label active
B29	Three containers under diffuse white illumination
B30	Visual observation only; subvisible particles reported separately
B31	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B32	SCDM20-25C; tested units only; no sterility assurance level assigned
B33	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B34	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B35	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B36	Residue-specific target from explicit structure. Mixed D/L ratios are intentional where stated; not total chemical-purity percentage.
B37	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B38	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B39	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B40	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: 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
C06	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
C07	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
C08	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
C09	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
C10	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
C11	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
C12	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 20; Units type: finished containers
C13	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
C14	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
C15	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 1; Units type: finished containers
C16	Analytical replicates: 0; Statistic type: individual/qualitative observation; Units sampled: 0; 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	342.22670545	Da Reference, not measured neutral mass
observed mz	343.234415	m/z
charge state	1	integer
adduct	[M+1H]^1+	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-2720; internal standard, not a purchased certified reference material	text

07 / GHK-Cu (1:1 complex) chromatographic purity

Field	Reported value	Unit / note
main peak retention time	8.951	min
main peak area	9990900	counts
total integrated area	10000000	counts

27 / GHK-Cu (1:1 complex) active content

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

31 / GHK-Cu (1:1 complex) 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.

55 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.007962906965024	factor For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor.

88 / 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.

101 / 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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