



CERTIFICATE OF ANALYSIS

CJC-1295 No DAC + Ipamorelin Blend

LOT NUMBER
APX-2026-0525-C

REPORT NUMBER
APX-COA-2026-0525-C

COA ISSUE DATE
2026-05-25

NOMINAL COMPOSITION

CJC-1295 No DAC: 5 mg; Ipamorelin: 5 mg
lyophilized solid in vial

RECORDED RESULTS

Purity
% integrated detector area

Active content

CJC-1295 No DAC

99.925%

4.9983 mg/vial

Ipamorelin

99.871%

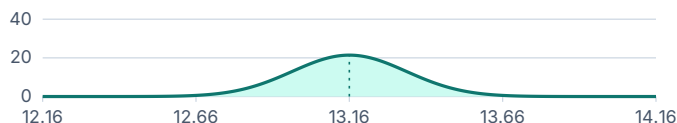
5.00355 mg/vial

ESTIMATED COMPONENT REFERENCE PROFILES

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

CJC-1295 No DAC

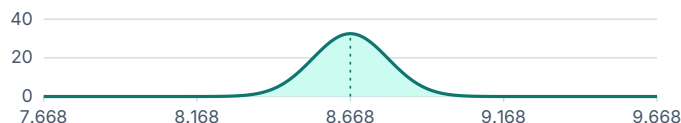
RT 13.159 min | 9,988,700 counts | APX-2026-0608-C



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

Ipamorelin

RT 8.668 min | 9,987,600 counts | APX-2026-0523-I



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

82 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 2026-05-25

ONLINE REPORT

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02 Contamination & microbiology
Metals, solvents and microbial results

03+ Complete assay results
Methods, specifications and analytical context

Contamination & microbiology

All applicable tested criteria met

32 applicable endpoints reviewed against their stated specifications.

ELEMENTAL IMPURITIES		
Lead	✓	PASS
Cadmium	✓	PASS
Arsenic	✓	PASS
Mercury	✓	PASS
Cobalt	✓	PASS
Vanadium	✓	PASS
Nickel	✓	PASS
Palladium	✓	PASS
Platinum	✓	PASS
Rhodium	✓	PASS
Ruthenium	✓	PASS
Iridium	✓	PASS

RESIDUAL SOLVENTS		
Methanol	✓	PASS
Acetonitrile	✓	PASS
Dichloromethane	✓	PASS
N, N-dimethylformamide	✓	PASS
Ethanol	✓	PASS
Acetone	✓	PASS
Ethyl acetate	✓	PASS
Toluene	✓	PASS
n-Hexane	✓	PASS
Benzene	✓	PASS

MICROBIOLOGY & ENDOTOXINS		
Sterility: FTM	✓	PASS
Sterility: SCDM	✓	PASS
Bacterial endotoxins	✓	PASS
TAMC	✓	PASS
TYMC	✓	PASS
Escherichia coli	✓	PASS
Staphylococcus aureus	✓	PASS
Pseudomonas aeruginosa	✓	PASS
Salmonella species	✓	PASS
Candida albicans	✓	PASS

PASS indicates that the recorded result meets its stated criterion for the tested sample. Exact values, detection limits, sampling scope and methods follow in the complete results. For research use only.

Complete assay results

Reported values, units and acceptance outcomes are reproduced separately for each endpoint. Method keys link to the method reference section.

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T01 / Identity and structure			
01 / Orthogonal identity against specified reference	Conforms to the assigned reference; see identity basis Unit: qualitative Basis B01	Conforms to the specified acceptance criterion Unit: qualitative	M01 PASS C01
02 / Orthogonal fingerprint similarity	= 0.9994 similarity (0-1) Basis B02	>= 0.995 Unit: similarity (0-1)	M01 PASS C02
03 / CJC-1295 No DAC HRMS ion mass error	= 1.1331 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
04 / Ipamorelin HRMS ion mass error	= 0.6525 ppm Basis B04	-5 to 5 Unit: ppm	M01 PASS C02
71 / CJC-1295 No DAC: Ala D fraction	= 25.01 mol% of selected amino acid Basis B31	24.5 to 25.5 Unit: mol% of selected amino acid	M20 PASS C17
72 / CJC-1295 No DAC: selected positional-epimer challenge resolution	= 3 Rs Basis B32	>= 1.5 Unit: Rs	M21 PASS C02
73 / Ipamorelin: Phe D fraction	= 99.98 mol% of selected amino acid Basis B31	99.9 to 100 Unit: mol% of selected amino acid	M20 PASS C17
74 / Ipamorelin: 2-naphthylalanine D fraction	= 99.98 mol% of selected amino acid Basis B31	99.9 to 100 Unit: mol% of selected amino acid	M20 PASS C17
75 / Ipamorelin: His D fraction	= 0.02 mol% of selected amino acid Basis B31	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C17
76 / Ipamorelin: selected positional-epimer challenge resolution	= 3 Rs Basis B32	>= 1.5 Unit: Rs	M21 PASS C02
T02 / Chromatographic purity			
05 / CJC-1295 No DAC chromatographic purity	= 99.925 % integrated detector area Basis B05	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
10 / Ipamorelin chromatographic purity	= 99.871 % integrated detector area Basis B05	99.7 to 100 Unit: % integrated detector area	M02 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T03 / Active content and assay			
15 / CJC-1295 No DAC active content	= 4.9983 mg/vial Basis B08	4.9 to 5.1 Unit: mg/vial	M04 PASS C02
16 / CJC-1295 No DAC label claim assay	= 99.966 % label claim Basis B09	98 to 102 Unit: % label claim	M04 PASS C02
22 / Ipamorelin active content	= 5.00355 mg/vial Basis B08	4.9 to 5.1 Unit: mg/vial	M04 PASS C02
23 / Ipamorelin label claim assay	= 100.071 % label claim Basis B09	98 to 102 Unit: % label claim	M04 PASS C02
T04 / Blend composition			
17 / CJC-1295 No DAC component identity	Conforms to specified component identity Unit: qualitative Basis B10	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
18 / CJC-1295 No DAC component content	= 4.9983 mg/vial Basis B11	4.9 to 5.1 Unit: mg/vial	M05 PASS C02
24 / Ipamorelin component identity	Conforms to specified component identity Unit: qualitative Basis B16	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
25 / Ipamorelin component content	= 5.00355 mg/vial Basis B11	4.9 to 5.1 Unit: mg/vial	M05 PASS C02
T05 / Related substances and degradants			
06 / CJC-1295 No DAC Unknown U1	= 0.037 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / CJC-1295 No DAC Unknown U2	= 0.022 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
08 / CJC-1295 No DAC Unknown U3	= 0.016 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
09 / CJC-1295 No DAC total related peaks	= 0.075 % integrated detector area Basis B07	<= 0.3 Unit: % integrated detector area	M03 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
11 / Ipamorelin Unknown U1	= 0.065 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
12 / Ipamorelin Unknown U2	= 0.039 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
13 / Ipamorelin Unknown U3	= 0.025 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
14 / Ipamorelin total related peaks	= 0.129 % integrated detector area Basis B07	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
29 / Residual water	= 0.819 % w/w finished fill Basis B17	<= 2 Unit: % w/w finished fill	M07 PASS C02
T07 / Counterions and associated species			
30 / Acetate content relative to parent active mass	= 1.5 % acetate/parent mass Basis B18	0.5 to 3 Unit: % acetate/parent mass	M08 PASS C02
T08 / Residual solvents			
31 / Methanol	= 22.142 ug/g finished fill Basis B19	<= 3000 Unit: ug/g finished fill	M09 PASS C05
32 / Acetonitrile	= 8.867 ug/g finished fill Basis B19	<= 410 Unit: ug/g finished fill	M09 PASS C06
33 / Dichloromethane	= 3.802 ug/g finished fill Basis B19	<= 600 Unit: ug/g finished fill	M09 PASS C07
34 / N, N-dimethylformamide	= 3.933 ug/g finished fill Basis B19	<= 880 Unit: ug/g finished fill	M09 PASS C08
35 / Ethanol	= 39.527 ug/g finished fill Basis B19	<= 5000 Unit: ug/g finished fill	M09 PASS C05
36 / Acetone	= 11.467 ug/g finished fill Basis B19	<= 5000 Unit: ug/g finished fill	M09 PASS C08
37 / Ethyl acetate	= 9.848 ug/g finished fill Basis B19	<= 5000 Unit: ug/g finished fill	M09 PASS C08

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
38 / Toluene	= 1.72 ug/g finished fill Basis B19	<= 890 Unit: ug/g finished fill	M09 PASS C09
39 / n-Hexane	= 1.18 ug/g finished fill Basis B19	<= 290 Unit: ug/g finished fill	M09 PASS C09
40 / Benzene	= 0.073 ug/g finished fill Basis B19	<= 2 Unit: ug/g finished fill	M09 PASS C10
T09 / Elemental impurities			
41 / Lead	= 0.0125 ug/g finished fill Basis B20	<= 0.5 Unit: ug/g finished fill	M10 PASS C11
42 / Cadmium	= 0.0087 ug/g finished fill Basis B20	<= 0.2 Unit: ug/g finished fill	M10 PASS C11
43 / Arsenic	= 0.0185 ug/g finished fill Basis B20	<= 0.5 Unit: ug/g finished fill	M10 PASS C11
44 / Mercury	= 0.0062 ug/g finished fill Basis B20	<= 0.1 Unit: ug/g finished fill	M10 PASS C11
45 / Cobalt	= 0.0204 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
46 / Vanadium	= 0.0247 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
47 / Nickel	= 0.037 ug/g finished fill Basis B20	<= 2 Unit: ug/g finished fill	M10 PASS C11
48 / Palladium	= 0.0111 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
49 / Platinum	= 0.0098 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
50 / Rhodium	= 0.0069 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
51 / Ruthenium	= 0.0092 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
52 / Iridium	= 0.0065 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
T10 / Sterility test			
57 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C12
58 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B26	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C12
T11 / Bacterial endotoxins			
59 / Bacterial endotoxins	<0.025 EU/mg active-equivalent Basis B27	<= 0.1 Unit: EU/mg active-equivalent	M15 PASS C13
T12 / Microbial enumeration			
60 / TAMC	<1 CFU/g finished fill Basis B28	<= 100 Unit: CFU/g finished fill	M16 PASS C14
61 / TYMC	<1 CFU/g finished fill Basis B28	<= 10 Unit: CFU/g finished fill	M16 PASS C14
62 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
63 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
64 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
65 / Salmonella species	Not detected in 1g Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
66 / Candida albicans	Not detected in 1g Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
T13 / pH and analytical solution			
53 / pH of specified buffered analytical solution	= 4.78 pH Basis B21	4.1 to 5.5 Unit: pH	M11 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T14 / Excipients and preservatives			
54 / Trehalose content	= 5.004 mg/vial Basis B22	4.75 to 5.25 Unit: mg/vial	M12 PASS C02
T15 / Unit uniformity			
19 / CJC-1295 No DAC individual-unit mean	= 99.966 % label claim Basis B12	98 to 102 Unit: % label claim Basis B13	M06 PASS C04
20 / CJC-1295 No DAC acceptance value (n=10)	= 0.8458 % label claim Basis B14	<= 15 Unit: % label claim	M06 PASS C04
21 / CJC-1295 No DAC individual-unit RSD	= 0.3525 % Basis B15	<= 2 Unit: %	M06 PASS C04
26 / Ipamorelin individual-unit mean	= 100.071 % label claim Basis B12	98 to 102 Unit: % label claim Basis B13	M06 PASS C04
27 / Ipamorelin acceptance value (n=10)	= 0.8458 % label claim Basis B14	<= 15 Unit: % label claim	M06 PASS C04
28 / Ipamorelin individual-unit RSD	= 0.3522 % Basis B15	<= 2 Unit: %	M06 PASS C04
T16 / Biological activity			
67 / GHRHR relative potency	= 100.05 % reference response potency Basis B30	90 to 110 Unit: % reference response potency	M17 PASS C02
68 / GHSR1a relative potency	= 100.08 % reference response potency Basis B30	90 to 110 Unit: % reference response potency	M17 PASS C02
T17 / Protein and conjugate characterization			
69 / 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 B12	Same as reported result Unit: qualitative Basis B13	M18 N/A — justified C16

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T18 / Process impurities			
70 / 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 B12	Same as reported result Unit: qualitative Basis B13	M19 N/A — justified C16
T19 / Particles and container closure			
77 / Subvisible particles >= 10um	= 21 particles/container Basis B33	<= 6000 Unit: particles/container	M22 PASS C17
78 / Subvisible particles >= 25um	= 2 particles/container Basis B33	<= 600 Unit: particles/container	M22 PASS C17
79 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B34	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C18
T20 / Stability observations			
80 / Reported 6 month assay retention	= 99.91 % of initial assay Basis B35	98 to 102 Unit: % of initial assay	M23 PASS C02
81 / Reported 6 month minimum component purity	= 99.829 % integrated detector area Basis B36	99.7 to 100 Unit: % integrated detector area	M23 PASS C02
82 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B35	Conforms to the specified acceptance criterion Unit: qualitative	M23 PASS C01
T21 / Appearance and physical inspection			
55 / Appearance	white to off-white; uniform lyophilized cake Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
56 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B24	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-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-T08-DEFAULT	Residual solvent panel	headspace GC-MS
M10 M-T09-DEFAULT	Elemental impurity panel	ICP-MS
M11 M-T13-DEFAULT	pH and solution state	Calibrated potentiometry
M12 M-T14-DEFAULT	Excipients/preservatives	Component-specific quantitative LC/CAD or formulation identity
M13 M-T21-DEFAULT	Appearance	Controlled visual examination
M14 M-T10-DEFAULT	Sterility observations in two media with matrix-specific preparation	Membrane filtration/rinsing or neutralized direct inoculation for Lemon dispersion
M15 M-T11-DEFAULT	Bacterial endotoxins	Recombinant factor C fluorometric assay
M16 M-T12-DEFAULT	Microbial enumeration/organisms	Membrane filtration enumeration and enrichment
M17 M-T16-DEFAULT	Functional biological activity	Reference-relative concentration-response assay
M18 M-T17-DEFAULT	Protein/conjugate characterization	SEC-MALS, CE-SDS, peptide mapping, glycan/PEG profiling

Key / method ID	Method	Technique
M19 M-T18-DEFAULT	Biological process impurity panel	Host/process-specific ELISA and qPCR
M20 M-T01-RESIDUE-CHIRAL-LC	Diagnostic amino-acid absolute-configuration/composition check	Marfey-type diastereomeric derivatization LC-MS with authentic L/D references
M21 M-T01-EPIMER-REFERENCE-C HALLENGE	Selected intact-peptide positional-epimer reference challenge	Compound-specific epimer-resolving RP-LC with parent/epimer coanalysis
M22 M-T19-DEFAULT	Particles and package integrity	Light obscuration plus vacuum decay
M23 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	Modified GRF(1-29)-amide as product 16,500 mg plus ipamorelin 5.000 mg; total 10.000 mg. Ipamorelin: H-Aib-L-His-D-2Nal-D-Phe-L-Lys-NH ₂ ; Aib achiral, 2Nal=3-(2-naphthyl)alanine.
B02	spectrum/peptide-map comparison; score is not proof of stereochemistry
B03	[M+3H] ³⁺ ; reference monoisotopic M=3365.89357833882 Da; molecule excludes associated salt/solvate
B04	[M+1H] ¹⁺ ; reference monoisotopic M=711.3856657 Da; molecule excludes associated salt/solvate
B05	Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation
B06	Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only
B07	Sum of U1+U2+U3; purity plus related areas = 100%
B08	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B09	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B10	no-DAC is modified GRF(1-29)-amide: H-Tyr-D-Ala-Asp-Ala-Ile-Phe-Thr-Gln-Ser-Tyr-Arg-Lys-Val-Leu-Ala-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Leu-Ser-Arg-NH ₂ . D-Ala ₂ only; no Lys ₃₀ or maleimide.
B11	Same independent component assay as T03, not a second independent test
B12	specified sample/form only
B13	material-specific limit
B14	AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5
B15	Precision criterion for the listed specification, independently of AV
B16	H-Aib-L-His-D-2Nal-D-Phe-L-Lys-NH ₂ , pentapeptide. Aib is achiral 2-aminoisobutyric acid; D-2Nal is D-3-(2-naphthyl)alanine. Free N-terminus; C-terminal amide.
B17	Water as percentage of total net formulation, not peptide area purity
B18	Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion.
B19	Material-based limit. Liquid numerical limits are listed specification and not ICH Option 1 mass ppm.
B20	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B21	1.000 mg active/mL in 25mM acetate buffer, pH 4.80, 25.0°C; buffer-solution compatibility is not the pH of dry material
B22	Separate excipient-specific assay; not label active
B23	Three containers under diffuse white illumination
B24	Visual observation only; subvisible particles reported separately
B25	FTM30-35°C; tested units only; growth-promotion/suitability controls conform
B26	SCDM20-25°C; tested units only; no sterility assurance level assigned
B27	Sample reporting limit after 1:5 dilution; threshold is and not based on administration route/dose

Key	Basis
B28	Zero colonies observed from 1g or 1 mL equivalent filter; report <1, not exact absence
B29	Specified-organism enrichment in explicit 1g/1 mL scope; not a universal pharmacopeial panel
B30	Relative to the specified reference response; activity units and mass units are evaluated separately. Method validation is not asserted by this report.
B31	Residue-specific target from explicit structure. Mixed D/L ratios are intentional where stated; not total chemical-purity percentage.
B32	$2 \times (tR_{\text{epimer}} - tR_{\text{main}}) / (\text{baseline_width_main} + \text{baseline_width_epimer})$; complements chiral amino-acid ratios
B33	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B34	method vacuum-decay threshold 0.20 kPa/60s; 5 µm 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: 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
identified structure or sequence	Modified GRF(1-29)-amide as product 16,500 mg plus ipamorelin 5.000 mg; total 10.000 mg. Ipamorelin: H-Aib-L-His-D-2Nal-D-Phe-L-Lys-NH ₂ ; Aib achiral, 2Nal=3-(2-naphthyl)alanine.	text
neutral average mass	Not assigned: construct/distribution or no supported unique species	Da or explicit reason
neutral monoisotopic mass	711.3856657	Da Reference, not measured neutral mass
observed m/z	712.393407	m/z
charge state	1	integer
adduct	[M+1H] ⁺	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-2603; internal standard, not a purchased certified reference material	text

05 / CJC-1295 No DAC chromatographic purity

Field	Reported value	Unit / note
main peak retention time	8.672	min
main peak area	9987100	counts
total integrated area	10000000	counts

15 / CJC-1295 No DAC active content

Field	Reported value	Unit / note
sample preparation volume	5	mL
dilution factor	10	fold

19 / CJC-1295 No DAC 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.

29 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.008257629989615	factor For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor.

59 / 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.

67 / GHRHR relative potency

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

77 / 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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