CERTIFICATE OF ANALYSIS

Cagrisema (2.5 mg+2.5 mg)

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0823-C	APX-COA-2026-0823-C	2026-08-23

NOMINAL COMPOSITION

Cagrilintide: 2.5 mg; Semaglutide: 2.5 mg

lyophilized solid in vial

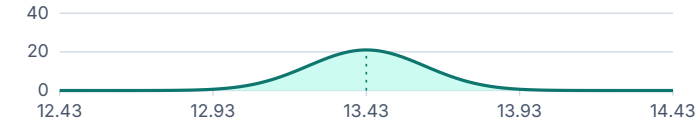
RECORDED RESULTS	Purity % integrated detector area	Active content
Cagrilintide	99.946%	2.502875 mg/vial
Semaglutide	99.854%	2.50685 mg/vial

ESTIMATED COMPONENT REFERENCE PROFILES

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

Cagrilintide

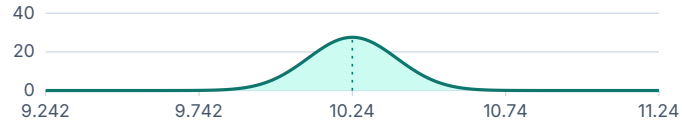
RT 13.431 min | 9,994,100 counts | APX-2026-0816-C



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

Semaglutide

RT 10.242 min | 9,994,500 counts | APX-2026-0721-S



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

77 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 2026-08-23

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 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 / Cagrilintide HRMS ion mass error	= -0.011 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
04 / Semaglutide HRMS ion mass error	= -0.4629 ppm Basis B04	-5 to 5 Unit: ppm	M01 PASS C02
71 / Semaglutide: Ala D fraction	= 0.02 mol% of selected amino acid Basis B31	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C17
T02 / Chromatographic purity			
05 / Cagrilintide chromatographic purity	= 99.946 % integrated detector area Basis B05	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
10 / Semaglutide chromatographic purity	= 99.854 % integrated detector area Basis B05	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
15 / Cagrilintide active content	= 2.50287 mg/vial Numeric value: 2.502875 Basis B08	2.45 to 2.55 Unit: mg/vial	M04 PASS C02
16 / Cagrilintide label claim assay	= 100.115 % label claim Basis B09	98 to 102 Unit: % label claim	M04 PASS C02
22 / Semaglutide active content	= 2.50685 mg/vial Basis B08	2.45 to 2.55 Unit: mg/vial	M04 PASS C02
23 / Semaglutide label claim assay	= 100.274 % label claim Basis B09	98 to 102 Unit: % label claim	M04 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T04 / Blend composition			
17 / Cagrilintide component identity	Conforms to specified component identity Unit: qualitative Basis B10	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
18 / Cagrilintide component content	= 2.50287 mg/vial Numeric value: 2.502875 Basis B11	2.45 to 2.55 Unit: mg/vial	M05 PASS C02
24 / Semaglutide component identity	Conforms to specified component identity Unit: qualitative Basis B16	Conforms to the specified acceptance criterion Unit: qualitative	M05 PASS C01
25 / Semaglutide component content	= 2.50685 mg/vial Basis B11	2.45 to 2.55 Unit: mg/vial	M05 PASS C02
T05 / Related substances and degradants			
06 / Cagrilintide Unknown U1	= 0.027 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / Cagrilintide Unknown U2	= 0.016 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
08 / Cagrilintide Unknown U3	= 0.011 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
09 / Cagrilintide total related peaks	= 0.054 % integrated detector area Basis B07	<= 0.3 Unit: % integrated detector area	M03 PASS C02
11 / Semaglutide Unknown U1	= 0.073 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
12 / Semaglutide Unknown U2	= 0.044 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
13 / Semaglutide Unknown U3	= 0.029 % integrated detector area Basis B06	<= 0.1 Unit: % integrated detector area	M03 PASS C03
14 / Semaglutide total related peaks	= 0.146 % integrated detector area Basis B07	<= 0.3 Unit: % integrated detector area	M03 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T06 / Water content			
29 / Residual water	= 0.628 % 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	= 20.01 ug/g finished fill Basis B19	<= 3000 Unit: ug/g finished fill	M09 PASS C05
32 / Acetonitrile	= 7.769 ug/g finished fill Basis B19	<= 410 Unit: ug/g finished fill	M09 PASS C06
33 / Dichloromethane	= 3.244 ug/g finished fill Basis B19	<= 600 Unit: ug/g finished fill	M09 PASS C07
34 / N, N-dimethylformamide	= 4.168 ug/g finished fill Basis B19	<= 880 Unit: ug/g finished fill	M09 PASS C08
35 / Ethanol	= 41.577 ug/g finished fill Basis B19	<= 5000 Unit: ug/g finished fill	M09 PASS C05
36 / Acetone	= 12.424 ug/g finished fill Basis B19	<= 5000 Unit: ug/g finished fill	M09 PASS C08
37 / Ethyl acetate	= 9.46 ug/g finished fill Basis B19	<= 5000 Unit: ug/g finished fill	M09 PASS C08
38 / Toluene	= 1.652 ug/g finished fill Basis B19	<= 890 Unit: ug/g finished fill	M09 PASS C09
39 / n-Hexane	= 1.155 ug/g finished fill Basis B19	<= 290 Unit: ug/g finished fill	M09 PASS C09
40 / Benzene	= 0.074 ug/g finished fill Basis B19	<= 2 Unit: ug/g finished fill	M09 PASS C10

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T09 / Elemental impurities			
41 / Lead	= 0.0118 ug/g finished fill Basis B20	<= 0.5 Unit: ug/g finished fill	M10 PASS C11
42 / Cadmium	= 0.0079 ug/g finished fill Basis B20	<= 0.2 Unit: ug/g finished fill	M10 PASS C11
43 / Arsenic	= 0.0196 ug/g finished fill Basis B20	<= 0.5 Unit: ug/g finished fill	M10 PASS C11
44 / Mercury	= 0.0063 ug/g finished fill Basis B20	<= 0.1 Unit: ug/g finished fill	M10 PASS C11
45 / Cobalt	= 0.0241 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
46 / Vanadium	= 0.0228 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
47 / Nickel	= 0.0319 ug/g finished fill Basis B20	<= 2 Unit: ug/g finished fill	M10 PASS C11
48 / Palladium	= 0.0119 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
49 / Platinum	= 0.0089 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
50 / Rhodium	= 0.0063 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
51 / Ruthenium	= 0.0082 ug/g finished fill Basis B20	<= 1 Unit: ug/g finished fill	M10 PASS C11
52 / Iridium	= 0.0056 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

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
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	= 4.81 pH Basis B21	4.1 to 5.5 Unit: pH	M11 PASS C02
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 / Cagrilintide individual-unit mean	= 100.115 % label claim Basis B12	98 to 102 Unit: % label claim Basis B13	M06 PASS C04

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
20 / Cagrilintide acceptance value (n=10)	= 0.8458 % label claim Basis B14	<= 15 Unit: % label claim	M06 PASS C04
21 / Cagrilintide individual-unit RSD	= 0.352 % Basis B15	<= 2 Unit: %	M06 PASS C04
26 / Semaglutide individual-unit mean	= 100.274 % label claim Basis B12	98 to 102 Unit: % label claim Basis B13	M06 PASS C04
27 / Semaglutide acceptance value (n=10)	= 0.8458 % label claim Basis B14	<= 15 Unit: % label claim	M06 PASS C04
28 / Semaglutide individual-unit RSD	= 0.3515 % Basis B15	<= 2 Unit: %	M06 PASS C04
T16 / Biological activity			
67 / Amylin receptor relative potency	= 100.05 % reference response potency Basis B30	90 to 110 Unit: % reference response potency	M17 PASS C02
68 / GLP1R 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
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

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T19 / Particles and container closure			
72 / Subvisible particles >= 10um	= 21 particles/container Basis B32	<= 6000 Unit: particles/container	M21 PASS C17
73 / Subvisible particles >= 25um	= 2 particles/container Basis B32	<= 600 Unit: particles/container	M21 PASS C17
74 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B33	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C18
T20 / Stability observations			
75 / Reported 6 month assay retention	= 99.9101 % of initial assay Basis B34	98 to 102 Unit: % of initial assay	M22 PASS C02
76 / Reported 6 month minimum component purity	= 99.812 % integrated detector area Basis B35	99.7 to 100 Unit: % integrated detector area	M22 PASS C02
77 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B34	Conforms to the specified acceptance criterion Unit: qualitative	M22 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-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	Physical mixture2.500 mg cagrilintide plus2.500 mg semaglutide,5.000 mg total per vial. Cagrilintide identity as product13; semaglutide is GLP1(7-37) analogue[Aib8, Arg34] with Lys26 epsilon acylated via2xAEEA-gammaGlu-C18 diacid linker and free C-terminal acid.
B02	spectrum/peptide-map comparison; score is not proof of stereochemistry
B03	[M+3H]^3+; reference monoisotopic M=4406.2515111 Da; molecule excludes associated salt/solvate
B04	[M+3H]^3+; reference monoisotopic M=4111.115377 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	Cagrilintide:KCNTATCATQRLAEFLRHSSNNFGPILPPTNVGSNTP-NH2,37-residue all-L peptide; Cys2-Cys7 disulfide. Lys1 alpha-amino group is acylated through gamma-L-Glu linked to C20 icosanedioic acid; Lys1 epsilon amino remains free.
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	Semaglutide: H-His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys*-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly-OH;31 residues. Lys20 in this chain (GLP-1 Lys26) epsilon-N attached via two AEEA spacers to N-octadecanedioyl-gamma-L-Glu; linker direction Lys-NH-CO-CH2-O-CH2CH2-O-CH2CH2-NH-CO-CH2-O-CH2CH2-O-CH2CH2-NH-CO-CH2CH2-CH(COOH)-NH-CO-(CH2)16-COOH. Aib achiral; all other encoded chiral residues L. material is acetate-associated with variable acetate composition.
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 Option1 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, pH4.80,25.0C; 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

Key	Basis
B25	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B26	SCDM20-25C; tested units only; no sterility assurance level assigned
B27	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B28	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B29	Specified-organism enrichment in explicit1g/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	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B33	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B34	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B35	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	Physical mixture2.500 mg cagrilintide plus2.500 mg semaglutide,5.000 mg total per vial. Cagrilintide identity as product13; semaglutide is GLP1(7-37) analogue[Aib8, Arg34] with Lys26 epsilon acylated via2xAEEA-gammaGlu-C18 diacid linker and free C-terminal acid.	text
neutral average mass	Not assigned: construct/distribution or no supported unique species	Da or explicit reason
neutral monoisotopic mass	4111.115377	Da Reference, not measured neutral mass
observed mz	1371.378434	m/z
charge state	3	integer
adduct	[M+3H]^3+	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-2588; internal standard, not a purchased certified reference material	text

05 / Cagrilintide chromatographic purity

Field	Reported value	Unit / note
main peak retention time	10.242	min
main peak area	9985400	counts
total integrated area	10000000	counts

15 / Cagrilintide active content

Field	Reported value	Unit / note
sample preparation volume	2.5	mL
dilution factor	10	fold

19 / Cagrilintide 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	1.006319687638369	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 / Amylin receptor relative potency

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

72 / Subvisible particles >= 10um

Field	Reported value	Unit / note
packaging sample count	10	Explicit context; see value Method and sample context; reference facts are in Identity Reference.

END OF REPORT

Apex Laboratory | APX-COA-2026-0823-C | APX-2026-0823-C