CERTIFICATE OF ANALYSIS

# Liraglutide

30 mg

| LOT NUMBER | REPORT NUMBER | COA ISSUE DATE |
|---|---|---|
| APX-2026-0728-L | APX-COA-2026-0728-L | 2026-07-28 |

## COMPOUND REFERENCE

Material family
defined peptide

Reference formula
$C_{172}H_{265}N_{43}O_{51}$

Average mass
3751.2 Da

Monoisotopic mass
3748.9464612 Da

## RECORDED IDENTITY

Observed ion
1250.655134 m/z

Ion assignment
[M+3H]^3+ | charge 3

Sequence / construct
See complete identity results

Recorded storage
-20 +/-5 C, protected from light; sealed dry vial

Formula and neutral masses describe the stated reference species. Counterions, solvates, formulation and measured ions retain their own reporting basis.

| RECORDED RESULTS | Purity<br>% integrated detector area | Active content |
|---|---|---|
| Liraglutide | 99.881% | 30.0009 mg/vial |

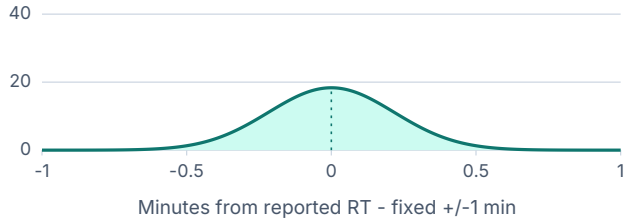
## ESTIMATED PEAK PROFILE

Reported RT: 15.357 min

Reported integrated area: 9,988,100 counts

Modeled area density (10^6 counts/min)


0-20 min model view




Minutes from reported RT - fixed +/-1 min

Gaussian model; N = 5,000 assumed. Width and height estimated; not detector measurements.

62 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 2026-07-28

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<br>Unit: qualitative<br>Basis B01 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M01<br>PASS<br>C01 |
| 02 / Orthogonal fingerprint similarity | = 0.9994 similarity (0-1)<br>Basis B02 | >= 0.995<br>Unit: similarity (0-1) | M01<br>PASS<br>C02 |
| 03 / Liraglutide HRMS ion mass error | = -0.7699 ppm<br>Basis B03 | -5 to 5<br>Unit: ppm | M01<br>PASS<br>C02 |
| 56 / Liraglutide: Ala D fraction | = 0.02 mol% of selected amino acid<br>Basis B27 | 0 to 0.1<br>Unit: mol% of selected amino acid | M20<br>PASS<br>C17 |
| **T02 / Chromatographic purity** | | | |
| 04 / Liraglutide chromatographic purity | = 99.881 % integrated detector area<br>Basis B04 | 99.7 to 100<br>Unit: % integrated detector area | M02<br>PASS<br>C02 |
| **T03 / Active content and assay** | | | |
| 09 / Liraglutide active content | = 30.0009 mg/vial<br>Basis B07 | 29.4 to 30.6<br>Unit: mg/vial | M04<br>PASS<br>C02 |
| 10 / Liraglutide label claim assay | = 100.003 % label claim<br>Basis B08 | 98 to 102<br>Unit: % label claim | M04<br>PASS<br>C02 |
| **T04 / Blend composition** | | | |
| 14 / Applicability decision | Not applicable — One declared active or a water/preservative reagent. Preservative is separately quantified under T14; there is no multi-active blend ratio.<br>Unit: qualitative<br>Basis B09 | Same as reported result<br>Unit: qualitative<br>Basis B10 | M06<br>N/A — justified<br>C05 |
| **T05 / Related substances and degradants** | | | |
| 05 / Liraglutide Unknown U1 | = 0.059 % integrated detector area<br>Basis B05 | <= 0.1<br>Unit: % integrated detector area | M03<br>PASS<br>C03 |

| Endpoint | Reported result / basis | Acceptance criterion | Method / outcome |
|---|---|---|---|
| 06 / Liraglutide Unknown U2 | = 0.036 % integrated detector area<br>Basis B05 | <= 0.1<br>Unit: % integrated detector area | M03<br>PASS<br>C03 |
| 07 / Liraglutide Unknown U3 | = 0.024 % integrated detector area<br>Basis B05 | <= 0.1<br>Unit: % integrated detector area | M03<br>PASS<br>C03 |
| 08 / Liraglutide total related peaks | = 0.119 % integrated detector area<br>Basis B06 | <= 0.3<br>Unit: % integrated detector area | M03<br>PASS<br>C02 |
| **T06 / Water content** | | | |
| 15 / Residual water | = 0.66 % w/w finished fill<br>Basis B13 | <= 2<br>Unit: % w/w finished fill | M07<br>PASS<br>C02 |
| **T07 / Counterions and associated species** | | | |
| 16 / Acetate content relative to parent active mass | = 1.5 % acetate/parent mass<br>Basis B14 | 0.5 to 3<br>Unit: % acetate/parent mass | M08<br>PASS<br>C02 |
| **T08 / Residual solvents** | | | |
| 17 / Methanol | = 21.624 ug/g finished fill<br>Basis B15 | <= 3000<br>Unit: ug/g finished fill | M09<br>PASS<br>C06 |
| 18 / Acetonitrile | = 9.11 ug/g finished fill<br>Basis B15 | <= 410<br>Unit: ug/g finished fill | M09<br>PASS<br>C07 |
| 19 / Dichloromethane | = 3.632 ug/g finished fill<br>Basis B15 | <= 600<br>Unit: ug/g finished fill | M09<br>PASS<br>C08 |
| 20 / N, N-dimethylformamide | = 3.935 ug/g finished fill<br>Basis B15 | <= 880<br>Unit: ug/g finished fill | M09<br>PASS<br>C09 |
| 21 / Ethanol | = 36.698 ug/g finished fill<br>Basis B15 | <= 5000<br>Unit: ug/g finished fill | M09<br>PASS<br>C06 |
| 22 / Acetone | = 11.306 ug/g finished fill<br>Basis B15 | <= 5000<br>Unit: ug/g finished fill | M09<br>PASS<br>C09 |
| 23 / Ethyl acetate | = 9.436 ug/g finished fill<br>Basis B15 | <= 5000<br>Unit: ug/g finished fill | M09<br>PASS<br>C09 |
| 24 / Toluene | = 1.8 ug/g finished fill<br>Basis B15 | <= 890<br>Unit: ug/g finished fill | M09<br>PASS<br>C10 |

| Endpoint | Reported result / basis | Acceptance criterion | Method / outcome |
|---|---|---|---|
| 25 / n-Hexane | = 1.133 ug/g finished fill<br>Basis B15 | <= 290<br>Unit: ug/g finished fill | M09<br>PASS<br>C10 |
| 26 / Benzene | = 0.077 ug/g finished fill<br>Basis B15 | <= 2<br>Unit: ug/g finished fill | M09<br>PASS<br>C11 |
| T09 / Elemental impurities | | | |
| 27 / Lead | = 0.0126 ug/g finished fill<br>Basis B16 | <= 0.5<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 28 / Cadmium | = 0.0075 ug/g finished fill<br>Basis B16 | <= 0.2<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 29 / Arsenic | = 0.0174 ug/g finished fill<br>Basis B16 | <= 0.5<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 30 / Mercury | = 0.0057 ug/g finished fill<br>Basis B16 | <= 0.1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 31 / Cobalt | = 0.0208 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 32 / Vanadium | = 0.0235 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 33 / Nickel | = 0.0384 ug/g finished fill<br>Basis B16 | <= 2<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 34 / Palladium | = 0.0113 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 35 / Platinum | = 0.0091 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 36 / Rhodium | = 0.0068 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 37 / Ruthenium | = 0.0098 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |
| 38 / Iridium | = 0.0056 ug/g finished fill<br>Basis B16 | <= 1<br>Unit: ug/g finished fill | M10<br>PASS<br>C12 |

| Endpoint | Reported result / basis | Acceptance criterion | Method / outcome |
|---|---|---|---|
| **T10 / Sterility test** | | | |
| 43 / Sterility: FTM | No growth at 14 days in all 20 units<br>Unit: qualitative<br>Basis B21 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M14<br>PASS<br>C13 |
| 44 / Sterility: SCDM | No growth at 14 days in all 20 units<br>Unit: qualitative<br>Basis B22 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M14<br>PASS<br>C13 |
| **T11 / Bacterial endotoxins** | | | |
| 45 / Bacterial endotoxins | <0.025 EU/mg active-equivalent<br>Basis B23 | <= 0.1<br>Unit: EU/mg active-equivalent | M15<br>PASS<br>C14 |
| **T12 / Microbial enumeration** | | | |
| 46 / TAMC | <1 CFU/g finished fill<br>Basis B24 | <= 100<br>Unit: CFU/g finished fill | M16<br>PASS<br>C15 |
| 47 / TYMC | <1 CFU/g finished fill<br>Basis B24 | <= 10<br>Unit: CFU/g finished fill | M16<br>PASS<br>C15 |
| 48 / Escherichia coli | Not detected in 1g<br>Unit: qualitative<br>Basis B25 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 49 / Staphylococcus aureus | Not detected in 1g<br>Unit: qualitative<br>Basis B25 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 50 / Pseudomonas aeruginosa | Not detected in 1g<br>Unit: qualitative<br>Basis B25 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 51 / Salmonella species | Not detected in 1g<br>Unit: qualitative<br>Basis B25 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 52 / Candida albicans | Not detected in 1g<br>Unit: qualitative<br>Basis B25 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| **T13 / pH and analytical solution** | | | |
| 39 / pH of specified buffered analytical solution | = 4.82 pH<br>Basis B17 | 4.1 to 5.5<br>Unit: pH | M11<br>PASS<br>C02 |
| **T14 / Excipients and preservatives** | | | |
| 40 / Trehalose content | = 5.004 mg/vial<br>Basis B18 | 4.75 to 5.25<br>Unit: mg/vial | M12<br>PASS<br>C02 |

| Endpoint | Reported result / basis | Acceptance criterion | Method / outcome |
|---|---|---|---|
| **T15 / Unit uniformity** | | | |
| 11 / Liraglutide individual-unit mean | = 100.003 % label claim<br>Basis B09 | 98 to 102<br>Unit: % label claim<br>Basis B10 | M05<br>PASS<br>C04 |
| 12 / Liraglutide acceptance value (n=10) | = 0.8458 % label claim<br>Basis B11 | <= 15<br>Unit: % label claim | M05<br>PASS<br>C04 |
| 13 / Liraglutide individual-unit RSD | = 0.3524 %<br>Basis B12 | <= 2<br>Unit: % | M05<br>PASS<br>C04 |
| **T16 / Biological activity** | | | |
| 53 / GLP1R cAMP response relative potency | = 100.05 % reference response potency<br>Basis B26 | 90 to 110<br>Unit: % reference response potency | M17<br>PASS<br>C02 |
| **T17 / Protein and conjugate characterization** | | | |
| 54 / 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.<br>Unit: qualitative<br>Basis B09 | Same as reported result<br>Unit: qualitative<br>Basis B10 | M18<br>N/A — justified<br>C05 |
| **T18 / Process impurities** | | | |
| 55 / 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.<br>Unit: qualitative<br>Basis B09 | Same as reported result<br>Unit: qualitative<br>Basis B10 | M19<br>N/A — justified<br>C05 |
| **T19 / Particles and container closure** | | | |
| 57 / Subvisible particles >= 10um | = 21 particles/container<br>Basis B28 | <= 6000<br>Unit: particles/container | M21<br>PASS<br>C17 |
| 58 / Subvisible particles >= 25um | = 2 particles/container<br>Basis B28 | <= 600<br>Unit: particles/container | M21<br>PASS<br>C17 |
| 59 / Vacuum decay package integrity | 10/10test closures conform; positive-leak controls detected<br>Unit: qualitative<br>Basis B29 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M21<br>PASS<br>C18 |

| Endpoint | Reported result / basis | Acceptance criterion | Method / outcome |
|---|---|---|---|
| **T20 / Stability observations** | | | |
| 60 / Reported 6 month assay retention | = 99.91 % of initial assay<br>Basis B30 | 98 to 102<br>Unit: % of initial assay | M22<br>PASS<br>C02 |
| 61 / Reported 6 month minimum component purity | = 99.839 % integrated detector area<br>Basis B31 | 99.7 to 100<br>Unit: % integrated detector area | M22<br>PASS<br>C02 |
| 62 / Dating disposition | 6 month review point; actual expiry/retest not assigned<br>Unit: qualitative<br>Basis B30 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M22<br>PASS<br>C01 |
| **T21 / Appearance and physical inspection** | | | |
| 41 / Appearance | white to off-white; uniform lyophilized cake<br>Unit: qualitative<br>Basis B19 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M13<br>PASS<br>C01 |
| 42 / Visible foreign matter | None observed in 3 inspected units<br>Unit: qualitative<br>Basis B20 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M13<br>PASS<br>C01 |

# Method reference

The keys below identify the methods referenced in the result tables.

| Key / method ID | Method | Technique |
|---|---|---|
| M01<br>M-T01-DEFAULT | Orthogonal chemical/structural identity | LC-HRMS/MS plus sequence/connectivity-sensitive reference comparison |
| M02<br>M-T02-RP-UPLC-DAD | Component-specific reversed-phase chromatographic response purity | RP-UPLC with diode-array detection |
| M03<br>M-T05-DEFAULT | Related substances | Stability-indicating LC integration; orthogonal size/charge separation for biologics |
| M04<br>M-T03-DEFAULT | Calibrated material content | Independent quantitative LC/CAD, protein assay or bioactivity calibration for IU |
| M05<br>M-T15-DEFAULT | Individual-unit uniformity | Ten separate unit preparations and fill measurements |
| M06<br>M-T04-DEFAULT | Component-resolved blend assay | Separate calibrated selective assay for every declared component |
| M07<br>M-T06-KF | Residual formulation water on a defined mass basis | Coulometric Karl Fischer with oven transfer |
| M08<br>M-T07-DEFAULT | Counterion composition | Ion chromatography and stoichiometric accounting |
| M09<br>M-T08-DEFAULT | Residual solvent panel | headspace GC-MS |
| M10<br>M-T09-DEFAULT | Elemental impurity panel | ICP-MS |
| M11<br>M-T13-DEFAULT | pH and solution state | Calibrated potentiometry |
| M12<br>M-T14-DEFAULT | Excipients/preservatives | Component-specific quantitative LC/CAD or formulation identity |
| M13<br>M-T21-DEFAULT | Appearance | Controlled visual examination |
| M14<br>M-T10-DEFAULT | Sterility observations in two media with matrix-specific preparation | Membrane filtration/rinsing or neutralized direct inoculation for Lemon dispersion |
| M15<br>M-T11-DEFAULT | Bacterial endotoxins | Recombinant factor C fluorometric assay |
| M16<br>M-T12-DEFAULT | Microbial enumeration/organisms | Membrane filtration enumeration and enrichment |
| M17<br>M-T16-DEFAULT | Functional biological activity | Reference-relative concentration-response assay |
| M18<br>M-T17-DEFAULT | Protein/conjugate characterization | SEC-MALS, CE-SDS, peptide mapping, glycan/PEG profiling |

| Key / method ID | Method | Technique |
|---|---|---|
| M19<br>M-T18-DEFAULT | Biological process impurity panel | Host/process-specific ELISA and qPCR |
| M20<br>M-T01-RESIDUE-CHIRAL-LC | Diagnostic amino-acid absolute-configuration/composition check | Marfey-type diastereomeric derivatization LC-MS with authentic L/D references |
| M21<br>M-T19-DEFAULT | Particles and package integrity | Light obscuration plus vacuum decay |
| M22<br>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 | H-HAEGTFTSDVSSYLEGQAAK(20)EFIAWLVRGRG-OH; all chiral amino-acid residues L. Lys20 of this31-residue sequence (GLP-1 position26) is epsilon-acylated with N-alpha-palmitoyl-L-gamma-glutamyl; Arg replaces native Lys at GLP-1 position34. Free N-terminal His and C-terminal Gly acid. |
| B02 | spectrum/peptide-map comparison; score is not proof of stereochemistry |
| B03 | [M+3H]^3+; reference monoisotopic M=3748.9464612 Da; molecule excludes associated salt/solvate |
| B04 | Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation |
| B05 | Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only |
| B06 | Sum of U1+U2+U3; purity plus related areas = 100% |
| B07 | Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification |
| B08 | Independent calibrated amount / nominal amount x 100; not chromatographic area purity |
| B09 | specified sample/form only |
| B10 | material-specific limit |
| B11 | AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5 |
| B12 | Precision criterion for the listed specification, independently of AV |
| B13 | Water as percentage of total net formulation, not peptide area purity |
| B14 | Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion. |
| B15 | Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm. |
| B16 | Total element; no speciation. material-based criterion, not a dose/route-derived safety limit. |
| B17 | 1.000 mg active/mL in 25mM acetate buffer, pH4.80,25.0C; buffer-solution compatibility is not the pH of dry material |
| B18 | Separate excipient-specific assay; not label active |
| B19 | Three containers under diffuse white illumination |
| B20 | Visual observation only; subvisible particles reported separately |
| B21 | FTM30-35C; tested units only; growth-promotion/suitability controls conform |
| B22 | SCDM20-25C; tested units only; no sterility assurance level assigned |
| B23 | Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose |
| B24 | Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence |
| B25 | Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel |
| B26 | Relative to the specified reference response; activity units and mass units are evaluated separately. Method validation is not asserted by this report. |

| Key | Basis |
|---|---|
| B27 | Residue-specific target from explicit structure. Mixed D/L ratios are intentional where stated; not total chemical-purity percentage. |
| B28 | As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim |
| B29 | method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence. |
| B30 | Reported change relative to the initial assay. This report does not assign a retest date or shelf life. |
| B31 | Separate endpoint; no shelf-life claim |

## Sampling and detection context

| Key | Reported context |
|---|---|
| C01 | Analytical replicates: 2; Statistic type: individual/qualitative observation; Units sampled: 3; Units type: finished containers |
| C02 | Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers |
| C03 | Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.002 % integrated detector area; LOQ: 0.005 % integrated detector area |
| C04 | Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 10; Units type: finished containers |
| C05 | Analytical replicates: 0; Statistic type: individual/qualitative observation; Units sampled: 0; Units type: finished containers |
| C06 | Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 ug/g finished fill; LOQ: 3 ug/g finished fill |
| C07 | 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 |
| C08 | 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 |
| C09 | 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 |
| C10 | 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 |
| C11 | 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 |
| C12 | 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 |
| 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/mg active-equivalent; LOQ: 0.025 EU/mg active-equivalent |
| C15 | 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 |
| C16 | Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 1; Units type: finished containers |
| C17 | Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers |
| C18 | Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 10; Units type: finished containers |

# Supporting analytical details

## 01 / Orthogonal identity against specified reference

| Field | Reported value | Unit / note |
|---|---|---|
| identified structure or sequence | H-HAEGTFTSDVSSYLEGQAAK(20)EFIAWLVRGRG-OH; all chiral amino-acid residues L. Lys20 of this31-residue sequence (GLP-1 position26) is epsilon-acylated with N-alpha-palmitoyl-L-gamma-glutamyl; Arg replaces native Lys at GLP-1 position34. Free N-terminal His and C-terminal Gly acid. | text |
| neutral average mass | 3751.2 | Da or explicit reason |
| neutral monoisotopic mass | 3748.9464612 | Da<br>Reference, not measured neutral mass |
| observed mz | 1250.655134 | 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<br>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<br>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<br>Method and sample context; reference facts are in Identity Reference. |
| identity standard traceability | RS-2628; internal standard, not a purchased certified reference material | text |

## 04 / Liraglutide chromatographic purity

| Field | Reported value | Unit / note |
|---|---|---|
| main peak retention time | 15.357 | min |
| main peak area | 9988100 | counts |
| total integrated area | 10000000 | counts |

## 09 / Liraglutide active content

| Field | Reported value | Unit / note |
|---|---|---|
| sample preparation volume | 30 | mL |
| dilution factor | 10 | fold |

## 11 / Liraglutide individual-unit mean

| Field | Reported value | Unit / note |
|---|---|---|
| physical unit count | 1 | Explicit context; see value<br>Method and sample context; reference facts are in Identity Reference. |

## 15 / Residual water

| Field | Reported value | Unit / note |
|---|---|---|
| dry basis correction | 1.00664384940608 | factor<br>For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor. |

## 16 / Acetate content relative to parent active mass

| Field | Reported value | Unit / note |
|---|---|---|
| counterion molar ratio | 0.9529842151615744 | mol acetate/mol parent |

## 45 / Bacterial endotoxins

| Field | Reported value | Unit / note |
|---|---|---|
| dilution factor | 5 | Explicit context; see value<br>Method and sample context; reference facts are in Identity Reference. |
| maximum valid dilution if used | 20 | Explicit context; see value<br>Method and sample context; reference facts are in Identity Reference. |

## 53 / GLP1R cAMP response relative potency

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

## 57 / Subvisible particles >= 10um

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

END OF REPORT

Apex Laboratory | APX-COA-2026-0728-L | APX-2026-0728-L