



CERTIFICATE OF ANALYSIS

# ACE 031 1 mg

LOT NUMBER  
APX-2026-0702-A

REPORT NUMBER  
APX-COA-2026-0702-A

COA ISSUE DATE  
2026-07-02

## COMPOUND REFERENCE

Material family  
protein or glycoprotein  
Material form  
lyophilized solid in vial

## MATERIAL & COMPOSITION

Nominal component amounts  
ACE 031 1 mg: 1 mg  
Recorded storage  
-20 +/-5 C, protected from light; sealed dry vial

## RECORDED RESULTS

ACE 031 1 mg

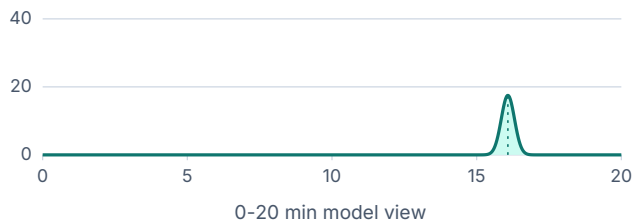
Purity  
% integrated detector area  
99.863%

Active content  
1.00209 mg/vial

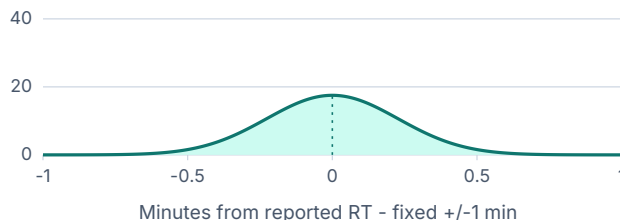
## ESTIMATED PEAK PROFILE

Reported RT: 16.079 min

Modeled area density (10<sup>6</sup> counts/min)



Reported integrated area: 9,986,300 counts



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

68 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 2026-07-02

## ONLINE REPORT

Scan to view this record  
and download the PDF.



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<br>Unit: qualitative<br><a href="#">Basis B01</a>                                                                                                       | Conforms to the specified acceptance criterion<br>Unit: qualitative       | <a href="#">M01</a><br>PASS<br><a href="#">C01</a>            |
| 02 / Orthogonal fingerprint similarity               | = 0.9994 similarity (0-1)<br><a href="#">Basis B02</a>                                                                                                                                                         | >= 0.995<br>Unit: similarity (0-1)                                        | <a href="#">M01</a><br>PASS<br><a href="#">C02</a>            |
| T02 / Chromatographic purity                         |                                                                                                                                                                                                                |                                                                           |                                                               |
| 03 / ACE 031 1 mg chromatographic purity             | = 99.863 % integrated detector area<br><a href="#">Basis B03</a>                                                                                                                                               | 99.7 to 100<br>Unit: % integrated detector area                           | <a href="#">M02</a><br>PASS<br><a href="#">C02</a>            |
| T03 / Active content and assay                       |                                                                                                                                                                                                                |                                                                           |                                                               |
| 08 / ACE 031 1 mg active content                     | = 1.00209 mg/vial<br><a href="#">Basis B06</a>                                                                                                                                                                 | 0.98 to 1.02<br>Unit: mg/vial                                             | <a href="#">M04</a><br>PASS<br><a href="#">C02</a>            |
| 09 / ACE 031 1 mg label claim assay                  | = 100.209 % label claim<br><a href="#">Basis B07</a>                                                                                                                                                           | 98 to 102<br>Unit: % label claim                                          | <a href="#">M04</a><br>PASS<br><a href="#">C02</a>            |
| T04 / Blend composition                              |                                                                                                                                                                                                                |                                                                           |                                                               |
| 13 / 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><a href="#">Basis B08</a> | Same as reported result<br>Unit: qualitative<br><a href="#">Basis B09</a> | <a href="#">M06</a><br>N/A — justified<br><a href="#">C05</a> |
| T05 / Related substances and degradants              |                                                                                                                                                                                                                |                                                                           |                                                               |
| 04 / ACE 031 1 mg Unknown U1                         | = 0.069 % integrated detector area<br><a href="#">Basis B04</a>                                                                                                                                                | <= 0.1<br>Unit: % integrated detector area                                | <a href="#">M03</a><br>PASS<br><a href="#">C03</a>            |
| 05 / ACE 031 1 mg Unknown U2                         | = 0.041 % integrated detector area<br><a href="#">Basis B04</a>                                                                                                                                                | <= 0.1<br>Unit: % integrated detector area                                | <a href="#">M03</a><br>PASS<br><a href="#">C03</a>            |
| 06 / ACE 031 1 mg Unknown U3                         | = 0.027 % integrated detector area<br><a href="#">Basis B04</a>                                                                                                                                                | <= 0.1<br>Unit: % integrated detector area                                | <a href="#">M03</a><br>PASS<br><a href="#">C03</a>            |

| Endpoint                                            | Reported result / basis                         | Acceptance criterion                       | Method / outcome   |
|-----------------------------------------------------|-------------------------------------------------|--------------------------------------------|--------------------|
| 07 / ACE 031 1 mg total related peaks               | = 0.137 % integrated detector area<br>Basis B05 | <= 0.3<br>Unit: % integrated detector area | M03<br>PASS<br>C02 |
| T06 / Water content                                 |                                                 |                                            |                    |
| 14 / Residual water                                 | = 0.539 % w/w finished fill<br>Basis B12        | <= 2<br>Unit: % w/w finished fill          | M07<br>PASS<br>C02 |
| T07 / Counterions and associated species            |                                                 |                                            |                    |
| 15 / Acetate content relative to parent active mass | = 1.5 % acetate/parent mass<br>Basis B13        | 0.5 to 3<br>Unit: % acetate/parent mass    | M08<br>PASS<br>C02 |
| T08 / Residual solvents                             |                                                 |                                            |                    |
| 16 / Methanol                                       | = 19.828 ug/g finished fill<br>Basis B14        | <= 3000<br>Unit: ug/g finished fill        | M09<br>PASS<br>C06 |
| 17 / Acetonitrile                                   | = 8.88 ug/g finished fill<br>Basis B14          | <= 410<br>Unit: ug/g finished fill         | M09<br>PASS<br>C07 |
| 18 / Dichloromethane                                | = 3.368 ug/g finished fill<br>Basis B14         | <= 600<br>Unit: ug/g finished fill         | M09<br>PASS<br>C08 |
| 19 / N, N-dimethylformamide                         | = 4.398 ug/g finished fill<br>Basis B14         | <= 880<br>Unit: ug/g finished fill         | M09<br>PASS<br>C09 |
| 20 / Ethanol                                        | = 40.861 ug/g finished fill<br>Basis B14        | <= 5000<br>Unit: ug/g finished fill        | M09<br>PASS<br>C06 |
| 21 / Acetone                                        | = 13.09 ug/g finished fill<br>Basis B14         | <= 5000<br>Unit: ug/g finished fill        | M09<br>PASS<br>C09 |
| 22 / Ethyl acetate                                  | = 8.795 ug/g finished fill<br>Basis B14         | <= 5000<br>Unit: ug/g finished fill        | M09<br>PASS<br>C09 |
| 23 / Toluene                                        | = 1.803 ug/g finished fill<br>Basis B14         | <= 890<br>Unit: ug/g finished fill         | M09<br>PASS<br>C10 |
| 24 / n-Hexane                                       | = 1.1 ug/g finished fill<br>Basis B14           | <= 290<br>Unit: ug/g finished fill         | M09<br>PASS<br>C10 |
| 25 / Benzene                                        | = 0.074 ug/g finished fill<br>Basis B14         | <= 2<br>Unit: ug/g finished fill           | M09<br>PASS<br>C11 |

| Endpoint                   | Reported result / basis                                                | Acceptance criterion                                                | Method / outcome   |
|----------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|
| T09 / Elemental impurities |                                                                        |                                                                     |                    |
| 26 / Lead                  | = 0.0118 ug/g finished fill<br>Basis B15                               | <= 0.5<br>Unit: ug/g finished fill                                  | M10<br>PASS<br>C12 |
| 27 / Cadmium               | = 0.0085 ug/g finished fill<br>Basis B15                               | <= 0.2<br>Unit: ug/g finished fill                                  | M10<br>PASS<br>C12 |
| 28 / Arsenic               | = 0.019 ug/g finished fill<br>Basis B15                                | <= 0.5<br>Unit: ug/g finished fill                                  | M10<br>PASS<br>C12 |
| 29 / Mercury               | = 0.0056 ug/g finished fill<br>Basis B15                               | <= 0.1<br>Unit: ug/g finished fill                                  | M10<br>PASS<br>C12 |
| 30 / Cobalt                | = 0.0239 ug/g finished fill<br>Basis B15                               | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 31 / Vanadium              | = 0.022 ug/g finished fill<br>Basis B15                                | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 32 / Nickel                | = 0.0365 ug/g finished fill<br>Basis B15                               | <= 2<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 33 / Palladium             | = 0.0117 ug/g finished fill<br>Basis B15                               | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 34 / Platinum              | = 0.0096 ug/g finished fill<br>Basis B15                               | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 35 / Rhodium               | = 0.0066 ug/g finished fill<br>Basis B15                               | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 36 / Ruthenium             | = 0.009 ug/g finished fill<br>Basis B15                                | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| 37 / Iridium               | = 0.0059 ug/g finished fill<br>Basis B15                               | <= 1<br>Unit: ug/g finished fill                                    | M10<br>PASS<br>C12 |
| T10 / Sterility test       |                                                                        |                                                                     |                    |
| 42 / Sterility: FTM        | No growth at 14 days in all 20 units<br>Unit: qualitative<br>Basis B20 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M14<br>PASS<br>C13 |

| Endpoint                                          | Reported result / basis                                                | Acceptance criterion                                                | Method / outcome   |
|---------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|
| 43 / Sterility: SCDM                              | 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 |
| T11 / Bacterial endotoxins                        |                                                                        |                                                                     |                    |
| 44 / Bacterial endotoxins                         | <0.025 EU/mg active-equivalent<br>Basis B22                            | <= 0.1<br>Unit: EU/mg active-equivalent                             | M15<br>PASS<br>C14 |
| T12 / Microbial enumeration                       |                                                                        |                                                                     |                    |
| 45 / TAMC                                         | <1 CFU/g finished fill<br>Basis B23                                    | <= 100<br>Unit: CFU/g finished fill                                 | M16<br>PASS<br>C15 |
| 46 / TYMC                                         | <1 CFU/g finished fill<br>Basis B23                                    | <= 10<br>Unit: CFU/g finished fill                                  | M16<br>PASS<br>C15 |
| 47 / Escherichia coli                             | Not detected in 1g<br>Unit: qualitative<br>Basis B24                   | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 48 / Staphylococcus aureus                        | Not detected in 1g<br>Unit: qualitative<br>Basis B24                   | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 49 / Pseudomonas aeruginosa                       | Not detected in 1g<br>Unit: qualitative<br>Basis B24                   | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 50 / Salmonella species                           | Not detected in 1g<br>Unit: qualitative<br>Basis B24                   | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| 51 / Candida albicans                             | Not detected in 1g<br>Unit: qualitative<br>Basis B24                   | Conforms to the specified acceptance criterion<br>Unit: qualitative | M16<br>PASS<br>C16 |
| T13 / pH and analytical solution                  |                                                                        |                                                                     |                    |
| 38 / pH of specified buffered analytical solution | = 4.8 pH<br>Basis B16                                                  | 4.1 to 5.5<br>Unit: pH                                              | M11<br>PASS<br>C02 |
| T14 / Excipients and preservatives                |                                                                        |                                                                     |                    |
| 39 / Trehalose content                            | = 5.004 mg/vial<br>Basis B17                                           | 4.75 to 5.25<br>Unit: mg/vial                                       | M12<br>PASS<br>C02 |
| T15 / Unit uniformity                             |                                                                        |                                                                     |                    |
| 10 / ACE 031 1 mg individual-unit mean            | = 100.209 % label claim<br>Basis B08                                   | 98 to 102<br>Unit: % label claim<br>Basis B09                       | M05<br>PASS<br>C04 |

| Endpoint                                                                     | Reported result / basis                                                        | Acceptance criterion                                                | Method / outcome   |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|
| 11 / ACE 031 1 mg acceptance value (n=10)                                    | = 0.8458 % label claim<br>Basis B10                                            | <= 15<br>Unit: % label claim                                        | M05<br>PASS<br>C04 |
| 12 / ACE 031 1 mg individual-unit RSD                                        | = 0.3517 %<br>Basis B11                                                        | <= 2<br>Unit: %                                                     | M05<br>PASS<br>C04 |
| T16 / Biological activity                                                    |                                                                                |                                                                     |                    |
| 52 / Activin A inhibition of SMAD2/3 reporter by ActRIIB-Fc relative potency | = 100.05 % reference response potency<br>Basis B25                             | 90 to 110<br>Unit: % reference response potency                     | M17<br>PASS<br>C02 |
| T17 / Protein and conjugate characterization                                 |                                                                                |                                                                     |                    |
| 53 / Size-exclusion main defined population                                  | = 99.863 % SEC response<br>Basis B26                                           | 99.7 to 100<br>Unit: % SEC response                                 | M18<br>PASS<br>C02 |
| 54 / High molecular weight aggregate fraction                                | = 0.069 % SEC response<br>Basis B08                                            | <= 0.1<br>Unit: % SEC response<br>Basis B09                         | M18<br>PASS<br>C02 |
| 55 / Low molecular weight non-reference fraction                             | = 0.068 % SEC response<br>Basis B08                                            | <= 0.1<br>Unit: % SEC response<br>Basis B09                         | M18<br>PASS<br>C02 |
| 56 / Orthogonal construct/fingerprint mapping                                | Conforms to explicit reference specification<br>Unit: qualitative<br>Basis B27 | Conforms to the specified acceptance criterion<br>Unit: qualitative | M18<br>PASS<br>C01 |
| 60 / Released N-glycan composition-profile cosine similarity                 | = 0.999999 similarity0-1<br>Numeric value: 0.9999993368264456<br>Basis B31     | 0.995 to 1<br>Unit: similarity0-1                                   | M20<br>PASS<br>C02 |
| 61 / Nonreducing CE-SDS intended chain-population fraction                   | = 99.88 % integrated CE-SDS area<br>Basis B32                                  | 99.7 to 100<br>Unit: % integrated CE-SDS area                       | M21<br>PASS<br>C02 |
| 62 / Reducing CE-SDS intended chain-population fraction                      | = 99.9 % integrated CE-SDS area<br>Basis B32                                   | 99.7 to 100<br>Unit: % integrated CE-SDS area                       | M21<br>PASS<br>C02 |
| T18 / Process impurities                                                     |                                                                                |                                                                     |                    |
| 57 / Residual source-process protein impurities                              | = 2.1 ng/mg assigned target material<br>Basis B28                              | <= 100<br>Unit: ng/mg assigned target material                      | M19<br>PASS<br>C17 |
| 58 / Residual source DNA                                                     | = 0.012 ng/vial<br>Basis B29                                                   | <= 1<br>Unit: ng/vial                                               | M19<br>PASS<br>C18 |

| Endpoint                                       | Reported result / basis                                                                          | Acceptance criterion                                                   | Method / outcome   |
|------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------|
| 59 / Residual Protein A                        | = 0.15 ng/mg target protein<br>Basis B30                                                         | <= 10<br>Unit: ng/mg target protein                                    | M19<br>PASS<br>C19 |
| T19 / Particles and container closure          |                                                                                                  |                                                                        |                    |
| 63 / Subvisible particles >= 10um              | = 21 particles/container<br>Basis B33                                                            | <= 6000<br>Unit: particles/container                                   | M22<br>PASS<br>C20 |
| 64 / Subvisible particles >= 25um              | = 2 particles/container<br>Basis B33                                                             | <= 600<br>Unit: particles/container                                    | M22<br>PASS<br>C20 |
| 65 / Vacuum decay package integrity            | 10/10test closures conform;<br>positive-leak controls detected<br>Unit: qualitative<br>Basis B34 | Conforms to the specified<br>acceptance criterion<br>Unit: qualitative | M22<br>PASS<br>C21 |
| T20 / Stability observations                   |                                                                                                  |                                                                        |                    |
| 66 / Reported 6 month assay retention          | = 99.9102 % of initial assay<br>Basis B35                                                        | 98 to 102<br>Unit: % of initial assay                                  | M23<br>PASS<br>C02 |
| 67 / Reported 6 month minimum component purity | = 99.821 % integrated detector area<br>Basis B36                                                 | 99.7 to 100<br>Unit: % integrated detector area                        | M23<br>PASS<br>C02 |
| 68 / Dating disposition                        | 6 month review point; actual<br>expiry/retest not assigned<br>Unit: qualitative<br>Basis B35     | Conforms to the specified<br>acceptance criterion<br>Unit: qualitative | M23<br>PASS<br>C01 |
| T21 / Appearance and physical inspection       |                                                                                                  |                                                                        |                    |
| 40 / Appearance                                | white to off-white; uniform lyophilized<br>cake<br>Unit: qualitative<br>Basis B18                | Conforms to the specified<br>acceptance criterion<br>Unit: qualitative | M13<br>PASS<br>C01 |
| 41 / Visible foreign matter                    | None observed in 3 inspected units<br>Unit: qualitative<br>Basis B19                             | Conforms to the specified<br>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-SEC-UV280 | Reference-defined protein size-population response purity            | Size-exclusion chromatography with UV detection at 280 nm                            |
| 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-T17-GLYCAN-COMPOSITIO<br>N-PROFILE | Released N-glycan composition-profile<br>comparison                   | PNGase-F release with composition-resolved,<br>response-calibrated LC-MS             |
| M21<br>M-T17-PROTEIN-CHAIN-PROFI<br>LE      | Reference-defined<br>reduced/nonreducing protein-chain<br>populations | CE-SDS with independent chain-reference<br>migration and subunit identity comparison |
| M22<br>M-T19-DEFAULT                        | Particles and package integrity                                       | Light obscuration plus vacuum decay                                                  |
| M23<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 | ACE-031/ramatercept reference construct: each chain is human ACVR2B precursor residues20-134 (construct1-115), GGG linker(116-118), human IGHG1*03 Fc H-CH2-CH3 fragment(119-343), including CH2 A115V at construct226; interchain disulfides122-122' and 125-125'. Two-chain glycosylated dimer; CHO-expressed material. |
| B02 | spectrum/peptide-map comparison; score is not proof of stereochemistry                                                                                                                                                                                                                                                    |
| B03 | Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation                                                                                                                                                                           |
| B04 | Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only                                                                                                                                                                                                                           |
| B05 | Sum of U1+U2+U3; purity plus related areas = 100%                                                                                                                                                                                                                                                                         |
| B06 | Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification                                                                                                                                                                                                      |
| B07 | Independent calibrated amount / nominal amount x 100; not chromatographic area purity                                                                                                                                                                                                                                     |
| B08 | specified sample/form only                                                                                                                                                                                                                                                                                                |
| B09 | material-specific limit                                                                                                                                                                                                                                                                                                   |
| B10 | AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5                                                                                                                                                                                                                                                       |
| B11 | Precision criterion for the listed specification, independently of AV                                                                                                                                                                                                                                                     |
| B12 | Water as percentage of total net formulation, not peptide area purity                                                                                                                                                                                                                                                     |
| B13 | Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion.                                                                                                                                  |
| B14 | Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.                                                                                                                                                                                                                      |
| B15 | Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.                                                                                                                                                                                                                            |
| B16 | 1.000 mg active/mL in 25mM acetate buffer, pH4.80,25.0C; buffer-solution compatibility is not the pH of dry material                                                                                                                                                                                                      |
| B17 | Separate excipient-specific assay; not label active                                                                                                                                                                                                                                                                       |
| B18 | Three containers under diffuse white illumination                                                                                                                                                                                                                                                                         |
| B19 | Visual observation only; subvisible particles reported separately                                                                                                                                                                                                                                                         |
| B20 | FTM30-35C; tested units only; growth-promotion/suitability controls conform                                                                                                                                                                                                                                               |
| B21 | SCDM20-25C; tested units only; no sterility assurance level assigned                                                                                                                                                                                                                                                      |
| B22 | Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose                                                                                                                                                                                                                         |
| B23 | Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence                                                                                                                                                                                                                                      |
| B24 | Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel                                                                                                                                                                                                                               |
| B25 | Relative to the specified reference response; activity units and mass units are evaluated separately. Method validation is not asserted by this report.                                                                                                                                                                   |
| B26 | Same primary SEC population result as T02 for proteins; orthogonal size separation for PEG/mixtures. Includes expected biological heterogeneity.                                                                                                                                                                          |

| Key | Basis                                                                                                                                                                                                               |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| B27 | Identity Reference defines construct, termini, and mixture caveats; no raw mass spectrum or gel image exists                                                                                                        |
| B28 | mammalian recombinant expression process; source-specific assay. For hydrolysates, intact source proteins outside the target digest are measured by selective separation; intended peptides are not HCP impurities. |
| B29 | Source-specific qPCR in process; extraction recovery demonstrated only                                                                                                                                              |
| B30 | Explicit Protein-A-affinity process for Fc construct                                                                                                                                                                |
| B31 | Cosine similarity of complete response-corrected fraction vectors to explicit reference; no site/linkage assignment                                                                                                 |
| B32 | Protein-specific reference profile; hCG/HMG expected alpha/beta subunits are intended species, not degraded monomer                                                                                                 |
| B33 | As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim                                                                                                 |
| B34 | method vacuum-decay threshold 0.20kPa/60s; 5um 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: 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: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.2 ng/mg assigned target material; LOQ: 0.6 ng/mg assigned target material |
| C18 | Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.001 ng/vial; LOQ: 0.003 ng/vial                                           |
| C19 | Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 ng/mg target protein; LOQ: 0.03 ng/mg target protein                   |

| Key | Reported context                                                                                                                     |
|-----|--------------------------------------------------------------------------------------------------------------------------------------|
| C20 | Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers |
| C21 | 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 | ACE-031/ramatercept reference construct: each chain is human ACVR2B precursor residues20-134 (construct1-115), GGG linker(116-118), human IGHG1*03 Fc H-CH2-CH3 fragment(119-343), including CH2 A115V at construct226; interchain disulfides122-122' and 125-125'. Two-chain glycosylated dimer; CHO-expressed material. | text                                                                                                 |
| neutral average mass             | Not assigned: construct/distribution or no supported unique species                                                                                                                                                                                                                                                       | Da or explicit reason                                                                                |
| neutral monoisotopic mass        | Not assigned — see component-specific HRMS records; a reference mass is not a measured neutral mass                                                                                                                                                                                                                       | Explicit context; see value<br>Method and sample context; reference facts are in Identity Reference. |
| observed mz                      | Not assigned — heterogeneous construct or no defined ion; orthogonal identity documented instead                                                                                                                                                                                                                          | Explicit context; see value<br>Method and sample context; reference facts are in Identity Reference. |
| mass tolerance                   | +/-5 ppm for an explicitly defined monoisotopic ion; not 5 Da.                                                                                                                                                                                                                                                            | Explicit context; see value<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-2578; internal standard, not a purchased certified reference material                                                                                                                                                                                                                                                  | text                                                                                                 |

03 / ACE 031 1 mg chromatographic purity

| Field                    | Reported value | Unit / note |
|--------------------------|----------------|-------------|
| main peak retention time | 16.079         | min         |
| main peak area           | 9986300        | counts      |
| total integrated area    | 10000000       | counts      |

## 08 / ACE 031 1 mg active content

| Field                     | Reported value | Unit / note |
|---------------------------|----------------|-------------|
| sample preparation volume | 1              | mL          |
| dilution factor           | 10             | fold        |

## 10 / ACE 031 1 mg 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. |

## 14 / Residual water

| Field                | Reported value    | Unit / note                                                                                                       |
|----------------------|-------------------|-------------------------------------------------------------------------------------------------------------------|
| dry basis correction | 1.005419209539417 | factor<br>For mass-fraction reporting only;<br>independent active assay is not blindly multiplied by this factor. |

## 44 / 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. |

## 52 / Activin A inhibition of SMAD2/3 reporter by ActRIIB-Fc 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. |

## 63 / Subvisible particles &gt;= 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-2026-0702-A | APX-2026-0702-A