CERTIFICATE OF ANALYSIS

Acetic Acid Solution 1% (10 ml)

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0703-A	APX-COA-2026-0703-A	2026-07-03

COMPOUND REFERENCE

Material family
solvent or reagent

Reference formula
$C_2H_4O_2$

Average mass
60.05 Da

Monoisotopic mass
60.021129366 Da

RECORDED IDENTITY

Observed ion
61.028397 m/z

Ion assignment
[M+1H]^1+ | charge 1

Reported sequence / structure
1.000%w/v aqueous acetic acid:10.00 mg/mL,10.00 mL container,100.0 mg CH3COOH equivalent. Solvent purified water.

Recorded storage
2-8 C, protected from light

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

Reagent quality measurements

pH of native liquid
2.73 pH

2.46 — 3.14

Criterion: 2.6 to 3
Criterion uses the result unit. Independent expanded scales.

Measured concentration

Acetic acid concentration
10.0241 mg/mL

9.66 — 10.34

Criterion: 9.8 to 10.2
Criterion uses the result unit. Independent expanded scales.

58 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 2026-07-03

ONLINE REPORT
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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 / Acetic acid HRMS ion mass error	= -0.1447 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
T02 / Chromatographic purity			
04 / Applicability decision	Not applicable — Bulk water or dilute aqueous reagent is controlled by calibrated concentration and reagent tests; 99.7% finished-solution HPLC area purity is not meaningful. Unit: qualitative Basis B04	Same as reported result Unit: qualitative Basis B05	M02 N/A — justified C03
T03 / Active content and assay			
06 / Acetic acid active content	= 100.241 mg/vial Basis B07	98 to 102 Unit: mg/vial	M04 PASS C02
07 / Acetic acid label claim assay	= 100.241 % label claim Basis B08	98 to 102 Unit: % label claim	M04 PASS C02
08 / Acetic acid concentration	= 10.0241 mg/mL Basis B09	9.8 to 10.2 Unit: mg/mL	M04 PASS C02
T04 / Blend composition			
11 / 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. Unit: qualitative Basis B04	Same as reported result Unit: qualitative Basis B05	M06 N/A — justified C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T05 / Related substances and degradants			
05 / Related organic impurity response in reagent assay	= 0.025 % of acetic acid or benzyl alcohol analyte response Basis B06	<= 0.1 Unit: % of acetic acid or benzyl alcohol analyte response	M03 PASS C04
T06 / Water content			
13 / Applicability decision	Not applicable — Water is the formulation vehicle; residual-moisture percentage would misdescribe an aqueous formulation. Vehicle quantity is specified separately. Unit: qualitative Basis B04	Same as reported result Unit: qualitative Basis B05	M07 N/A — justified C03
T07 / Counterions and associated species			
14 / Applicability decision	Not applicable — No fixed counterion salt is assigned in this formulation; vehicle ions and intentional metal complexes are treated by their component specifications. Unit: qualitative Basis B04	Same as reported result Unit: qualitative Basis B05	M08 N/A — justified C03
T08 / Residual solvents			
15 / Methanol	= 21.164 ug/mL formulation Basis B12	<= 3000 Unit: ug/mL formulation	M09 PASS C06
16 / Acetonitrile	= 8.072 ug/mL formulation Basis B12	<= 410 Unit: ug/mL formulation	M09 PASS C07
17 / Dichloromethane	= 3.595 ug/mL formulation Basis B12	<= 600 Unit: ug/mL formulation	M09 PASS C08
18 / N, N-dimethylformamide	= 4.258 ug/mL formulation Basis B12	<= 880 Unit: ug/mL formulation	M09 PASS C09
19 / Ethanol	= 39.374 ug/mL formulation Basis B12	<= 5000 Unit: ug/mL formulation	M09 PASS C06
20 / Acetone	= 11.105 ug/mL formulation Basis B12	<= 5000 Unit: ug/mL formulation	M09 PASS C09
21 / Ethyl acetate	= 9.597 ug/mL formulation Basis B12	<= 5000 Unit: ug/mL formulation	M09 PASS C09

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
22 / Toluene	= 1.772 ug/mL formulation Basis B12	<= 890 Unit: ug/mL formulation	M09 PASS C10
23 / n-Hexane	= 1.052 ug/mL formulation Basis B12	<= 290 Unit: ug/mL formulation	M09 PASS C10
24 / Benzene	= 0.072 ug/mL formulation Basis B12	<= 2 Unit: ug/mL formulation	M09 PASS C11
T09 / Elemental impurities			
25 / Lead	= 0.0127 ug/mL formulation Basis B13	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
26 / Cadmium	= 0.0076 ug/mL formulation Basis B13	<= 0.2 Unit: ug/mL formulation	M10 PASS C12
27 / Arsenic	= 0.019 ug/mL formulation Basis B13	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
28 / Mercury	= 0.0058 ug/mL formulation Basis B13	<= 0.1 Unit: ug/mL formulation	M10 PASS C12
29 / Cobalt	= 0.0241 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
30 / Vanadium	= 0.0226 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
31 / Nickel	= 0.0348 ug/mL formulation Basis B13	<= 2 Unit: ug/mL formulation	M10 PASS C12
32 / Palladium	= 0.01 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
33 / Platinum	= 0.0091 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
34 / Rhodium	= 0.0071 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
35 / Ruthenium	= 0.0082 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
36 / Iridium	= 0.0059 ug/mL formulation Basis B13	<= 1 Unit: ug/mL formulation	M10 PASS C12
T10 / Sterility test			
41 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
42 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B19	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
43 / Bacterial endotoxins	<0.025 EU/mL Basis B20	<= 0.1 Unit: EU/mL	M15 PASS C14
T12 / Microbial enumeration			
44 / TAMC	<1 CFU/mL Basis B21	<= 100 Unit: CFU/mL	M16 PASS C15
45 / TYMC	<1 CFU/mL Basis B21	<= 10 Unit: CFU/mL	M16 PASS C15
46 / Escherichia coli	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
47 / Staphylococcus aureus	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
48 / Pseudomonas aeruginosa	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
49 / Salmonella species	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
50 / Candida albicans	Not detected in 1 mL Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
T13 / pH and analytical solution			
37 / pH of native liquid	= 2.73 pH Basis B14	2.6 to 3 Unit: pH	M11 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T14 / Excipients and preservatives			
38 / Vehicle and preservative composition	Water q.s. declared volume; no added preservative Unit: qualitative Basis B15	Conforms to the specified acceptance criterion Unit: qualitative	M12 PASS C01
T15 / Unit uniformity			
09 / Acetic acid individual-unit mean	= 100.241 % label claim Basis B04	98 to 102 Unit: % label claim Basis B05	M05 PASS C05
10 / Acetic acid individual-unit RSD	= 0.3516 % Basis B10	<= 2 Unit: %	M05 PASS C05
12 / Mean extractable volume	= 10 mL/container Basis B11	9.9 to 10.2 Unit: mL/container	M05 PASS C05
T16 / Biological activity			
51 / Applicability decision	Not applicable — No qualified, reference-traceable potency endpoint is established for this selected identity. Identity/content data cannot justify an invented biological potency value; exploratory biological activity would require a separately defined assay. Unit: qualitative Basis B04	Same as reported result Unit: qualitative Basis B05	M17 N/A — justified C03
T17 / Protein and conjugate characterization			
52 / 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 B04	Same as reported result Unit: qualitative Basis B05	M18 N/A — justified C03
T18 / Process impurities			
53 / 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 B04	Same as reported result Unit: qualitative Basis B05	M19 N/A — justified C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T19 / Particles and container closure			
54 / Subvisible particles >= 10um	= 21 particles/container Basis B23	<= 6000 Unit: particles/container	M20 PASS C17
55 / Subvisible particles >= 25um	= 2 particles/container Basis B23	<= 600 Unit: particles/container	M20 PASS C17
56 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M20 PASS C18
T20 / Stability observations			
57 / Reported 6 month assay retention	= 99.9102 % of initial assay Basis B25	98 to 102 Unit: % of initial assay	M21 PASS C02
58 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01
T21 / Appearance and physical inspection			
39 / Appearance	colorless; clear solution Unit: qualitative Basis B16	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
40 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B17	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-DEFAULT	Chromatographic purity	RP-UPLC DAD; SEC for protein size species; HILIC/CAD for nonchromophoric analytes
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-T15-DEFAULT	Individual-unit uniformity	Ten separate unit preparations and fill measurements
M06 M-T04-DEFAULT	Component-resolved blend assay	Separate calibrated selective assay for every declared component
M07 M-T06-DEFAULT	Water	Coulometric Karl Fischer
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-T19-DEFAULT	Particles and package integrity	Light obscuration plus vacuum decay
M21 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	1.000%w/v aqueous acetic acid:10.00 mg/mL,10.00 mL container,100.0 mg CH3COOH equivalent. Solvent purified water.
B02	spectrum/peptide-map comparison; score is not proof of stereochemistry
B03	[M+1H]^1+; reference monoisotopic M=60.021129366 Da; molecule excludes associated salt/solvate
B04	specified sample/form only
B05	material-specific limit
B06	Analyte-specific reagent assay; not water-purity percentage
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	Amount per nominal 10 mL fill
B10	Precision criterion for the listed specification, independently of AV
B11	fill specification; no injection volume recommendation
B12	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B13	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B14	As supplied,25.0C; buffer-solution compatibility is not the pH of dry material
B15	Explicit formulation choice, not a statement about actual catalog formulation
B16	Three containers under diffuse white illumination
B17	Visual observation only; subvisible particles reported separately
B18	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B19	SCDM20-25C; tested units only; no sterility assurance level assigned
B20	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B21	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B22	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B23	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B24	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B25	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.

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: 0; Statistic type: individual/qualitative observation; Units sampled: 0; Units type: finished containers
C04	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.002 % of acetic acid or benzyl alcohol analyte response; LOQ: 0.005 % of acetic acid or benzyl alcohol analyte response
C05	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 10; 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/mL formulation; LOQ: 3 ug/mL formulation
C07	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.3 ug/mL formulation; LOQ: 1 ug/mL formulation
C08	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.2 ug/mL formulation; LOQ: 0.6 ug/mL formulation
C09	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.5 ug/mL formulation; LOQ: 1.5 ug/mL formulation
C10	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.1 ug/mL formulation; LOQ: 0.3 ug/mL formulation
C11	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 ug/mL formulation; LOQ: 0.03 ug/mL formulation
C12	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.0005 ug/mL formulation; LOQ: 0.002 ug/mL formulation
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/mL; LOQ: 0.025 EU/mL
C15	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 CFU/mL; LOQ: 1 CFU/mL
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	1.000%w/v aqueous acetic acid:10.00 mg/mL,10.00 mL container,100.0 mg CH3COOH equivalent. Solvent purified water.	text
neutral average mass	60.05	Da or explicit reason
neutral monoisotopic mass	60.021129366	Da Reference, not measured neutral mass
observed mz	61.028397	m/z
charge state	1	integer
adduct	[M+1H]^1+	text
mass tolerance	+/-5 ppm for an explicitly defined monoisotopic ion; not 5 Da.	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
reduced deglycosylated or intact	Intact specified parent for defined compounds; glycoproteins and PEG retain the specified population heterogeneity. No single exact intact glycoprotein mass is invented.	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
stereochemistry method	Component-specific chiral amino acid analysis or orthogonal structure comparison, where applicable; HRMS cannot distinguish stereoisomers.	Explicit context; see value Method and sample context; reference facts are in Identity Reference.
identity standard traceability	RS-2725; internal standard, not a purchased certified reference material	text

06 / Acetic acid active content

Field	Reported value	Unit / note
sample preparation volume	100	mL
dilution factor	10	fold

09 / Acetic acid 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.

43 / 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.

54 / Subvisible particles >= 10um

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

END OF REPORT

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