CERTIFICATE OF ANALYSIS

Adamax 10 mg

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0706-A	APX-COA-2026-0706-A	2026-07-06

COMPOUND REFERENCE

Material form
lyophilized solid in vial

MATERIAL & COMPOSITION

Nominal component amounts
Adamax 10 mg: 10 mg

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

RECORDED RESULTS

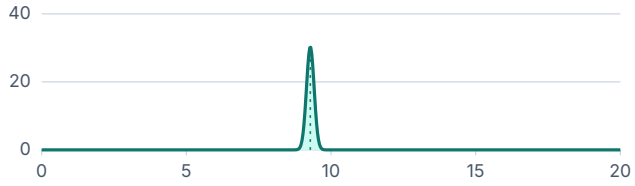
	Purity % integrated detector area	Active content
Adamax 10 mg	99.905%	10.0149 mg/vial

ESTIMATED PEAK PROFILE

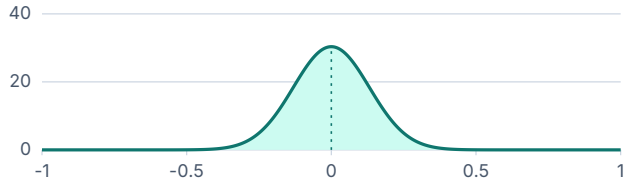
Reported RT: 9.285 min

Reported integrated area: 9,990,500 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.

60 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 2026-07-06

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	Conforms to the specified acceptance criterion Unit: qualitative	M01 PASS C01
02 / Orthogonal fingerprint similarity	= 0.9994 similarity (0-1) Basis B01	>= 0.995 Unit: similarity (0-1)	M01 PASS C02
T02 / Chromatographic purity			
03 / Adamax 10 mg chromatographic purity	= 99.905 % integrated detector area Basis B02	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
08 / Adamax 10 mg active content	= 10.0149 mg/vial Basis B05	9.8 to 10.2 Unit: mg/vial	M04 PASS C02
09 / Adamax 10 mg label claim assay	= 100.149 % label claim Basis B06	98 to 102 Unit: % label claim	M04 PASS C02
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. Unit: qualitative Basis B07	Same as reported result Unit: qualitative Basis B08	M06 N/A — justified C05
T05 / Related substances and degradants			
04 / Adamax 10 mg Unknown U1	= 0.048 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
05 / Adamax 10 mg Unknown U2	= 0.028 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03
06 / Adamax 10 mg Unknown U3	= 0.019 % integrated detector area Basis B03	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
07 / Adamax 10 mg total related peaks	= 0.095 % integrated detector area Basis B04	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
14 / Residual water	= 0.498 % w/w finished fill Basis B11	<= 2 Unit: % w/w finished fill	M07 PASS C02
T07 / Counterions and associated species			
15 / Acetate content relative to parent active mass	= 1.5 % acetate/parent mass Basis B12	0.5 to 3 Unit: % acetate/parent mass	M08 PASS C02
T08 / Residual solvents			
16 / Methanol	= 19.607 ug/g finished fill Basis B13	<= 3000 Unit: ug/g finished fill	M09 PASS C06
17 / Acetonitrile	= 7.736 ug/g finished fill Basis B13	<= 410 Unit: ug/g finished fill	M09 PASS C07
18 / Dichloromethane	= 3.436 ug/g finished fill Basis B13	<= 600 Unit: ug/g finished fill	M09 PASS C08
19 / N, N-dimethylformamide	= 4.554 ug/g finished fill Basis B13	<= 880 Unit: ug/g finished fill	M09 PASS C09
20 / Ethanol	= 34.719 ug/g finished fill Basis B13	<= 5000 Unit: ug/g finished fill	M09 PASS C06
21 / Acetone	= 11.409 ug/g finished fill Basis B13	<= 5000 Unit: ug/g finished fill	M09 PASS C09
22 / Ethyl acetate	= 8.285 ug/g finished fill Basis B13	<= 5000 Unit: ug/g finished fill	M09 PASS C09
23 / Toluene	= 1.86 ug/g finished fill Basis B13	<= 890 Unit: ug/g finished fill	M09 PASS C10
24 / n-Hexane	= 1.09 ug/g finished fill Basis B13	<= 290 Unit: ug/g finished fill	M09 PASS C10
25 / Benzene	= 0.073 ug/g finished fill Basis B13	<= 2 Unit: ug/g finished fill	M09 PASS C11

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T09 / Elemental impurities			
26 / Lead	= 0.0117 ug/g finished fill Basis B14	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
27 / Cadmium	= 0.008 ug/g finished fill Basis B14	<= 0.2 Unit: ug/g finished fill	M10 PASS C12
28 / Arsenic	= 0.0162 ug/g finished fill Basis B14	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
29 / Mercury	= 0.0061 ug/g finished fill Basis B14	<= 0.1 Unit: ug/g finished fill	M10 PASS C12
30 / Cobalt	= 0.0205 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
31 / Vanadium	= 0.0248 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
32 / Nickel	= 0.0366 ug/g finished fill Basis B14	<= 2 Unit: ug/g finished fill	M10 PASS C12
33 / Palladium	= 0.0117 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
34 / Platinum	= 0.0097 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
35 / Rhodium	= 0.0072 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
36 / Ruthenium	= 0.009 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
37 / Iridium	= 0.0057 ug/g finished fill Basis B14	<= 1 Unit: ug/g finished fill	M10 PASS C12
T10 / Sterility test			
42 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B19	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
43 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B20	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
44 / Bacterial endotoxins	<0.025 EU/mg active-equivalent Basis B21	<= 0.1 Unit: EU/mg active-equivalent	M15 PASS C14
T12 / Microbial enumeration			
45 / TAMC	<1 CFU/g finished fill Basis B22	<= 100 Unit: CFU/g finished fill	M16 PASS C15
46 / TYMC	<1 CFU/g finished fill Basis B22	<= 10 Unit: CFU/g finished fill	M16 PASS C15
47 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
48 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
49 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
50 / Salmonella species	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
51 / Candida albicans	Not detected in 1g Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
T13 / pH and analytical solution			
38 / pH of specified buffered analytical solution	= 4.8 pH Basis B15	4.1 to 5.5 Unit: pH	M11 PASS C02
T14 / Excipients and preservatives			
39 / Trehalose content	= 5.004 mg/vial Basis B16	4.75 to 5.25 Unit: mg/vial	M12 PASS C02
T15 / Unit uniformity			
10 / Adamax 10 mg individual-unit mean	= 100.149 % label claim Basis B07	98 to 102 Unit: % label claim Basis B08	M05 PASS C04

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
11 / Adamax 10 mg acceptance value (n=10)	= 0.8458 % label claim Basis B09	<= 15 Unit: % label claim	M05 PASS C04
12 / Adamax 10 mg individual-unit RSD	= 0.3519 % Basis B10	<= 2 Unit: %	M05 PASS C04
T16 / Biological activity			
52 / 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 B07	Same as reported result Unit: qualitative Basis B08	M17 N/A — justified C05
T17 / Protein and conjugate characterization			
53 / 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 B07	Same as reported result Unit: qualitative Basis B08	M18 N/A — justified C05
T18 / Process impurities			
54 / 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 B07	Same as reported result Unit: qualitative Basis B08	M19 N/A — justified C05
T19 / Particles and container closure			
55 / Subvisible particles >= 10um	= 21 particles/container Basis B24	<= 6000 Unit: particles/container	M20 PASS C17
56 / Subvisible particles >= 25um	= 2 particles/container Basis B24	<= 600 Unit: particles/container	M20 PASS C17
57 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M20 PASS C18

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T20 / Stability observations			
58 / Reported 6 month assay retention	= 99.9101 % of initial assay Basis B26	98 to 102 Unit: % of initial assay	M21 PASS C02
59 / Reported 6 month minimum component purity	= 99.863 % integrated detector area Basis B27	99.7 to 100 Unit: % integrated detector area	M21 PASS C02
60 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B26	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01
T21 / Appearance and physical inspection			
40 / Appearance	white to off-white; uniform lyophilized cake Unit: qualitative Basis B17	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
41 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01

Method reference

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

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

Key / method ID	Method	Technique
M19 M-T18-DEFAULT	Biological process impurity panel	Host/process-specific ELISA and qPCR
M20 M-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	spectrum/peptide-map comparison; score is not proof of stereochemistry
B02	Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation
B03	Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only
B04	Sum of U1+U2+U3; purity plus related areas = 100%
B05	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B06	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B07	specified sample/form only
B08	material-specific limit
B09	AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5
B10	Precision criterion for the listed specification, independently of AV
B11	Water as percentage of total net formulation, not peptide area purity
B12	Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion.
B13	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B14	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B15	1.000 mg active/mL in 25mM acetate buffer, pH4.80,25.0C; buffer-solution compatibility is not the pH of dry material
B16	Separate excipient-specific assay; not label active
B17	Three containers under diffuse white illumination
B18	Visual observation only; subvisible particles reported separately
B19	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B20	SCDM20-25C; tested units only; no sterility assurance level assigned
B21	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B22	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B23	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B24	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B25	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B26	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B27	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
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 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 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 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-2560; internal standard, not a purchased certified reference material	text

03 / Adamax 10 mg chromatographic purity

Field	Reported value	Unit / note
main peak retention time	9.285	min
main peak area	9990500	counts
total integrated area	10000000	counts

08 / Adamax 10 mg active content

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

10 / Adamax 10 mg 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.

14 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.00500492452413	factor For mass-fraction reporting only; 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 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.

55 / 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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