CERTIFICATE OF ANALYSIS

KPV

5 mg

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0513-K	APX-COA-2026-0513-K	2026-05-13

COMPOUND REFERENCE

Material family
defined peptide

Reference formula
$C_{16}H_{30}N_4O_4$

Average mass
342.43 Da

Monoisotopic mass
342.22670545 Da

RECORDED IDENTITY

Observed ion
343.233988 m/z

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

Sequence / construct
See complete identity results

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

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

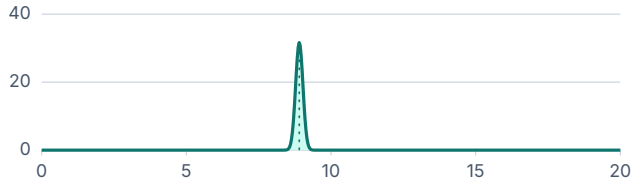
RECORDED RESULTS	Purity % integrated detector area	Active content
KPV	99.923%	5.0026 mg/vial

ESTIMATED PEAK PROFILE

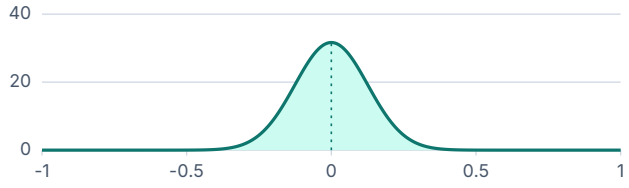
Reported RT: 8.904 min

Reported integrated area: 9,992,300 counts

Modeled area density (10^6 counts/min)



0-20 min model view



Minutes from reported RT - fixed +/-1 min

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

62 recorded endpoints across 21 test groups. Results apply to this configuration and lot. For research use only; not for human or animal use.

APPROVED BY

K. Norwood

COA issued 2026-05-13

ONLINE REPORT
Scan to view this record and download the PDF.

Contamination & microbiology

All applicable tested criteria met

32 applicable endpoints reviewed against their stated specifications.

ELEMENTAL IMPURITIES

Lead	✓ PASS
Cadmium	✓ PASS
Arsenic	✓ PASS
Mercury	✓ PASS
Cobalt	✓ PASS
Vanadium	✓ PASS
Nickel	✓ PASS
Palladium	✓ PASS
Platinum	✓ PASS
Rhodium	✓ PASS
Ruthenium	✓ PASS
Iridium	✓ PASS

RESIDUAL SOLVENTS

Methanol	✓ PASS
Acetonitrile	✓ PASS
Dichloromethane	✓ PASS
N, N-dimethylformamide	✓ PASS
Ethanol	✓ PASS
Acetone	✓ PASS
Ethyl acetate	✓ PASS
Toluene	✓ PASS
n-Hexane	✓ PASS
Benzene	✓ PASS

MICROBIOLOGY & ENDOTOXINS

Sterility: FTM	✓ PASS
Sterility: SCDM	✓ PASS
Bacterial endotoxins	✓ PASS
TAMC	✓ PASS
TYMC	✓ PASS
Escherichia coli	✓ PASS
Staphylococcus aureus	✓ PASS
Pseudomonas aeruginosa	✓ PASS
Salmonella species	✓ PASS
Candida albicans	✓ PASS

PASS indicates that the recorded result meets its stated criterion for the tested sample. Exact values, detection limits, sampling scope and methods follow in the complete results. For research use only.

Complete assay results

Reported values, units and acceptance outcomes are reproduced separately for each endpoint. Method keys link to the method reference section.

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T01 / Identity and structure			
01 / Orthogonal identity against specified reference	Conforms to the assigned reference; see identity basis Unit: qualitative Basis B01	Conforms to the specified acceptance criterion Unit: qualitative	M01 PASS C01
02 / Orthogonal fingerprint similarity	= 0.9994 similarity (0-1) Basis B02	>= 0.995 Unit: similarity (0-1)	M01 PASS C02
03 / KPV HRMS ion mass error	= 0.0177 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
56 / KPV: Val D fraction	= 0.02 mol% of selected amino acid Basis B26	0 to 0.1 Unit: mol% of selected amino acid	M20 PASS C17
T02 / Chromatographic purity			
04 / KPV chromatographic purity	= 99.923 % integrated detector area Basis B04	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
09 / KPV active content	= 5.0026 mg/vial Basis B07	4.9 to 5.1 Unit: mg/vial	M04 PASS C02
10 / KPV label claim assay	= 100.052 % label claim Basis B08	98 to 102 Unit: % label claim	M04 PASS C02
T04 / Blend composition			
14 / Applicability decision	Not applicable — One declared active or a water/preservative reagent. Preservative is separately quantified under T14; there is no multi-active blend ratio. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M06 N/A — justified C05
T05 / Related substances and degradants			
05 / KPV Unknown U1	= 0.038 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
06 / KPV Unknown U2	= 0.023 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / KPV Unknown U3	= 0.016 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03
08 / KPV total related peaks	= 0.077 % integrated detector area Basis B06	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
15 / Residual water	= 0.572 % w/w finished fill Basis B13	<= 2 Unit: % w/w finished fill	M07 PASS C02
T07 / Counterions and associated species			
16 / Acetate content relative to parent active mass	= 1.5 % acetate/parent mass Basis B14	0.5 to 3 Unit: % acetate/parent mass	M08 PASS C02
T08 / Residual solvents			
17 / Methanol	= 20.847 ug/g finished fill Basis B15	<= 3000 Unit: ug/g finished fill	M09 PASS C06
18 / Acetonitrile	= 8.276 ug/g finished fill Basis B15	<= 410 Unit: ug/g finished fill	M09 PASS C07
19 / Dichloromethane	= 3.451 ug/g finished fill Basis B15	<= 600 Unit: ug/g finished fill	M09 PASS C08
20 / N, N-dimethylformamide	= 3.843 ug/g finished fill Basis B15	<= 880 Unit: ug/g finished fill	M09 PASS C09
21 / Ethanol	= 40.007 ug/g finished fill Basis B15	<= 5000 Unit: ug/g finished fill	M09 PASS C06
22 / Acetone	= 13.123 ug/g finished fill Basis B15	<= 5000 Unit: ug/g finished fill	M09 PASS C09
23 / Ethyl acetate	= 9.097 ug/g finished fill Basis B15	<= 5000 Unit: ug/g finished fill	M09 PASS C09
24 / Toluene	= 1.71 ug/g finished fill Basis B15	<= 890 Unit: ug/g finished fill	M09 PASS C10

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
25 / n-Hexane	= 1.107 ug/g finished fill Basis B15	<= 290 Unit: ug/g finished fill	M09 PASS C10
26 / Benzene	= 0.077 ug/g finished fill Basis B15	<= 2 Unit: ug/g finished fill	M09 PASS C11
T09 / Elemental impurities			
27 / Lead	= 0.0125 ug/g finished fill Basis B16	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
28 / Cadmium	= 0.0074 ug/g finished fill Basis B16	<= 0.2 Unit: ug/g finished fill	M10 PASS C12
29 / Arsenic	= 0.0179 ug/g finished fill Basis B16	<= 0.5 Unit: ug/g finished fill	M10 PASS C12
30 / Mercury	= 0.0061 ug/g finished fill Basis B16	<= 0.1 Unit: ug/g finished fill	M10 PASS C12
31 / Cobalt	= 0.0231 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12
32 / Vanadium	= 0.0249 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12
33 / Nickel	= 0.0349 ug/g finished fill Basis B16	<= 2 Unit: ug/g finished fill	M10 PASS C12
34 / Palladium	= 0.0106 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12
35 / Platinum	= 0.0095 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12
36 / Rhodium	= 0.0073 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12
37 / Ruthenium	= 0.0092 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12
38 / Iridium	= 0.0064 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T10 / Sterility test			
43 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
44 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
45 / Bacterial endotoxins	<0.025 EU/mg active-equivalent Basis B23	<= 0.1 Unit: EU/mg active-equivalent	M15 PASS C14
T12 / Microbial enumeration			
46 / TAMC	<1 CFU/g finished fill Basis B24	<= 100 Unit: CFU/g finished fill	M16 PASS C15
47 / TYMC	<1 CFU/g finished fill Basis B24	<= 10 Unit: CFU/g finished fill	M16 PASS C15
48 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
49 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
50 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
51 / Salmonella species	Not detected in 1g Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
52 / Candida albicans	Not detected in 1g Unit: qualitative Basis B25	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
T13 / pH and analytical solution			
39 / pH of specified buffered analytical solution	= 4.8 pH Basis B17	4.1 to 5.5 Unit: pH	M11 PASS C02
T14 / Excipients and preservatives			
40 / Trehalose content	= 5.004 mg/vial Basis B18	4.75 to 5.25 Unit: mg/vial	M12 PASS C02

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T15 / Unit uniformity			
11 / KPV individual-unit mean	= 100.052 % label claim Basis B09	98 to 102 Unit: % label claim Basis B10	M05 PASS C04
12 / KPV acceptance value (n=10)	= 0.8458 % label claim Basis B11	<= 15 Unit: % label claim	M05 PASS C04
13 / KPV individual-unit RSD	= 0.3522 % Basis B12	<= 2 Unit: %	M05 PASS C04
T16 / Biological activity			
53 / 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 B09	Same as reported result Unit: qualitative Basis B10	M17 N/A — justified C05
T17 / Protein and conjugate characterization			
54 / Applicability decision	Not applicable — No recombinant protein, polymer conjugate or complex mixture for this material. Defined synthetic peptide identity is characterized under T01; GHK copper speciation, when relevant, is explicit. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M18 N/A — justified C05
T18 / Process impurities			
55 / Applicability decision	Not applicable — chemical synthesis without cell/tissue manufacturing inputs; HCP, host DNA and Protein A are not relevant. Chemical process impurities are covered under T05/T08/T09. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M19 N/A — justified C05
T19 / Particles and container closure			
57 / Subvisible particles >= 10um	= 21 particles/container Basis B27	<= 6000 Unit: particles/container	M21 PASS C17

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
58 / Subvisible particles >= 25um	= 2 particles/container Basis B27	<= 600 Unit: particles/container	M21 PASS C17
59 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B28	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C18
T20 / Stability observations			
60 / Reported 6 month assay retention	= 99.91 % of initial assay Basis B29	98 to 102 Unit: % of initial assay	M22 PASS C02
61 / Reported 6 month minimum component purity	= 99.881 % integrated detector area Basis B30	99.7 to 100 Unit: % integrated detector area	M22 PASS C02
62 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B29	Conforms to the specified acceptance criterion Unit: qualitative	M22 PASS C01
T21 / Appearance and physical inspection			
41 / Appearance	white to off-white; uniform lyophilized cake Unit: qualitative Basis B19	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
42 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B20	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-T01-RESIDUE-CHIRAL-LC	Diagnostic amino-acid absolute-configuration/composition check	Marfey-type diastereomeric derivatization LC-MS with authentic L/D references
M21 M-T19-DEFAULT	Particles and package integrity	Light obscuration plus vacuum decay
M22 M-T20-DEFAULT	Stability observation	Time-zero/1/3/6-month trend

Analytical detail appendix

Basis keys preserve the exact analytical scope of each result. Detection limits and sampling context are reported separately from measured values. N/A limits are not numerical detection limits and are omitted from the context key.

Result and criterion bases

Key	Basis
B01	H-L-Lys-L-Pro-L-Val-OH; unacetylated N-terminus and free C-terminal acid. This is the free-acid reference represented by PubChem CID125672.
B02	spectrum/peptide-map comparison; score is not proof of stereochemistry
B03	[M+1H]^1+; reference monoisotopic M=342.22670545 Da; molecule excludes associated salt/solvate
B04	Single analyte method scope; intended blend co-components and excipients excluded by analyte-specific selectivity, not denominator manipulation
B05	Same analyte-specific chromatogram as T02; response factor assumed 1.00 for unknowns; area only
B06	Sum of U1+U2+U3; purity plus related areas = 100%
B07	Assigned component material basis; excludes vehicle/excipient/water; salt basis explicitly in identity specification
B08	Independent calibrated amount / nominal amount x 100; not chromatographic area purity
B09	specified sample/form only
B10	material-specific limit
B11	AV=abs(M-mean)+2.4 sample SD; target 100%; M=mean within 98.5-101.5
B12	Precision criterion for the listed specification, independently of AV
B13	Water as percentage of total net formulation, not peptide area purity
B14	Explicit process/counterion basis; acetate-associated material. No fixed stoichiometric salt is asserted; acidic peptides may contain residual process acetate rather than a counterion.
B15	Material-based limit. Liquid numerical limits are listed specification and not ICH Option1 mass ppm.
B16	Total element; no speciation. material-based criterion, not a dose/route-derived safety limit.
B17	1.000 mg active/mL in 25mM acetate buffer, pH4.80,25.0C; buffer-solution compatibility is not the pH of dry material
B18	Separate excipient-specific assay; not label active
B19	Three containers under diffuse white illumination
B20	Visual observation only; subvisible particles reported separately
B21	FTM30-35C; tested units only; growth-promotion/suitability controls conform
B22	SCDM20-25C; tested units only; no sterility assurance level assigned
B23	Sample reporting limit after1:5 dilution; threshold is and not based on administration route/dose
B24	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B25	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B26	Residue-specific target from explicit structure. Mixed D/L ratios are intentional where stated; not total chemical-purity percentage.
B27	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim

Key	Basis
B28	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B29	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B30	Separate endpoint; no shelf-life claim

Sampling and detection context

Key	Reported context
C01	Analytical replicates: 2; Statistic type: individual/qualitative observation; Units sampled: 3; Units type: finished containers
C02	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers
C03	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.002 % integrated detector area; LOQ: 0.005 % integrated detector area
C04	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 10; Units type: finished containers
C05	Analytical replicates: 0; Statistic type: individual/qualitative observation; Units sampled: 0; Units type: finished containers
C06	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 ug/g finished fill; LOQ: 3 ug/g finished fill
C07	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.3 ug/g finished fill; LOQ: 1 ug/g finished fill
C08	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.2 ug/g finished fill; LOQ: 0.6 ug/g finished fill
C09	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.5 ug/g finished fill; LOQ: 1.5 ug/g finished fill
C10	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.1 ug/g finished fill; LOQ: 0.3 ug/g finished fill
C11	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 ug/g finished fill; LOQ: 0.03 ug/g finished fill
C12	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.0005 ug/g finished fill; LOQ: 0.002 ug/g finished fill
C13	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 20; Units type: finished containers
C14	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 0.01 EU/mg active-equivalent; LOQ: 0.025 EU/mg active-equivalent
C15	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers; LOD: 1 CFU/g finished fill; LOQ: 1 CFU/g finished fill
C16	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 1; Units type: finished containers
C17	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: finished containers
C18	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 10; Units type: finished containers

Supporting analytical details

01 / Orthogonal identity against specified reference

Field	Reported value	Unit / note
identified structure or sequence	H-L-Lys-L-Pro-L-Val-OH; unacetylated N-terminus and free C-terminal acid. This is the free-acid reference represented by PubChem CID125672.	text
neutral average mass	342.43	Da or explicit reason
neutral monoisotopic mass	342.22670545	Da Reference, not measured neutral mass
observed mz	343.233988	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-2657; internal standard, not a purchased certified reference material	text

04 / KPV chromatographic purity

Field	Reported value	Unit / note
main peak retention time	8.904	min
main peak area	9992300	counts
total integrated area	10000000	counts

09 / KPV active content

Field	Reported value	Unit / note
sample preparation volume	5	mL
dilution factor	10	fold

11 / KPV 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.

15 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.0057529066259	factor For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor.

16 / Acetate content relative to parent active mass

Field	Reported value	Unit / note
counterion molar ratio	0.08699359799471582	mol acetate/mol parent

45 / 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.

57 / 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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