CERTIFICATE OF ANALYSIS

L-Carnitine 5000 mg

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0609-L	APX-COA-2026-0609-L	2026-06-09

COMPOUND REFERENCE

Material family
small molecule or cofactor

Reference formula
$C_7H_{15}NO_3$

Average mass
161.2 Da

Monoisotopic mass
161.10519334 Da

RECORDED IDENTITY

Observed ion
162.112494 m/z

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

Sequence / construct
See complete identity results

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.

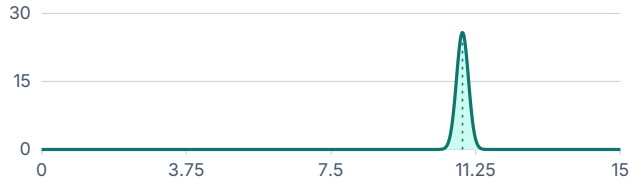
RECORDED RESULTS	Purity % integrated detector area	Concentration
L-Carnitine 5000 mg	99.929%	500.935 mg/mL

ESTIMATED PEAK PROFILE

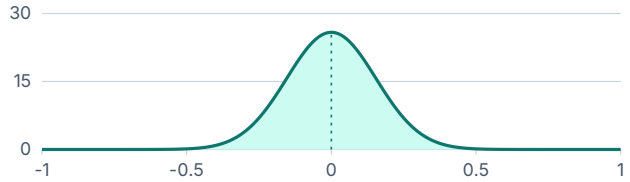
Reported RT: 10.908 min

Reported integrated area: 9,992,900 counts

Modeled area density (10^6 counts/min)



0-15 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 2026-06-09

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 / L-Carnitine 5000 mg HRMS ion mass error	= 0.1492 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
T02 / Chromatographic purity			
04 / L-Carnitine 5000 mg chromatographic purity	= 99.929 % integrated detector area Basis B04	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
09 / L-Carnitine 5000 mg active content	= 5009.35 mg/vial Basis B07	4900 to 5100 Unit: mg/vial	M04 PASS C02
10 / L-Carnitine 5000 mg label claim assay	= 100.187 % label claim Basis B08	98 to 102 Unit: % label claim	M04 PASS C02
11 / L-Carnitine 5000 mg concentration	= 500.935 mg/mL Basis B09	490 to 510 Unit: mg/mL	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 B10	Same as reported result Unit: qualitative Basis B11	M06 N/A — justified C05
T05 / Related substances and degradants			
05 / L-Carnitine 5000 mg Unknown U1	= 0.035 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
06 / L-Carnitine 5000 mg Unknown U2	= 0.021 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03
07 / L-Carnitine 5000 mg Unknown U3	= 0.015 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03
08 / L-Carnitine 5000 mg total related peaks	= 0.071 % integrated detector area Basis B06	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
16 / 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 B10	Same as reported result Unit: qualitative Basis B11	M07 N/A — justified C05
T07 / Counterions and associated species			
17 / 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 B10	Same as reported result Unit: qualitative Basis B11	M08 N/A — justified C05
T08 / Residual solvents			
18 / Methanol	= 19.633 ug/mL formulation Basis B14	<= 3000 Unit: ug/mL formulation	M09 PASS C06
19 / Acetonitrile	= 8.61 ug/mL formulation Basis B14	<= 410 Unit: ug/mL formulation	M09 PASS C07
20 / Dichloromethane	= 3.503 ug/mL formulation Basis B14	<= 600 Unit: ug/mL formulation	M09 PASS C08
21 / N, N-dimethylformamide	= 4.351 ug/mL formulation Basis B14	<= 880 Unit: ug/mL formulation	M09 PASS C09
22 / Ethanol	= 34.484 ug/mL formulation Basis B14	<= 5000 Unit: ug/mL formulation	M09 PASS C06
23 / Acetone	= 11.505 ug/mL formulation Basis B14	<= 5000 Unit: ug/mL formulation	M09 PASS C09

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
24 / Ethyl acetate	= 9.815 ug/mL formulation Basis B14	<= 5000 Unit: ug/mL formulation	M09 PASS C09
25 / Toluene	= 1.899 ug/mL formulation Basis B14	<= 890 Unit: ug/mL formulation	M09 PASS C10
26 / n-Hexane	= 0.998 ug/mL formulation Basis B14	<= 290 Unit: ug/mL formulation	M09 PASS C10
27 / Benzene	= 0.083 ug/mL formulation Basis B14	<= 2 Unit: ug/mL formulation	M09 PASS C11
T09 / Elemental impurities			
28 / Lead	= 0.0127 ug/mL formulation Basis B15	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
29 / Cadmium	= 0.0086 ug/mL formulation Basis B15	<= 0.2 Unit: ug/mL formulation	M10 PASS C12
30 / Arsenic	= 0.018 ug/mL formulation Basis B15	<= 0.5 Unit: ug/mL formulation	M10 PASS C12
31 / Mercury	= 0.0062 ug/mL formulation Basis B15	<= 0.1 Unit: ug/mL formulation	M10 PASS C12
32 / Cobalt	= 0.0204 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
33 / Vanadium	= 0.0253 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
34 / Nickel	= 0.0346 ug/mL formulation Basis B15	<= 2 Unit: ug/mL formulation	M10 PASS C12
35 / Palladium	= 0.0116 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
36 / Platinum	= 0.0086 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
37 / Rhodium	= 0.0063 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
38 / Ruthenium	= 0.0088 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
39 / Iridium	= 0.0056 ug/mL formulation Basis B15	<= 1 Unit: ug/mL formulation	M10 PASS C12
T10 / Sterility test			
44 / Sterility: FTM	No growth at 14 days in all 20 units Unit: qualitative Basis B20	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
45 / Sterility: SCDM	No growth at 14 days in all 20 units Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M14 PASS C13
T11 / Bacterial endotoxins			
46 / Bacterial endotoxins	<0.025 EU/mL Basis B22	<= 0.1 Unit: EU/mL	M15 PASS C14
T12 / Microbial enumeration			
47 / TAMC	<1 CFU/mL Basis B23	<= 100 Unit: CFU/mL	M16 PASS C15
48 / TYMC	<1 CFU/mL Basis B23	<= 10 Unit: CFU/mL	M16 PASS C15
49 / Escherichia coli	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
50 / Staphylococcus aureus	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
51 / Pseudomonas aeruginosa	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
52 / Salmonella species	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16
53 / Candida albicans	Not detected in 1 mL Unit: qualitative Basis B24	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C16

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T13 / pH and analytical solution			
40 / pH of native liquid	= 5.48 pH Basis B16	4.8 to 6.2 Unit: pH	M11 PASS C02
T14 / Excipients and preservatives			
41 / Vehicle and preservative composition	Water q.s. declared volume; no added preservative Unit: qualitative Basis B17	Conforms to the specified acceptance criterion Unit: qualitative	M12 PASS C01
T15 / Unit uniformity			
12 / L-Carnitine 5000 mg individual-unit mean	= 100.187 % label claim Basis B10	98 to 102 Unit: % label claim Basis B11	M05 PASS C04
13 / L-Carnitine 5000 mg individual-unit RSD	= 0.3518 % Basis B12	<= 2 Unit: %	M05 PASS C04
15 / Mean extractable volume	= 10 mL/container Basis B13	9.9 to 10.2 Unit: mL/container	M05 PASS C04
T16 / Biological activity			
54 / 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 B10	Same as reported result Unit: qualitative Basis B11	M17 N/A — justified C05
T17 / Protein and conjugate characterization			
55 / 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 B10	Same as reported result Unit: qualitative Basis B11	M18 N/A — justified C05

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T18 / Process impurities			
56 / 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 B10	Same as reported result Unit: qualitative Basis B11	M19 N/A — justified C05
T19 / Particles and container closure			
57 / Subvisible particles >= 10um	= 21 particles/container Basis B25	<= 6000 Unit: particles/container	M20 PASS C17
58 / Subvisible particles >= 25um	= 2 particles/container Basis B25	<= 600 Unit: particles/container	M20 PASS C17
59 / Vacuum decay package integrity	10/10test closures conform; positive-leak controls detected Unit: qualitative Basis B26	Conforms to the specified acceptance criterion Unit: qualitative	M20 PASS C18
T20 / Stability observations			
60 / Reported 6 month assay retention	= 99.9102 % of initial assay Basis B27	98 to 102 Unit: % of initial assay	M21 PASS C02
61 / Reported 6 month minimum component purity	= 99.887 % integrated detector area Basis B28	99.7 to 100 Unit: % integrated detector area	M21 PASS C02
62 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B27	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01
T21 / Appearance and physical inspection			
42 / Appearance	colorless; clear solution Unit: qualitative Basis B18	Conforms to the specified acceptance criterion Unit: qualitative	M13 PASS C01
43 / Visible foreign matter	None observed in 3 inspected units Unit: qualitative Basis B19	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-HILIC-CAD	Nonchromophoric component chromatographic response purity	HILIC with charged aerosol 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-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	Levocarnitine: natural (R)-3-hydroxy-4-(trimethylammonio)butanoate zwitterion, free L-carnitine rather than tartrate, chloride or acetyl-L-carnitine.
B02	spectrum/peptide-map comparison; score is not proof of stereochemistry
B03	[M+1H]^1+; reference monoisotopic M=161.10519334 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	Amount per nominal 10 mL fill
B10	specified sample/form only
B11	material-specific limit
B12	Precision criterion for the listed specification, independently of AV
B13	fill specification; no injection volume recommendation
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	As supplied,25.0C; buffer-solution compatibility is not the pH of dry material
B17	Explicit formulation choice, not a statement about actual catalog formulation
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	As-supplied liquid or entire dry vial dissolved to stated analytical volume; limits, no injectable compliance claim
B26	method vacuum-decay threshold0.20kPa/60s;5um positive defect control. No universal leakage-to-sterility equivalence.
B27	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B28	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/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	Levocarnitine: natural (R)-3-hydroxy-4-(trimethylammonio)butanoate zwitterion, free L-carnitine rather than tartrate, chloride or acetyl-L-carnitine.	text
neutral average mass	161.2	Da or explicit reason
neutral monoisotopic mass	161.10519334	Da Reference, not measured neutral mass
observed mz	162.112494	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-2719; internal standard, not a purchased certified reference material	text

04 / L-Carnitine 5000 mg chromatographic purity

Field	Reported value	Unit / note
main peak retention time	10.908	min
main peak area	9992900	counts
total integrated area	10000000	counts

09 / L-Carnitine 5000 mg active content

Field	Reported value	Unit / note
sample preparation volume	5000	mL
dilution factor	10	fold

12 / L-Carnitine 5000 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.

46 / 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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