CERTIFICATE OF ANALYSIS

Dihexa 10 mg (60pcs)

LOT NUMBER	REPORT NUMBER	COA ISSUE DATE
APX-2026-0404-D	APX-COA-2026-0404-D	2026-04-04

COMPOUND REFERENCE

Material family
peptidomimetic formulation

Reference formula
$C_{27}H_{44}N_4O_5$

Average mass
504.7 Da

Monoisotopic mass
504.33117052 Da

RECORDED IDENTITY

Observed ion
505.337923 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.

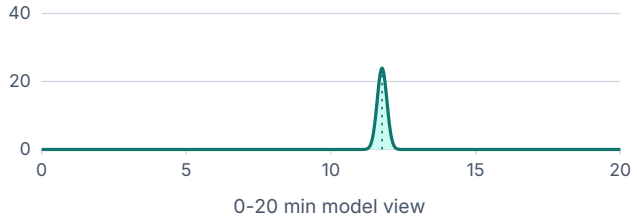
RECORDED RESULTS	Purity % integrated detector area	Active content
Dihexa 10 mg (60pcs)	99.938%	10.0085 mg/capsule

ESTIMATED PEAK PROFILE

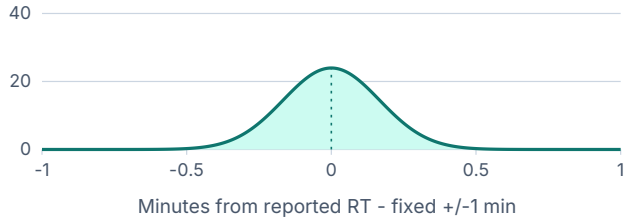
Reported RT: 11.764 min

Reported integrated area: 9,993,800 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.

59 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 2026-04-04

ONLINE REPORT
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Contamination & microbiology

All applicable tested criteria met

29 applicable endpoints reviewed against their stated specifications. 2 scope decisions are marked N/A below.

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	N/A
Bacterial endotoxins	N/A
TAMC	✓ PASS
TYMC	✓ PASS
Escherichia coli	✓ PASS
Staphylococcus aureus	✓ PASS
Pseudomonas aeruginosa	✓ PASS
Salmonella species	✓ PASS
Candida albicans	✓ PASS

N/A: sterility and endotoxin specifications are not assigned to this nonsterile capsule configuration. Microbial limits are reported separately; N/A is not a passing test.

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 / Dihexa 10 mg (60pcs) HRMS ion mass error	= -1.0369 ppm Basis B03	-5 to 5 Unit: ppm	M01 PASS C02
T02 / Chromatographic purity			
04 / Dihexa 10 mg (60pcs) chromatographic purity	= 99.938 % integrated detector area Basis B04	99.7 to 100 Unit: % integrated detector area	M02 PASS C02
T03 / Active content and assay			
09 / Dihexa 10 mg (60pcs) active content	= 10.0085 mg/capsule Basis B07	9.8 to 10.2 Unit: mg/capsule	M04 PASS C02
10 / Dihexa 10 mg (60pcs) label claim assay	= 100.085 % 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 / Dihexa 10 mg (60pcs) Unknown U1	= 0.031 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03
06 / Dihexa 10 mg (60pcs) Unknown U2	= 0.019 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
07 / Dihexa 10 mg (60pcs) Unknown U3	= 0.012 % integrated detector area Basis B05	<= 0.1 Unit: % integrated detector area	M03 PASS C03
08 / Dihexa 10 mg (60pcs) total related peaks	= 0.062 % integrated detector area Basis B06	<= 0.3 Unit: % integrated detector area	M03 PASS C02
T06 / Water content			
16 / Residual water	= 0.78 % w/w finished fill Basis B14	<= 2 Unit: % w/w finished fill	M07 PASS C02
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 B09	Same as reported result Unit: qualitative Basis B10	M08 N/A — justified C05
T08 / Residual solvents			
18 / Methanol	= 23.096 ug/g finished fill Basis B15	<= 3000 Unit: ug/g finished fill	M09 PASS C07
19 / Acetonitrile	= 7.699 ug/g finished fill Basis B15	<= 410 Unit: ug/g finished fill	M09 PASS C08
20 / Dichloromethane	= 3.924 ug/g finished fill Basis B15	<= 600 Unit: ug/g finished fill	M09 PASS C09
21 / N, N-dimethylformamide	= 3.899 ug/g finished fill Basis B15	<= 880 Unit: ug/g finished fill	M09 PASS C10
22 / Ethanol	= 40.024 ug/g finished fill Basis B15	<= 5000 Unit: ug/g finished fill	M09 PASS C07
23 / Acetone	= 11.956 ug/g finished fill Basis B15	<= 5000 Unit: ug/g finished fill	M09 PASS C10
24 / Ethyl acetate	= 9.807 ug/g finished fill Basis B15	<= 5000 Unit: ug/g finished fill	M09 PASS C10
25 / Toluene	= 1.839 ug/g finished fill Basis B15	<= 890 Unit: ug/g finished fill	M09 PASS C11

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
26 / n-Hexane	= 1.03 ug/g finished fill Basis B15	<= 290 Unit: ug/g finished fill	M09 PASS C11
27 / Benzene	= 0.083 ug/g finished fill Basis B15	<= 2 Unit: ug/g finished fill	M09 PASS C12
T09 / Elemental impurities			
28 / Lead	= 0.0123 ug/g finished fill Basis B16	<= 0.5 Unit: ug/g finished fill	M10 PASS C13
29 / Cadmium	= 0.0085 ug/g finished fill Basis B16	<= 0.2 Unit: ug/g finished fill	M10 PASS C13
30 / Arsenic	= 0.0174 ug/g finished fill Basis B16	<= 0.5 Unit: ug/g finished fill	M10 PASS C13
31 / Mercury	= 0.0055 ug/g finished fill Basis B16	<= 0.1 Unit: ug/g finished fill	M10 PASS C13
32 / Cobalt	= 0.0201 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13
33 / Vanadium	= 0.0238 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13
34 / Nickel	= 0.0344 ug/g finished fill Basis B16	<= 2 Unit: ug/g finished fill	M10 PASS C13
35 / Palladium	= 0.01 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13
36 / Platinum	= 0.0083 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13
37 / Rhodium	= 0.0073 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13
38 / Ruthenium	= 0.0082 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13
39 / Iridium	= 0.0063 ug/g finished fill Basis B16	<= 1 Unit: ug/g finished fill	M10 PASS C13

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T10 / Sterility test			
44 / Applicability decision	Not applicable — capsules are nonsterile solids. Microbial limits are appropriate; reporting a passing sterility test would imply an unassigned sterile product specification. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M14 N/A — justified C05
T11 / Bacterial endotoxins			
45 / Applicability decision	Not applicable — No endotoxin-controlled intended use or specification is assigned to the nonsterile capsule . Microbial counts cannot be substituted for endotoxin testing. Unit: qualitative Basis B09	Not applicable — No endotoxin-controlled intended use or specification is assigned to the nonsterile capsule scenario. Microbial counts cannot be substituted for endotoxin testing. Unit: qualitative Basis B10	M15 N/A — justified C05
T12 / Microbial enumeration			
46 / TAMC	<1 CFU/g finished fill Basis B20	<= 100 Unit: CFU/g finished fill	M16 PASS C14
47 / TYMC	<1 CFU/g finished fill Basis B20	<= 10 Unit: CFU/g finished fill	M16 PASS C14
48 / Escherichia coli	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
49 / Staphylococcus aureus	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
50 / Pseudomonas aeruginosa	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
51 / Salmonella species	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15
52 / Candida albicans	Not detected in 1g Unit: qualitative Basis B21	Conforms to the specified acceptance criterion Unit: qualitative	M16 PASS C15

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
T13 / pH and analytical solution			
40 / Applicability decision	Not applicable — No validated aqueous solution pH specification for this capsule/poorly aqueous-soluble material. Extraction conditions for identity/assay are separately specified; no pH value is invented for dry powder. Unit: qualitative Basis B09	Same as reported result Unit: qualitative Basis B10	M11 N/A — justified C05
T14 / Excipients and preservatives			
41 / Microcrystalline cellulose content	= 188.591 mg/capsule Numeric value: 188.59075 Basis B17	179.018 to 197.862 Unit: mg/capsule	M12 PASS C02
T15 / Unit uniformity			
11 / Dihexa 10 mg (60pcs) individual-unit mean	= 100.085 % label claim Basis B09	98 to 102 Unit: % label claim Basis B10	M05 PASS C04
12 / Dihexa 10 mg (60pcs) acceptance value (n=10)	= 0.8458 % label claim Basis B11	<= 15 Unit: % label claim	M05 PASS C04
13 / Dihexa 10 mg (60pcs) individual-unit RSD	= 0.3521 % Basis B12	<= 2 Unit: %	M05 PASS C04
15 / Physical capsule count	= 60 capsules/bottle Basis B13	60 to 60 Unit: capsules/bottle	M05 PASS C06
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

Endpoint	Reported result / basis	Acceptance criterion	Method / outcome
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			
56 / Container closure and visible package condition	No damage; closure and seal conform in 10 packages Unit: qualitative Basis B22	Conforms to the specified acceptance criterion Unit: qualitative	M20 PASS C16
T20 / Stability observations			
57 / Reported 6 month assay retention	= 99.9101 % of initial assay Basis B23	98 to 102 Unit: % of initial assay	M21 PASS C02
58 / Reported 6 month minimum component purity	= 99.896 % integrated detector area Basis B24	99.7 to 100 Unit: % integrated detector area	M21 PASS C02
59 / Dating disposition	6 month review point; actual expiry/retest not assigned Unit: qualitative Basis B23	Conforms to the specified acceptance criterion Unit: qualitative	M21 PASS C01
T21 / Appearance and physical inspection			
42 / Appearance	white to off-white; uniform intact capsule 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-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	Dihexa: N-hexanoyl-L-Tyr-L-Ile-NH-(CH2)5-C(O)NH2; TyrS and Ile2S,3S. 60 capsules with 10.00 mg anhydrous Dihexa equivalent each.
B02	spectrum/peptide-map comparison; score is not proof of stereochemistry
B03	[M+1H]^1+; reference monoisotopic M=504.33117052 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	three-bottle count inspection
B14	Water as percentage of total net formulation, not peptide area purity
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	Separate excipient-specific assay; not label active
B18	Three containers under diffuse white illumination
B19	Visual observation only; subvisible particles reported separately
B20	Zero colonies observed from1g or1 mL equivalent filter; report <1, not exact absence
B21	Specified-organism enrichment in explicit1g/1 mL scope; not a universal pharmacopeial panel
B22	Nonsterile capsule bottle or intentional dispersion; light-obscuration particulate numbers inappropriate for these matrices
B23	Reported change relative to the initial assay. This report does not assign a retest date or shelf life.
B24	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: capsules
C02	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules
C03	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; 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: capsules
C05	Analytical replicates: 0; Statistic type: individual/qualitative observation; Units sampled: 0; Units type: capsules
C06	Analytical replicates: 1; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules
C07	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 1 ug/g finished fill; LOQ: 3 ug/g finished fill
C08	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 0.3 ug/g finished fill; LOQ: 1 ug/g finished fill
C09	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 0.2 ug/g finished fill; LOQ: 0.6 ug/g finished fill
C10	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 0.5 ug/g finished fill; LOQ: 1.5 ug/g finished fill
C11	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 0.1 ug/g finished fill; LOQ: 0.3 ug/g finished fill
C12	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 0.01 ug/g finished fill; LOQ: 0.03 ug/g finished fill
C13	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 0.0005 ug/g finished fill; LOQ: 0.002 ug/g finished fill
C14	Analytical replicates: 2; Statistic type: mean of independent sample preparations; Units sampled: 3; Units type: capsules; LOD: 1 CFU/g finished fill; LOQ: 1 CFU/g finished fill
C15	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 1; Units type: capsules
C16	Analytical replicates: 1; Statistic type: individual/qualitative observation; Units sampled: 10; Units type: capsules

Supporting analytical details

01 / Orthogonal identity against specified reference

Field	Reported value	Unit / note
identified structure or sequence	Dihexa: N-hexanoyl-L-Tyr-L-Ile-NH-(CH2)5-C(O)NH2; TyrS and Ile2S,3S. 60 capsules with 10.00 mg anhydrous Dihexa equivalent each.	text
neutral average mass	504.7	Da or explicit reason
neutral monoisotopic mass	504.33117052	Da Reference, not measured neutral mass
observed mz	505.337923	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-2724; internal standard, not a purchased certified reference material	text

04 / Dihexa 10 mg (60pcs) chromatographic purity

Field	Reported value	Unit / note
main peak retention time	11.764	min
main peak area	9993800	counts
total integrated area	10000000	counts

09 / Dihexa 10 mg (60pcs) active content

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

11 / Dihexa 10 mg (60pcs) individual-unit mean

Field	Reported value	Unit / note
physical unit count	60	Explicit context; see value Method and sample context; reference facts are in Identity Reference.

16 / Residual water

Field	Reported value	Unit / note
dry basis correction	1.007861318282604	factor For mass-fraction reporting only; independent active assay is not blindly multiplied by this factor.

56 / Container closure and visible package condition

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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