Example report · not a test result

Product name as received

BPC-157 10 mg client-supplied

Tested for **Example client** (name chosen by the client)

Analyte tested for **BPC-157** $C_{62}H_{98}N_{16}O_{22}$ monoisotopic 1418.7042 Da

Ordered	Received	Tested	Issued
2026-09-12	2026-09-14	2026-09-15 to 2026-09-17	2026-09-25

Scan for live status, or check at **hkanalytical.com/verify**

Client relationship · part of the signed record

No link to HK Analytical. The client who ordered this test has no ownership, staff, funding, family or commercial link to HK Analytical, other than paying for this test. Basis: Client declaration on the order form, checked against the conflict-of-interest register. Declared on 2026-09-12; checked by Example approver, Quality manager.

Identity
BPC-157
Identity level L3
Conforms
label claim client-supplied

Purity
99.0 % area
U ± 0.3 (k = 2)
Conforms
client spec

Net content
10.34 mg/vial
103.4 % of label claim
client-supplied
Reported
no specification

Endotoxin
0.096 EU/mg
1.00 EU/vial
Reported
no specification

Sterility
Not tested

Counter-ion
TFA 11.8 % w/w
Acetate < 0.5 % w/w
Reported
no specification

Metals
Pb 0.031 µg/vial
As, Cd, Hg below LOQ
Reported
no specification

Test and method	Result	Specification	Conclusion	Data
Identity (LC-MS) EX-M-002 v1	Consistent with BPC-157 (L3)	= BPC-157 label claim (client-supplied)	Conforms	p. 3
Purity (RP-HPLC-UV, 214 nm) EX-M-001 v1	99.0 ± 0.3 % area (k = 2)	≥ 98.0 % area client specification	Conforms	p. 5
Net peptide content (free base) EX-M-003 v1	10.34 ± 0.41 mg/vial (k = 2), 103.4 % of label claim client-supplied	None applied	Reported	p. 7
Bacterial endotoxins (kinetic chromogenic LAL) EX-M-010 v1	0.50 EU/mL (U not estimated for this method) 1.00 EU/vial (U not stated: calculated from values without U) 0.096 EU/mg (U not stated: calculated from values without U)	None applied	Reported	p. 8
Sterility (USP <71>, 14 days)	Not tested		Not tested	
Counter-ions (TFA, acetate, chloride) EX-M-020 v1	TFA 11.8 ± 1.2 % w/w (k = 2); Acetate < 0.5 % w/w (below LOQ)	None applied	Reported	p. 9
Elemental impurities (ICP-MS) EX-M-030 v1	As < 0.020 µg/vial (below LOQ); Cd < 0.010 µg/vial (below LOQ); Hg < 0.020 µg/vial (below LOQ); Pb 0.031 ± 0.008 µg/vial (k = 2)	None applied	Reported	p. 9

What we received observed by HK on receipt

Received	2 vials, 2026-09-14 10:02 UTC
Container	2 mL clear glass vial, grey rubber stopper, aluminium crimp with flip-off cap
Cap and crimp	blue cap, silver crimp
Contents	Lyophilised cake. White lyophilised cake, intact.
Lot on container	EX-BPC-2609
Seal	Intact

What the client told us client-supplied

Product name	BPC-157 10 mg
Label claim	10 mg per vial
Lot	EX-BPC-2609
Vendor	Example client
Manufacturer	Not provided by the client

2 lab photos taken on receipt, fingerprints on page 2 (example: generated fingerprints, no image files).

Read this first

1. Results apply only to the 2 vials we received. They do not prove that other vials or batches are the same.
2. Net content is mg of BPC-157 free base per vial, measured against reference standard lot EX-RS-BPC157-01.
3. Purity is the share of UV signal at 214 nm that comes from BPC-157. It does not measure water, salts, microbes or endotoxin.
4. No official endotoxin limit exists for a research peptide without a labelled dose. We report the number; we do not call it safe.
5. Sterility was not tested. This report says nothing about live microbes.

Example report · not a test result

Sample, custody and vial allocation

Sample ID S-260914-9001

Observed by HK on receipt

Units received	2 vials
Received	2026-09-14 10:02 UTC, by Example sample clerk
Package	Padded envelope, intact. Vials in a sealed zip bag.
Container	2 mL clear glass vial, grey rubber stopper, aluminium crimp with flip-off cap
Cap colour	blue
Crimp colour	silver
Fill state	Lyophilised cake
Appearance	White lyophilised cake, intact
Label text as read	BPC-157 10mg | Lot EX-BPC-2609 | For research use only
Lot on container	EX-BPC-2609
Seal intact	Yes
Temperature on arrival	21 °C
Storage before analysis	-20 °C, dark
Receipt deviations	None recorded

Supplied by the client (not verified by HK)

client-supplied

Product name	BPC-157 10 mg
Label claim	10 mg per vial
Lot	EX-BPC-2609
Vendor	Example client
Manufacturer	Not provided by the client
Claimed sequence	Not provided by the client
Expiry	Not provided by the client
Other label text	Not provided by the client

Photos taken by HK on receipt

Photo	Caption and file	Taken	SHA-256 (first 16)
Photo 1 of 2 All units	Both vials on receipt with lab labels S-260914-9001-V1 and -V2 S-260914-9001_receipt_all_units.jpg	2026-09-14 10:14:02 UTC Example sample clerk	d06f cf5d 4968 2e30
Photo 2 of 2 Cap and crimp	Vial 1: printed label, blue flip-off cap, silver crimp, fill level S-260914-9001_V1_label_and_cap.jpg	2026-09-14 10:15:30 UTC Example sample clerk	741c e9ad 277c 6407

Example: these fingerprints were generated for the example; no photo files exist.

Vial allocation

Vial	Lab label	Used for tests	After testing
1	S-260914-9001-V1	T1, T2, T3	Consumed
2	S-260914-9001-V2	T3, T4, T5, T6	Consumed

Chain of custody

Time	Event	By	Location	Vials	Detail
2026-09-14 10:02 UTC	Received	Example sample clerk	Sample reception	1, 2	Tracking number checked against the order.
2026-09-14 10:14:02 UTC	Photographed	Example sample clerk	Sample reception	1, 2	
2026-09-14 10:20 UTC	Stored	Example sample clerk	Freezer EX-FRZ-1, -20 °C	1, 2	
2026-09-15 07:50 UTC	Reconstituted	Example analyst A	HPLC lab	1	Whole vial in 2.000 mL diluent
2026-09-15 07:55 UTC	Reconstituted	Example analyst A	HPLC lab	2	Whole vial in 2.000 mL LAL reagent water; aliquots for T3-T6
2026-09-17 10:30 UTC	Disposed	Example analyst A	HPLC lab	1, 2	Solutions used up or discarded after review

Sampling. HK Analytical did not take the sample. Results apply to the sample as received.

Retention. No sample retained (all vials were used).

Example report · not a test result

Identity (LC-MS)

T1 EX-M-002 v1

Consistent with BPC-157 · identity level L3

Conforms

Method	EX-M-002 v1 Peptide identity by LC-HRMS	Analysts	Example analyst B
Technique	RP-UHPLC-ESI-QTOF, positive mode	Technical review	Example reviewer
Validation	Validated (ICH Q2(R2)), report EX-VAL-002	Started	2026-09-15 12:40 UTC
Accreditation	Not accredited	Completed	2026-09-15 15:10 UTC
Performed	In house, site example-site	Vials	1
		Instruments	INS-EX-HRMS1 LC-QTOF mass spectrometer

Raw data files: F6 S-260914-9001-V1_LCMS_INJ-01.mzML SHA-256 b3b1 f4bf 0e9b 52e0

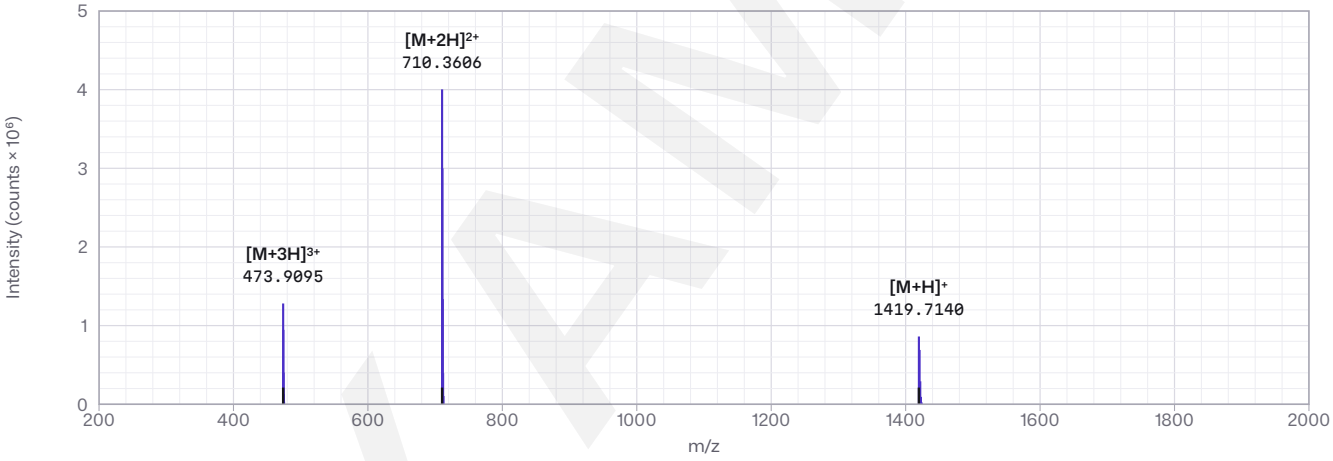
Mass spectrometry

Analyser	Q-TOF, resolving power 40000 at m/z 1222 ESI+ scan m/z 300-2000
Mass calibration	Calibrant mix, 2026-09-15 08:30 UTC; lock mass m/z 922.0098
Deconvolution	Example data system 0.0, Isotope-resolved charge deconvolution output monoisotopic

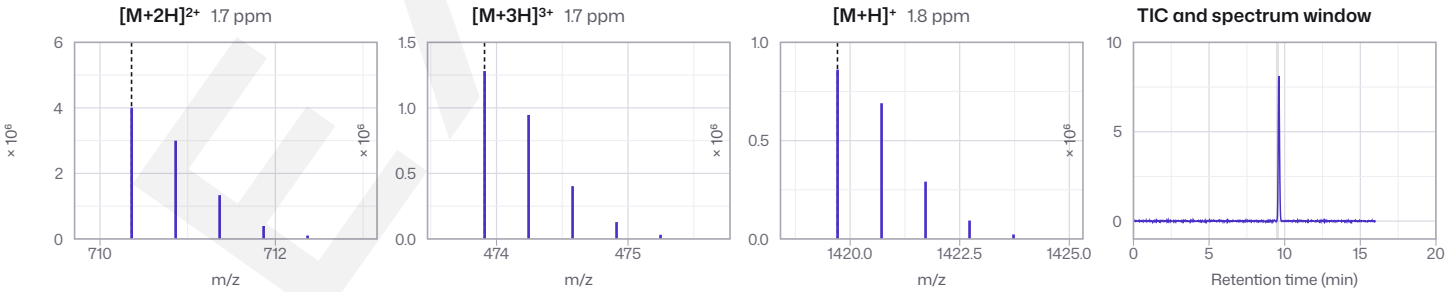
Liquid chromatography

Column	C18 peptide column, C18, wide pore, 150 × 2.1 mm, 1.7 µm, 300 Å serial or lot EX-COL-0102
Mobile phase A	0.1 % formic acid in water
Mobile phase B	0.1 % formic acid in acetonitrile
Gradient (min, % B)	0.0 min 5 % · 12.0 min 45 % · 12.5 min 95 % · 14.0 min 95 % · 14.1 min 5 % · 16.0 min 5 %
Flow, temperature	0.30 mL/min; column 60 °C; autosampler 8 °C
Injection, run time	1.0 µL; 16.0 min
Detection	ESI-QTOF, full scan m/z 300-2000
Sample preparation	Aliquot of the vial 1 solution (T2) diluted 1:50 in 0.1 % formic acid. Diluent: 0.1 % formic acid in water. Dilution factor 50.

Mass spectrum SP-1 ms1, centroid, RT 9.55–9.68 min



Centroids exactly as exported. Black ticks on the axis: expected m/z of each matched ion, calculated from the formula. S-260914-9001-V1_LCMS_INJ-01.mzML · SHA-256 b3b1 f4bf 0e9b 52e0…



Isotope envelopes: violet sticks are observed centroids; the dashed line is the expected monoisotopic m/z.

Example report · not a test result

Ions: expected vs observed

Ion	Analyte	z	Expected m/z	Observed m/z	Error (ppm)	Isotope fit	Rel. intensity
$[M+2H]^{2+}$	BPC-157	2	710.3594	710.3606	1.7	0.97	100 %
$[M+H]^{+}$	BPC-157	1	1419.7114	1419.7140	1.8	Not recorded	22 %
$[M+3H]^{3+}$	BPC-157	3	473.9087	473.9095	1.7	0.95	31 %

Intact mass (deconvoluted)	Basis	Expected (Da)	Observed (Da)	Error
BPC-157	monoisotopic	1418.7042	1418.7067	1.8 ppm

Expected m/z calculated from the molecular formula with monoisotopic element masses and a proton mass of 1.007276 Da. BPC-157: $C_{62}H_{98}N_{16}O_{22}$, monoisotopic 1418.7042 Da (Published molecular formula of the free peptide (check against the reference standard certificate)).

Acceptance criteria (EX-VAL-002 section 4)

Criterion	Found (calculated from the table above)	Met
Mass error |ppm| ≤ 5.0 for every matched ion	largest 1.8 ppm	Met
At least 2 charge states	3 (z = 1, 2, 3)	Met
Isotope fit ≥ 0.90	lowest 0.95	Met

Level reached: **L3** (level ordered: L3). The level printed is the level the evidence reaches.

Related species

Observed mass (Da)	Mass difference (Da)	RT (min)	Relative abundance	Interpretation
1361.683	−57.021	9.29	0.7 % (uv area)	See interpretation OP-1

Specification and conclusion

Specification	= BPC-157
Source	Label claim (client-supplied): Client label claim: BPC-157
Decision rule	`DR-ID-CRITERIA v1`, qualitative criteria. Identity conforms when every acceptance criterion of the identity method is met for the specified analyte and no other screened candidate is detected.
Conclusion	Conforms

> Mass spectrometry shows the molecular mass. Forms with the same mass (for example D-amino-acid isomers) are not told apart by this test; chromatographic purity is reported separately.

Identity levels

Level	Evidence	HK use
L0	Retention time only	Never reported as identity
L1	Retention time and UV spectrum	Supporting only
L2	Intact mass at unit resolution, at least 2 charge states	Minimum for “consistent with”
L3	Accurate mass with ppm error, isotope fit, at least 2 charge states	HK standard
L4	L3 plus MS/MS fragments with sequence coverage	Disputes, on request

Example report · not a test result

Purity (RP-HPLC-UV, 214 nm)

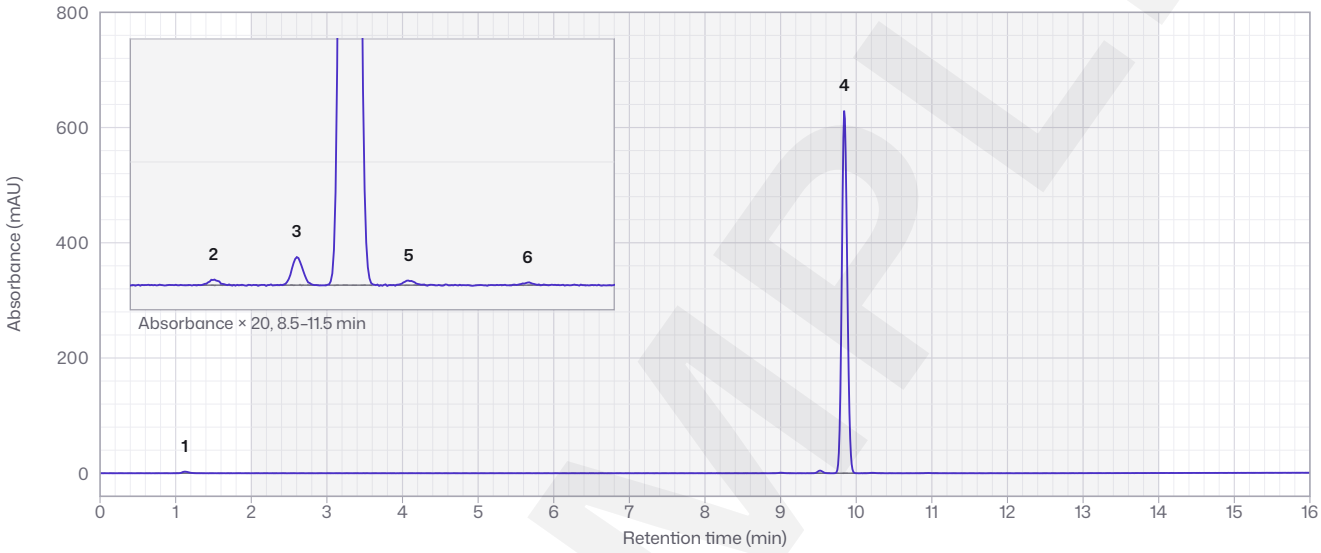
T2 EX-M-001 v1

99.0 ± 0.3 % area (k = 2) at 214 nm · reporting threshold 0.05 % — Conforms

Method	EX-M-001 v1 Peptide purity by RP-UHPLC-UV	Analysts	Example analyst A
Technique	RP-UHPLC-UV, 214 nm, area normalisation	Technical review	Example reviewer
Validation	Validated (ICH Q2(R2)), report EX-VAL-001	Started	2026-09-15 08:05 UTC
Accreditation	Not accredited	Completed	2026-09-15 11:30 UTC
Performed	In house, site example-site	Vials	1
		Instruments	INS-EX-UHPLC1 UHPLC with diode-array detector

Raw data files: F1 S-260914-9001_BLANK_INJ-01.cdf SHA-256 3201 2751 0d82 a2f8 F2 S-260914-9001-V1_P1_INJ-02.cdf SHA-256 17c5 6ae1 2c24 33db F3 S-260914-9001-V1_P1_INJ-03.cdf SHA-256 04e4 9bfd 8dc5 7ac6

Chromatogram, injection INJ-02



DAD A, 214 nm (bw 4), ref off. Violet: sample S-260914-9001-V1 prep 1, acquired 2026-09-15 09:21:40 UTC, min–max decimated from 9601 to 1601 points, so every local maximum (each peak apex) is kept. Grey dashed: blank injection INJ-01. Shaded: integration window 2.00–14.00 min. Grey lines under the peaks: integration baselines exported by the data system. Numbers match the peak table. S-260914-9001-V1_P1_INJ-02.cdf · SHA-256 17c5 6ae1 2c24 33db…

Peak table, injection INJ-02

#	RT (min)	RRT	Start–end	Area	Area %	Height	Tailing	Plates	Res.	S/N	Assignment and use
1	1.120	0.114	1.000–1.320	16.5	0.00	2.74	1.33	783		20	Blank peak. Not counted: Also present in the blank (injection/solvent peak); outside the integration window
2	9.004	0.915	8.888–9.140	4.1	0.13	0.87	1.09	81629	55.25	6	Impurity
3	9.520	0.967	9.404–9.656	21.5	0.68	4.55	1.09	91253	4.10	34	Impurity (OP-1)
4	9.842	1.000	9.722–9.986	3129.8	99.01	630.60	1.10	88865	2.50	4671	Main peak
5	10.213	1.038	10.097–10.349	3.7	0.12	0.78	1.09	105022	2.88	6	Impurity
6	10.951	1.113	10.835–11.087	1.9	0.06	0.40	1.09	120748	5.87	3	Impurity

Replicate injections

Injection	Sample in file	Main peak area %
INJ-02	S-260914-9001-V1 prep 1	99.01
INJ-03	S-260914-9001-V1 prep 1	98.99
Reported		**99.0 ± 0.3 % area (k = 2)**

Impurities at or above the reporting threshold

RT (min)	RRT	Area %	Observed mass (Da)	Interpretation
9.004	0.915	0.13		
9.520	0.967	0.69	1361.683	See interpretation OP-1
10.213	1.038	0.12		
10.951	1.113	0.06		

Example report · not a test result

Largest single impurity: 0.69 % area at 9.520 min. Total impurities: 1.00 % area.

Integration parameters

Software, method	Example data system 0.0 processing method EX-PEPTIDE-PURITY v1
Window, baseline	2.00–14.00 min; valley to valley
Detection settings	slope sensitivity 1.0; peak width 0.04 min; area reject 0.5; height reject 0.10
Reporting threshold	0.05 %; blank subtraction no
Exclusion rule	Peaks that also appear in the blank injection at the same retention time (+/- 0.05 min) are excluded. The void volume before 2.00 min is not integrated.
Manual integration	No
Integration events	None

System suitability (passed)

Parameter	Applies to	Measured	Limit	Met
Resolution	BPC-157 and impurity at RRT 0.967	2.50	≥ 1.5	Met
Tailing factor	BPC-157	1.10	≤ 1.8	Met
Repeatability rsd	BPC-157 area, 5 standard injections	0.42 %	≤ 2.0 %	Met
Signal to noise	0.05 % sensitivity solution	14	≥ 10	Met
Blank interference	Blank at BPC-157 RT	0.00 % area	≤ 0.05 % area	Met

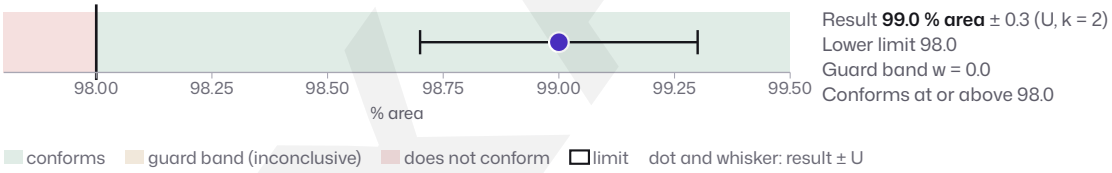
Conditions

Column	C18 peptide column, C18, wide pore, 150 × 2.1 mm, 1.7 µm, 300 Å serial or lot EX-COL-0101
Mobile phase A	0.1 % TFA in water
Mobile phase B	0.1 % TFA in acetonitrile
Gradient (min, % B)	0.0 min 5 % · 1.0 min 5 % · 13.0 min 45 % · 13.5 min 95 % · 14.5 min 95 % · 14.6 min 5 % · 16.0 min 5 %
Flow, temperature	0.30 mL/min; column 60 °C; autosampler 8 °C
Injection, run time	2.0 µL; 16.0 min
Detection	DAD 214 nm (bandwidth 4 nm), reference off
Sample preparation	Whole vial dissolved in 2.000 mL diluent (vial 1) or in 2.000 mL LAL reagent water (vial 2), then diluted 1:10 in diluent. Two injections per preparation. Diluent: Water/acetonitrile 90:10 with 0.1 % TFA. Reconstitution 2.000 mL. Dilution factor 10.0. Nominal 0.500 mg/mL.

Specification and conclusion

Specification	≥ 98.0 % area
Source	Client specification: Client order O-7K2M9Q4D
Decision rule	DR-SIMPLE v1, simple acceptance. Simple acceptance: the result conforms when the measured value is inside the limit. Uncertainty is not subtracted, so a value close to the limit carries up to about 50 % risk of a wrong decision.
Conclusion	Conforms

Acceptance zones for purity area pct calculated



Example report · not a test result

Net peptide content (free base)

T3 EX-M-003 v1

10.34 ± 0.41 mg/vial (k = 2) (mean of 2 vials) · 103.4 % of label claim client-supplied **· BPC-157 free base**

Reported, no specification applied

Method	EX-M-003 v1 Peptide content per vial by RP-UHPLC-UV, external standard	Analysts	Example analyst A
Technique	RP-UHPLC-UV, 214 nm, 5-level external calibration	Technical review	Example reviewer
Validation	Validated (ICH Q2(R2)), report EX-VAL-003	Started	2026-09-15 08:05 UTC
Accreditation	Not accredited	Completed	2026-09-15 11:30 UTC
Performed	In house, site example-site	Vials	1, 2
		Instruments	INS-EX-UHPLC1 UHPLC with diode-array detector

Raw data files: F9 S-260914-9001_CAL_BPC157.cdf SHA-256 253a 15d7 de0f a69a F2 S-260914-9001-V1_P1_INJ-02.cdf SHA-256 17c5 6ae1 2c24 33db F3 S-260914-9001-V1_P1_INJ-03.cdf SHA-256 04e4 9bfd 8dc5 7ac6 F4 S-260914-9001-V2_P1_INJ-04.cdf SHA-256 1f85 c628 1e16 791c F5 S-260914-9001-V2_P1_INJ-05.cdf SHA-256 9d05 4720 eb54 cde4

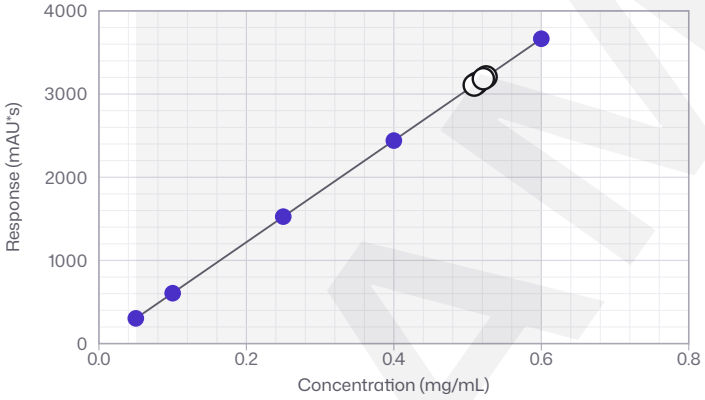
> Free base: mg of the peptide itself, without counter-ions or water. The reference standard content is assigned as free base, so results are mg of BPC-157 free base per vial. Counter-ion (TFA) is reported separately in T5.

Reference standard

Standard	BPC-157 reference standard RS-EX-BPC157-01
Supplier, lot	Example supplier, EX-CAT-157, lot EX-RS-BPC157-01
Grade	Secondary standard, qualified in house
Assigned content	86.4 % (free base), U 1.5 %; purity 99.6 %
Expiry	2027-06-01; qualification EX-QUAL-RS-157
Certificate	F14 EX-RS-BPC157-01_certificate.pdf SHA-256 a207 de03 0386 02c4

Calibration model

Model	linear, weighting none
Slope, intercept	6112.4, −3.1
R^2	0.99997
Calibrated range	0.050–0.600 mg/mL
Check standard	0.2493 found, 0.250 nominal: 99.7 % (98.0-102.0 %), passed
Standard used	RS-EX-BPC157-01



Level	Conc. (mg/mL)	Response (mAU*s)
1	0.050	303.6
2	0.100	606.1
3	0.250	1526.6
4	0.400	2440.7
5	0.600	3665.1

Filled dots: calibration levels. Open circles: sample responses. Line: the lab's fitted model over the calibrated range (shaded).

Replicates

Vial	Prep.	Injection	Response	Measured conc.	Volume (mL)	Dilution	mg per vial
1	1	INJ-02	3129.8	0.5125 mg/mL	2.000	10.0	10.25
1	1	INJ-03	3107.9	0.5090 mg/mL	2.000	10.0	10.18
2	1	INJ-04	3206.5	0.5251 mg/mL	2.000	10.0	10.50
2	1	INJ-05	3184.1	0.5214 mg/mL	2.000	10.0	10.43

Results

	mg per vial	Note
Vial 1	10.21 ± 0.41 mg/vial (k = 2)	2 injections
Vial 2	10.46 ± 0.42 mg/vial (k = 2)	2 injections
Mean	**10.34 ± 0.41 mg/vial (k = 2)**	n = 2 vials, SD 0.18 mg, RSD 1.7 %
Label claim client-supplied	10 mg per vial	**103.4 % of label claim** client-supplied

Specification and conclusion

Specification	None applied. The result is reported without a conformity statement.
Conclusion	Reported, no specification applied

Example report · not a test result

Bacterial endotoxins (kinetic chromogenic LAL)

T4 EX-M-010 v1

0.50 EU/mL · 1.00 EU/vial · 0.096 EU/mg

Reported, no specification applied

Method	EX-M-010 v1 Bacterial endotoxins, kinetic chromogenic LAL	Analysts	Example analyst B
Technique	Kinetic chromogenic LAL, 405 nm	Technical review	Example reviewer
Validation	Compendial method, verified in this lab, report EX-VAL-010	Started	2026-09-16 10:30 UTC
Accreditation	Not accredited	Completed	2026-09-16 12:05 UTC
Compendial reference	USP <85>	Vials	2
Performed	In house, site example-site	Instruments	INS-EX-READER1 Incubating microplate reader

Raw data files: F10 S-260914-9001-V2_LAL_plate.csv SHA-256 347e 04f3 8bca 5971

Reagent and sample

Reagent	LAL, Kinetic chromogenic LAL reagent (Example reagent maker), lot EX-LAL-2608
Sensitivity	0.005 EU/mL; control standard lot EX-CSE-11
Vial	Vial 2, reconstituted in 2.000 mL LAL reagent water
Test dilution	1:10; maximum valid dilution 1:200
MVD basis	MVD for a reference limit of 1 EU/mg at 5 mg/mL and lambda 0.005 EU/mL; the test used 1:10.
LOQ	0.050 EU/mL (Lowest standard 0.005 EU/mL x dilution 10)

Standard curve

Endotoxin (EU/mL)	Response (onset time s)
5.0	612
0.50	1218
0.050	2391
0.005	4702

|r| = 0.9994 slope -0.2934, intercept 3.4812

Replicates and controls

	Result	Note	Control
Replicate 1	0.0512 EU/mL	test solution	
Replicate 2	0.0487 EU/mL	test solution	
Negative control	< 0.005 EU/mL		Passed
Positive product control	92 % recovery of 0.50 EU/mL	limits 50–200 %	Passed
Replicate CV	3.5 %	limit 25 %	Passed

Results

Result	Value	How it is calculated
Endotoxin per mL of the reconstituted vial	0.50 EU/mL (U not estimated for this method)	calculated mean test-solution result x dilution 10
Endotoxin per vial	1.00 EU/vial (U not stated: calculated from values without U)	calculated EU/mL x 2.000 mL reconstitution volume
Endotoxin per mg of peptide	0.096 EU/mg (U not stated: calculated from values without U)	calculated EU/vial / measured content of vial 2 (T3)

Mass used for EU/mg: measured content of the same vial, 10.46 mg (test T3).

Specification and conclusion

Specification	None applied. The result is reported without a conformity statement.
Conclusion	Reported, no specification applied

Lab notes

- No official endotoxin limit exists for a research peptide without a labelled dose (USP <85> limit = K/M). No limit was requested, so none is applied.

> USP limits are K/M and need a labelled dose. A research peptide has none, so any limit shown is client-chosen or an HK reference value with its basis stated.
> Endotoxin is not a sterility test. It does not show whether live microbes are present.

Example report · not a test result

Elemental impurities (ICP-MS)

T6 EX-M-030 v1

As < 0.020 µg/vial (below LOQ); Cd < 0.010 µg/vial (below LOQ); Hg < 0.020 µg/vial (below LOQ); Pb 0.031 ± 0.008 µg/vial (k = 2) — Reported, no specification applied

Method	EX-M-030 v1 Elemental impurities by ICP-MS	Analysts	Example analyst B
Technique	ICP-MS after closed-vessel acid digestion	Technical review	Example reviewer
Validation	Compendial method, verified in this lab, report EX-VAL-030	Started	2026-09-16 15:30 UTC
Accreditation	Not accredited	Completed	2026-09-17 10:10 UTC
Compendial reference	USP <233>	Vials	2
Performed	Subcontracted to Example subcontract lab, Address not shown in this example their report EX-SUB-4471. Accreditation not stated in this example	Instruments	INS-EX-BAL1 5-place analytical balance

Raw data files: F12 S-260914-9001-V2_ICPMS.csv SHA-256 ded2 44e7 47fc fc09

Elemental impurities

Element	ICH Q3D class	Result per vial	Result per g (mass basis)	LOQ	Parenteral PDE (µg/day)
As	1	< 0.020 µg/vial (below LOQ)		0.020	15 context
Cd	1	< 0.010 µg/vial (below LOQ)		0.010	2 context
Hg	1	< 0.020 µg/vial (below LOQ)		0.020	3 context
Pb	1	0.031 ± 0.008 µg/vial (k = 2)	2.5 µg/g (ppm) calculated		5 context

PDE: ICH Q3D permitted daily exposure for a parenteral medicine. Shown for context only; it is not a limit for a vial. Pb per g: µg/vial / gross powder mass 12.41 mg

Sample preparation

Basis	solution aliquot
Gross powder	12.41 mg (Difference weighing of vial 2 (see T5).)
Aliquot	0.500 mL
Digestion	Closed-vessel microwave digestion, HNO3 + HCl
Final volume	10.0 mL

Quality control

Method blank	Passed
Calibration verification	Passed
Internal standards	Sc, Ge, In, Bi

Spike	Recovery	Limits	Met
As	96 %	70–150 %	Passed
Cd	101 %	70–150 %	Passed
Hg	88 %	70–150 %	Passed
Pb	99 %	70–150 %	Passed

Specification and conclusion

Specification	None applied. The result is reported without a conformity statement.
Conclusion	Reported, no specification applied

Lab notes

- ICH Q3D parenteral PDEs (µg/day) are shown for context only. They are daily-intake limits for a medicine, not limits for a vial, so no conformity statement is made.

Counter-ions (TFA, acetate, chloride)

T5 EX-M-020 v1

TFA 11.8 ± 1.2 % w/w (k = 2); Acetate < 0.5 % w/w (below LOQ) — Reported, no specification applied

Method	EX-M-020 v1 Trifluoroacetate and acetate by ion chromatography	Analysts	Example analyst B
Technique	Ion chromatography, suppressed conductivity	Technical review	Example reviewer
Validation	Fit for purpose, not fully validated	Started	2026-09-15 07:45 UTC
Accreditation	Not accredited	Completed	2026-09-16 15:00 UTC
Performed	In house, site example-site	Vials	2
		Instruments	INS-EX-UHPLC1 UHPLC with diode-array detector INS-EX-BAL1 5-place analytical balance

Raw data files: F11 S-260914-9001-V2_IC_TFA.cdf SHA-256 ff5b 4674 ebdc 6ad2 F13 S-260914-9001-V2_balance_log.csv SHA-256 3d52 eec7 e1ef 9fcf

Ion	% w/w of the gross powder	mg per vial
Trifluoroacetate (TFA)	11.8 ± 1.2 % w/w (k = 2)	Not calculated
Acetate	< 0.5 % w/w (below LOQ)	Not calculated

Gross powder 12.41 mg. Difference weighing of vial 2 before reconstitution (2026-09-15) and after emptying, rinsing and drying (2026-09-16), 5-place balance INS-EX-BAL1. Technique: ion chromatography.

Specification and conclusion

Specification	None applied. The result is reported without a conformity statement.
Conclusion	Reported, no specification applied

Deviations from the method

What was different	Why	Impact
Method EX-M-020 is fit-for-purpose and not fully validated.	Validation not completed in this example	The uncertainty is an estimate from spiked recoveries only.

Methods, instruments and materials

Methods

Method	Title and technique	Validation	Compendial reference	Accreditation
EX-M-002 v1 T1	Peptide identity by LC-HRMS RP-UHPLC-ESI-QTOF, positive mode	Validated (ICH Q2(R2)), report EX-VAL-002	None	Not accredited
EX-M-001 v1 T2	Peptide purity by RP-UHPLC-UV RP-UHPLC-UV, 214 nm, area normalisation	Validated (ICH Q2(R2)), report EX-VAL-001	None	Not accredited
EX-M-003 v1 T3	Peptide content per vial by RP-UHPLC-UV, external standard RP-UHPLC-UV, 214 nm, 5-level external calibration	Validated (ICH Q2(R2)), report EX-VAL-003	None	Not accredited
EX-M-010 v1 T4	Bacterial endotoxins, kinetic chromogenic LAL Kinetic chromogenic LAL, 405 nm	Compendial method, verified in this lab, report EX-VAL-010	USP <85>	Not accredited
EX-M-020 v1 T5	Trifluoroacetate and acetate by ion chromatography Ion chromatography, suppressed conductivity	Fit for purpose, not fully validated	None	Not accredited
EX-M-030 v1 T6	Elemental impurities by ICP-MS ICP-MS after closed-vessel acid digestion	Compendial method, verified in this lab, report EX-VAL-030	USP <233>	Not accredited

Instruments

ID	Type	Make and model	Serial	Software	Calibrated	Next due
INS-EX-UHPLC1	UHPLC	Example instrument maker UHPLC with diode-array detector	EX-0001	Example data system 0.0	2026-08-03	2027-02-03
INS-EX-HRMS1	LC-HRMS	Example instrument maker LC-QTOF mass spectrometer	EX-0002	Example data system 0.0	2026-08-10	2027-02-10
INS-EX-READER1	Microplate reader	Example instrument maker Incubating microplate reader	EX-0003	Example data system 0.0	2026-07-21	2027-01-21
INS-EX-BAL1	Balance	Example instrument maker 5-place analytical balance	EX-0004	Not recorded	2026-09-01	2026-12-01

Reference standards

ID	Name and supplier	Lot	Assigned content	Expiry
RS-EX-BPC157-01	BPC-157 reference standard Example supplier	EX-RS-BPC157-01	86.4 % (free base)	2027-06-01

Decision rules

Rule	Statement (printed in full)
DR-SIMPLE v1 simple acceptance	Simple acceptance: the result conforms when the measured value is inside the limit. Uncertainty is not subtracted, so a value close to the limit carries up to about 50 % risk of a wrong decision. ILAC G8:09/2019, simple acceptance (guard band w = 0)
DR-GUARDED-U v1 guarded acceptance	Guarded acceptance with w = U: conforms when the value is inside the limit by at least U; does not conform when it is outside the limit by more than U; otherwise the result is inconclusive (conditional pass or conditional fail). With w = U (k = 2) the risk that a result marked 'conforms' is really outside the limit is at most about 2.5 %. ILAC G8:09/2019, guarded acceptance (w = U, k = 2), non-binary statement
DR-ID-CRITERIA v1 qualitative criteria	Identity conforms when every acceptance criterion of the identity method is met for the specified analyte and no other screened candidate is detected. Acceptance criteria of the stated identity method

Example fingerprints. These values were generated for the example; no raw files exist.

ID	File name and SHA-256	Kind	Size	Created	Visibility
F1	S-260914-9001_BLANK_INJ-01.cdf 320127510d82a2f88b89c28e99ad5f490588d9ac271af7cc94c47b3f8825b468	chromatography raw	125 kB	2026-09-15 09:02:11 UTC	private
F2	S-260914-9001-V1_P1_INJ-02.cdf 17c56ae12c2433db2457be17d72b8622bf677254e3111b8c1fb1292773107e74	chromatography raw	133 kB	2026-09-15 09:21:40 UTC	private
F3	S-260914-9001-V1_P1_INJ-03.cdf 04e49bfd8dc57ac6e014e97668b858916a7f3377df6d52160fd201f607ed88ed	chromatography raw	140 kB	2026-09-15 09:40:02 UTC	private
F4	S-260914-9001-V2_P1_INJ-04.cdf 1f85c6281e16791c3590f1bb8dbb4733c9ec9acdc0fa8456c66cdf99c7cb0ce2	chromatography raw	148 kB	2026-09-15 09:58:31 UTC	private
F5	S-260914-9001-V2_P1_INJ-05.cdf 9d054720eb54cde4ed89c5a49f307437f2d61ed94078e4529dc77435ddef4d09	chromatography raw	156 kB	2026-09-15 10:16:55 UTC	private
F6	S-260914-9001-V1_LCMS_INJ-01.mzML b3b1f4bf0e9b52e04e2f1b55393ffe02123109c542f405dd831b51fc4908ea1d	ms raw	164 kB	2026-09-15 13:05:40 UTC	private
F7	S-260914-9001_receipt_all_units.jpg d06fcf5d49682e309646310e0641441836920l7f14dd8217185478f7c8ab957b	photo	171 kB	2026-09-14 10:14:02 UTC	public
F8	S-260914-9001_V1_label_and_cap.jpg 741ce9ad277c6407c8ba779611798b6650b497f7a0ae3969dd2a2c235109e7a8	photo	179 kB	2026-09-14 10:15:30 UTC	public
F9	S-260914-9001_CAL_BPC157.cdf 253a15d7de0fa69abd11cce0c29dd8c0239f8ca37fe74a3f7c2446265c137d35	calibration data	187 kB	2026-09-15 08:10 UTC	private
F10	S-260914-9001-V2_LAL_plate.csv 347e04f38bca597164e390a6438efb39b301a8d9007f88f5eb25b610650002a7	plate reader raw	195 kB	2026-09-16 11:48 UTC	private
F11	S-260914-9001-V2_IC_TFA.cdf ff5b4674ebdc6ad2c9f2d3eee12f2888a75b98c2e42de0f6f976814501a7b5e5	ic raw	202 kB	2026-09-16 14:20 UTC	private
F12	S-260914-9001-V2_ICPMS.csv ded244e747fcfc0913dc0d1ac32fb62c89e1919f572c7853467294b70a452218	icp raw	210 kB	2026-09-16 16:02 UTC	private
F13	S-260914-9001-V2_balance_log.csv 3d52eec7e1ef9fcf02572d423e60074e4cbfb910fbaad6825a25610ca5f92d31	other	218 kB	2026-09-16 08:31 UTC	private
F14	EX-RS-BPC157-01_certificate.pdf a207de03038602c4c8eb09c17221d809aebdf32911fda30c1ea45c35316b1b1f	certificate	225 kB	2026-06-02 12:00 UTC	private
F15	EX-SUB-4471_report.pdf 43f56be4095557ba28bff98c0eb1a0deb5a300a41eda4bacddf1254b6a946c51	subcontractor report	233 kB	2026-09-17 10:05 UTC	on request

Subcontracted tests

Test	Laboratory	Their report	Their accreditation statement
T6	Example subcontract lab Address not shown in this example	EX-SUB-4471 F15 EX- SUB-4471_report.pdf SHA-256 43f5 6be4 0955 57ba	Accreditation not stated in this example

Interpretations, deviations and notes

Interpretation (opinion) OP-1

The impurity at RRT 0.967 has a mass 57.02 Da lower than BPC-157. This is consistent with a peptide that is missing one glycine (a des-Gly deletion from synthesis). This is an interpretation, not a measured identity.

Based on: LC-HRMS mass of the co-eluting species (T1, related species) and its UV area share (T2). Related tests: T1, T2. Author: Example reviewer, Technical reviewer.

Example report · not a test result

Deviations, additions and exclusions

What	Why	Tests affected
Only two vials were received. Vial 2 was shared between content, endotoxin, counter-ion and elemental tests, so smaller aliquots were used and the LOQs for elements are higher than with a dedicated vial.	Sample amount limited by the client.	T4, T5, T6

Deviations of single tests are listed in their sections.

Authorisation and verification

Approvals

Analysts: Example analyst B (tests T1, T4, T5, T6); Example analyst A (tests T2, T3).

Person	Role	Date and time	Meaning
Example reviewer	Technical reviewer	2026-09-17 16:40 UTC	Technical review completed
Example approver	Quality manager	2026-09-18 08:55 UTC	Approved for release

Approvals are recorded in the signed record. HK does not use handwriting images; the cryptographic signature below is the lab's seal over the whole record.

Contract review: order `0-7K2M9Q4D` reviewed 2026-09-12 09:05 UTC by Example approver. Terms EX-TERMS-1. Decision rules agreed with the client: DR-SIMPLE, DR-GUARDED-U, DR-ID-CRITERIA.

Verification

hkanalytical.com

COA ID	**HK-260925-1V5R1B** Version 1
Access key	**04NBZ-QSWSY-8EESH-MJYQB-VAMBNM**
Issued	2026-09-25 20:10 UTC
Record SHA-256	`f67a4ee7a8e6316b473225e0dbcce3f31e4bce7060b4d2948dfe2aa97d80217f`
Signature (Ed25519)	`IZaFC4WSKKgiFgYPNq4hlI5FYeDDNHzR0cmuggPZYVD K4JS2A_nCRDdqi6sLovCh-fHlMPOqjjiHqiLMiHcXBg`
Signing key	`hk-demo-1` · fingerprint `221C 513E 8091 01F5` · demo key: it signs example reports only
Public keys	hkanalytical.com/.well-known/hk-coa-keys.json

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Version history

Version	COA ID	Issued	Reason
1	`HK-260925-1V5R1B`	2026-09-25 20:10 UTC	First issue

The live status of every version (valid, superseded or withdrawn) is on the report page.

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