Example report · not a test result

Product name as received

Blind GLP-1 vial client-supplied

Tested for **Example market survey**
Blind panel Semaglutide, Tirzepatide, Retatrutide, Liraglutide (formulas and masses on the identity page)

Ordered	Received	Tested	Issued
2026-09-14	2026-09-15	2026-09-16 to 2026-09-17	2026-09-25

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

Client relationship · part of the signed record

Affiliated client. In this example, HK Analytical bought this vial itself for a market survey, so the client is HK Analytical. The purchasing staff did not tell the analysts the product name or label claim until the results were final. Type of link: HK Analytical's own sample (market survey, proficiency or validation). Basis: Internal order, recorded in the conflict-of-interest register. Declared on 2026-09-14; checked by Example approver, Quality manager.

Identity
Tirzepatide
Identity level L3
Conforms
label claim client-supplied

Purity
98.7 % area
U ± 0.3 (k = 2)
Reported
no specification

Net content
10.86 mg/vial
108.6 % of label claim
client-supplied
Inconclusive
conditional pass

Endotoxin
0.044 EU/mg
0.48 EU/vial
Reported
no specification

Sterility
Not tested

Uniformity
RSD 1.2 %
n = 3
Conforms
HK ref. spec

Test and method	Result	Specification	Conclusion	Data
Identity, blind panel (LC-MS) EX-M-004 v1	Consistent with Tirzepatide (L3)	= Tirzepatide label claim (client-supplied)	Conforms	p. 3
Purity (RP-HPLC-UV, 214 nm) EX-M-001 v1	98.7 ± 0.3 % area (k = 2)	None applied	Reported	p. 5
Net peptide content (free base) EX-M-003 v1	10.86 ± 0.43 mg/vial (k = 2), 108.6 % of label claim client-supplied	90.0–110.0 % of label claim HK reference specification	Inconclusive (conditional pass)	p. 7
Bacterial endotoxins (kinetic chromogenic LAL) EX-M-010 v1	0.24 EU/mL (U not estimated for this method) 0.48 EU/vial (U not stated: calculated from values without U) 0.044 EU/mg (U not stated: calculated from values without U)	None applied	Reported	p. 8
Sterility (USP <71>, 14 days)	Not tested		Not tested	
Vial-to-vial uniformity EX-M-003 v1	RSD 1.2 % (n = 3)	≤ 5.0 % HK reference specification	Conforms	p. 9

What we received observed by HK on receipt

Received	3 vials, 2026-09-15 09:31 UTC
Container	3 mL clear glass vial, grey rubber stopper, aluminium crimp with flip-off cap
Cap and crimp	purple cap, silver crimp
Contents	Lyophilised cake. White lyophilised cake, partly detached from the vial wall.
Lot on container	No lot printed
Seal	Intact

What the client told us client-supplied

Product name	Blind GLP-1 vial
Label claim	10 mg per vial
Lot	EX-TZ-0826
Vendor	Example vendor
Manufacturer	Not provided by the client

Label claim withheld from the analysts until 2026-09-18 09:30 UTC, after the results were final. 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 3 vials we received. They do not prove that other vials or batches are the same.
2. The analysts did not know the product name or label claim until the results were final.
3. Net content is mg of Tirzepatide free base per vial, measured against reference standard lot EX-RS-TIRZ-01.
4. Purity is the share of UV signal at 214 nm that comes from Tirzepatide. It does not measure water, salts, microbes or endotoxin.
5. No official endotoxin limit exists for a research peptide without a labelled dose. We report the number; we do not call it safe.

Example report · not a test result

Sample, custody and vial allocation

Sample ID S-260915-9002

Observed by HK on receipt

Units received	3 vials
Received	2026-09-15 09:31 UTC, by Example sample clerk
Package	Box intact. Three vials in foam insert, labels covered with opaque tape (blind).
Container	3 mL clear glass vial, grey rubber stopper, aluminium crimp with flip-off cap
Cap colour	purple
Crimp colour	silver
Fill state	Lyophilised cake
Appearance	White lyophilised cake, partly detached from the vial wall
Label text as read	Covered with tape on receipt (blind handling)
Lot on container	No lot printed
Seal intact	Yes
Temperature on arrival	19 °C
Storage before analysis	-20 °C, dark
Receipt deviations	None recorded

Supplied by the client (not verified by HK)

client-supplied

Product name	Blind GLP-1 vial
Label claim	10 mg per vial
Lot	EX-TZ-0826
Vendor	Example vendor
Manufacturer	Not provided by the client
Claimed sequence	Not provided by the client
Expiry	Not provided by the client
Other label text	The label was covered with tape by the purchasing staff before the vials reached the lab; claim revealed on 2026-09-18.

Photos taken by HK on receipt

Photo	Caption and file	Taken	SHA-256 (first 16)
Photo 1 of 2 All units	Three vials on receipt, labels taped over, lab labels V1-V3 attached S-260915-9002_receipt_all_units.jpg	2026-09-15 09:40 UTC Example sample clerk	e1f5 796c 36ec 8af2
Photo 2 of 2 Fill level	Vial 1: purple cap, silver crimp, cake detached from wall S-260915-9002_V1_cap_fill.jpg	2026-09-15 09:41:10 UTC Example sample clerk	91ee b033 9185 23c2

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

Vial allocation

Vial	Lab label	Used for tests	After testing
1	S-260915-9002-V1	T1, T2, T3, T4	Consumed
2	S-260915-9002-V2	T3, T4	Consumed
3	S-260915-9002-V3	T3, T4, T5	Consumed

Chain of custody

Time	Event	By	Location	Vials	Detail
2026-09-15 09:31 UTC	Received	Example sample clerk	Sample reception	1, 2, 3	
2026-09-15 09:40 UTC	Photographed	Example sample clerk	Sample reception	1, 2, 3	
2026-09-15 09:50 UTC	Stored	Example sample clerk	Freezer EX-FRZ-1, -20 °C	1, 2, 3	
2026-09-16 08:45 UTC	Reconstituted	Example analyst B	HPLC lab	1	Whole vial in 2.000 mL diluent
2026-09-17 07:40 UTC	Reconstituted	Example analyst A	HPLC lab	2, 3	Vial 2 in diluent; vial 3 in LAL reagent water
2026-09-18 15:00 UTC	Disposed	Example analyst A	HPLC lab	1, 2, 3	Solutions 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).

Blind handling. The product name and label claim were withheld from the analysts. They were revealed on 2026-09-18 09:30 UTC, after the identity, purity and content results were complete (checked before issue).

Example report · not a test result

Identity, blind panel (LC-MS)

T1 EX-M-004 v1

Consistent with Tirzepatide · identity level L3

Conforms

Method	EX-M-004 v1 Blind GLP-1 identity panel by LC-HRMS	Analysts	Example analyst B
Technique	RP-UHPLC-ESI-QTOF, positive mode, extracted-ion screening of 4 candidates	Technical review	Example reviewer
Validation	Validated (ICH Q2(R2)), report EX-VAL-004	Started	2026-09-16 09:00 UTC
Accreditation	Not accredited	Completed	2026-09-16 12:30 UTC
Performed	In house, site example-site	Vials	1
		Instruments	INS-EX-HRMS1 LC-QTOF mass spectrometer

Raw data files: F3 S-260915-9002-V1_LCMS_BLINDPANEL.mzML SHA-256 c553 8edd 5aa3 ce14

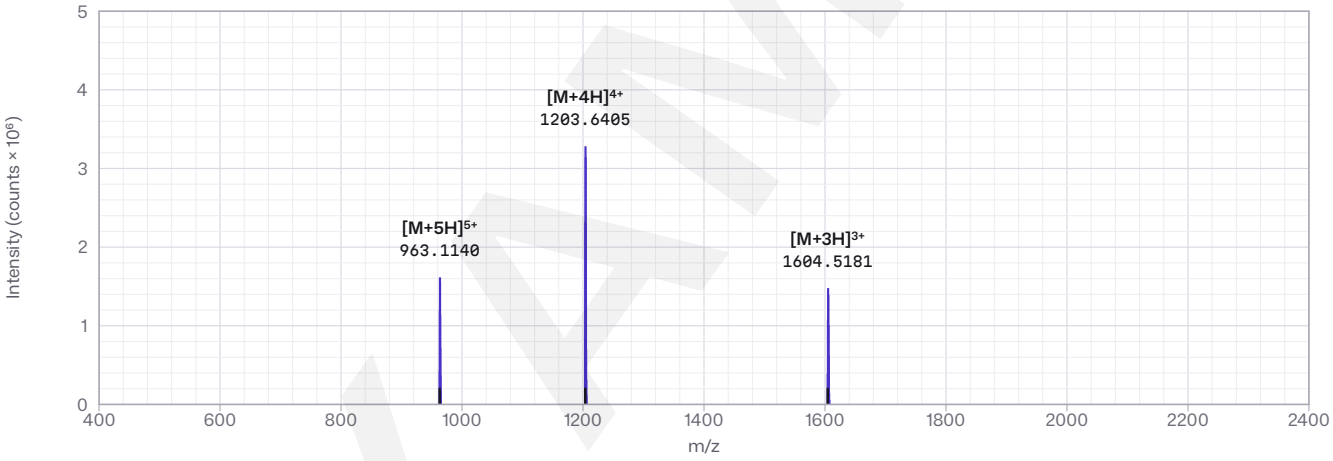
Mass spectrometry

Analyser	Q-TOF, resolving power 40000 at m/z 1222 ESI+ scan m/z 400–2400
Mass calibration	Calibrant mix, 2026-09-16 08:20 UTC; lock mass m/z 922.0098
Deconvolution	Example data system 0.0, Isotope-resolved charge deconvolution output monoisotopic

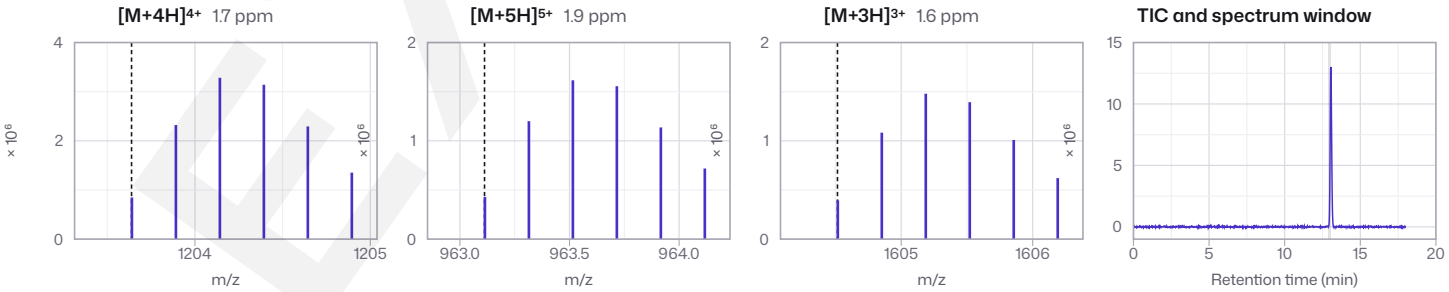
Liquid chromatography

Column	C18 peptide column, C18, wide pore, 150 × 2.1 mm, 1.7 µm, 300 Å serial or lot EX-COL-0104
Mobile phase A	0.1 % formic acid in water
Mobile phase B	0.1 % formic acid in acetonitrile
Gradient (min, % B)	0.0 min 20 % · 14.0 min 60 % · 14.5 min 95 % · 16.0 min 95 % · 16.1 min 20 % · 18.0 min 20 %
Flow, temperature	0.30 mL/min; column 60 °C; autosampler 8 °C
Injection, run time	1.0 µL; 18.0 min
Detection	ESI-QTOF, full scan m/z 400-2400
Sample preparation	Aliquot of the vial 1 solution 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 12.98–13.14 min



Centroids exactly as exported. Black ticks on the axis: expected m/z of each matched ion, calculated from the formula. S-260915-9002-V1_LCMS_BLINDPANEL.mzML · SHA-256 c553 8edd 5aa3 ce14…



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
$[M+4H]^{4+}$	Tirzepatide	4	1203.6385	1203.6405	1.7	0.96	100 %
$[M+3H]^{3+}$	Tirzepatide	3	1604.5156	1604.5181	1.6	0.94	46 %
$[M+5H]^{5+}$	Tirzepatide	5	963.1122	963.1140	1.9	0.93	52 %

Intact mass (deconvoluted)	Basis	Expected (Da)	Observed (Da)	Error
Tirzepatide	monoisotopic	4810.5249	4810.5330	1.7 ppm

Expected m/z calculated from the molecular formula with monoisotopic element masses and a proton mass of 1.007276 Da. Semaglutide: $C_{187}H_{291}N_{45}O_{59}$, monoisotopic 4111.1154 Da (Published molecular formula (check against the reference standard certificate)); Tirzepatide: $C_{225}H_{348}N_{48}O_{68}$, monoisotopic 4810.5249 Da (Published molecular formula (check against the reference standard certificate)); Retatrutide: $C_{221}H_{342}N_{46}O_{68}$, monoisotopic 4728.4718 Da (Published molecular formula (check against the reference standard certificate)); Liraglutide: $C_{172}H_{265}N_{43}O_{51}$, monoisotopic 3748.9465 Da (Published molecular formula (check against the reference standard certificate)).

Acceptance criteria (EX-VAL-004 section 4)

Criterion	Found (calculated from the table above)	Met
Mass error |ppm| ≤ 5.0 for every matched ion	largest 1.9 ppm	✓ Met
At least 2 charge states	3 (z = 3, 4, 5)	✓ Met
Isotope fit ≥ 0.90	lowest 0.93	✓ Met

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

Blind panel: every candidate in the method

Candidate	Formula	Monoisotopic (Da)	Outcome	LOD	Evidence
Semaglutide	$C_{187}H_{291}N_{45}O_{59}$	4111.1154	Not detected	< 5 µg/vial	No signal in the XICs of [M+3H]3+ and [M+4H]4+ (+/- 10 ppm)
Tirzepatide	$C_{225}H_{348}N_{48}O_{68}$	4810.5249	**Detected**		[M+3H]3+, [M+4H]4+ and [M+5H]5+ within 2 ppm; isotope fit >= 0.93
Retatrutide	$C_{221}H_{342}N_{46}O_{68}$	4728.4718	Not detected	< 5 µg/vial	No signal in the XICs of [M+3H]3+ and [M+4H]4+ (+/- 10 ppm)
Liraglutide	$C_{172}H_{265}N_{43}O_{51}$	3748.9465	Not detected	< 5 µg/vial	No signal in the XICs of [M+3H]3+ and [M+4H]4+ (+/- 10 ppm)

Related species

Observed mass (Da)	Mass difference (Da)	RT (min)	Relative abundance	Interpretation
4826.520	15.995	12.76	0.6 % (uv area)	See interpretation OP-1

Specification and conclusion

Specification	= Tirzepatide
Source	Label claim (client-supplied): Label claim revealed to the analyst after results were final (2026-09-18)
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)

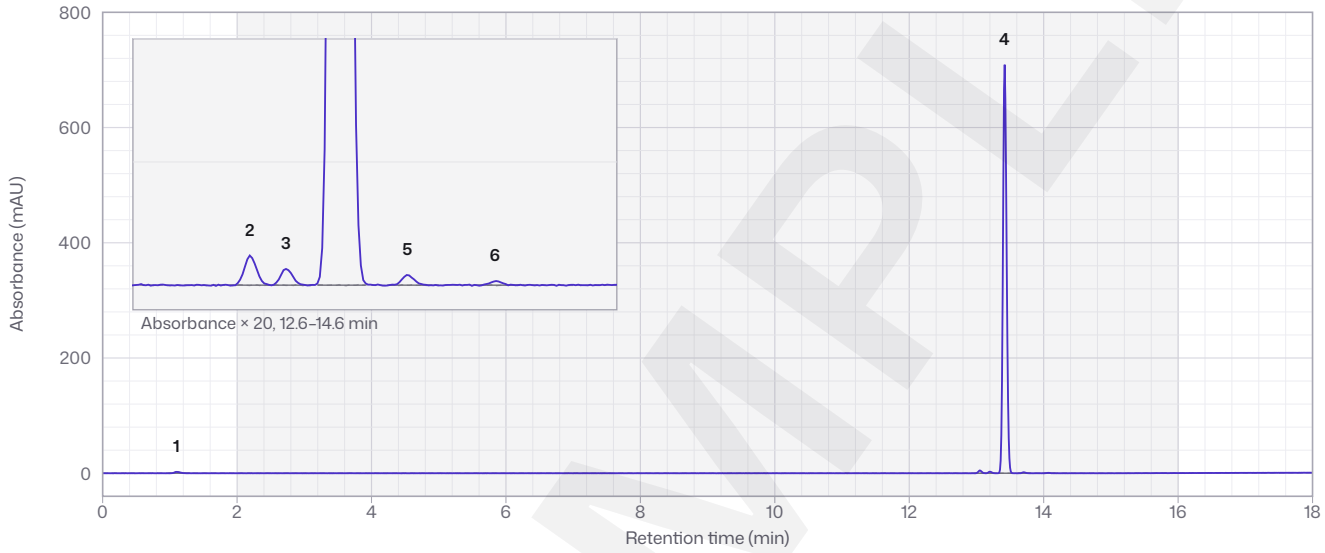
T2 EX-M-001 v1

98.7 ± 0.3 % area (k = 2) at 214 nm · reporting threshold 0.05 % — Reported, no specification applied

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	2026-09-17 08:00 UTC
Accreditation	Not accredited	Completed	2026-09-17 11:10 UTC
Performed	In house, site example-site	Vials	1
		Instruments	INS-EX-UHPLC1 UHPLC with diode-array detector

Raw data files: F5 S-260915-9002_BLANK_INJ-01.cdf SHA-256 b2d4 2e77 fb3d 69de F8 S-260915-9002-V1_P1_INJ-02.cdf SHA-256 ab2c 099c 9425 9d26 F9 S-260915-9002-V1_P1_INJ-03.cdf SHA-256 6f87 2825 f923 6d40

Chromatogram, injection INJ-02



DAD A, 214 nm (bw 4), ref off. Violet: sample S-260915-9002-V1 prep 1, acquired 2026-09-17 09:02 UTC, min–max decimated from 10801 to 1801 points, so every local maximum (each peak apex) is kept. Grey dashed: blank injection INJ-01. Shaded: integration window 2.00–16.00 min. Grey lines under the peaks: integration baselines exported by the data system. Numbers match the peak table. S-260915-9002-V1_P1_INJ-02.cdf · SHA-256 ab2c 099c 9425 9d26…

Peak table, injection INJ-02

#	RT (min)	RRT	Start–end	Area	Area %	Height	Tailing	Plates	Res.	S/N	Assignment and use
1	1.100	0.082	0.980–1.300	14.0	0.00	2.33	1.33	756		16	Blank peak. Not counted: Also present in the blank (injection/solvent peak); outside the integration window
2	13.050	0.973	12.966–13.125	16.8	0.62	4.75	1.12	308091	94.30	32	Impurity (OP-1)
3	13.200	0.984	13.125–13.304	9.4	0.35	2.66	1.12	315215	1.60	18	Impurity
4	13.418	1.000	13.330–13.530	2672.8	98.73	710.86	1.14	287799	2.25	4739	Main peak
5	13.703	1.021	13.619–13.807	5.7	0.21	1.61	1.12	339696	2.94	11	Impurity
6	14.066	1.048	13.982–14.170	2.4	0.09	0.67	1.12	357931	3.87	4	Impurity

Replicate injections

Injection	Sample in file	Main peak area %
INJ-02	S-260915-9002-V1 prep 1	98.73
INJ-03	S-260915-9002-V1 prep 1	98.72
Reported		**98.7 ± 0.3 % area (k = 2)**

Impurities at or above the reporting threshold

RT (min)	RRT	Area %	Observed mass (Da)	Interpretation
13.050	0.973	0.62	4826.520	See interpretation OP-1
13.200	0.984	0.35		
13.703	1.021	0.21		
14.066	1.048	0.09		

Example report · not a test result

Largest single impurity: 0.62 % area at 13.050 min. Total impurities: 1.28 % area.

Integration parameters

Software, method	Example data system 0.0 processing method EX-PEPTIDE-PURITY v1
Window, baseline	2.00–16.00 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	Tirzepatide and impurity at RRT 0.984	2.25	≥ 1.5	Met
Tailing factor	Tirzepatide	1.14	≤ 1.8	Met
Repeatability rsd	Tirzepatide area, 5 standard injections	0.51 %	≤ 2.0 %	Met
Signal to noise	0.05 % sensitivity solution	12	≥ 10	Met

Conditions

Column	C18 peptide column, C18, wide pore, 150 × 2.1 mm, 1.7 µm, 300 Å serial or lot EX-COL-0103
Mobile phase A	0.1 % TFA in water
Mobile phase B	0.1 % TFA in acetonitrile
Gradient (min, % B)	0.0 min 20 % · 1.0 min 20 % · 15.0 min 60 % · 15.5 min 95 % · 16.5 min 95 % · 16.6 min 20 % · 18.0 min 20 %
Flow, temperature	0.30 mL/min; column 60 °C; autosampler 8 °C
Injection, run time	2.0 µL; 18.0 min
Detection	DAD 214 nm (bandwidth 4 nm), reference off
Sample preparation	Whole vial dissolved in 2.000 mL (vials 1 and 2: diluent; vial 3: LAL reagent water, 0.2 mL taken for T5 first), then diluted 1:10 in diluent. Two injections per vial. Diluent: Water/acetonitrile 80:20 with 0.1 % TFA. Reconstitution 2.000 mL. Dilution factor 10.0. Nominal 0.500 mg/mL.

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

Net peptide content (free base)

T3 EX-M-003 v1

10.86 ± 0.43 mg/vial (k = 2) (mean of 3 vials) · 108.6 % of label claim
client-supplied · **Tirzepatide free base**

Inconclusive (conditional pass)

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	2026-09-17 08:00 UTC
Accreditation	Not accredited	Completed	2026-09-17 11:10 UTC
Performed	In house, site example-site	Vials	1, 2, 3
		Instruments	INS-EX-UHPLC1 UHPLC with diode-array detector

Raw data files: F4 S-260915-9002_CAL_TIRZ.cdf SHA-256 a255 894d f799 3bc0 F8 S-260915-9002-V1_P1_INJ-02.cdf SHA-256 ab2c 099c 9425 9d26 F9 S-260915-9002-V1_P1_INJ-03.cdf SHA-256 6f87 2825 f923 6d40 F10 S-260915-9002-V2_P1_INJ-04.cdf SHA-256 b127 346e c761 70dc F11 S-260915-9002-V2_P1_INJ-05.cdf SHA-256 413e 68a5 0ea7 1104 F12 S-260915-9002-V3_P1_INJ-06.cdf SHA-256 51af 5132 ffed e05f F13 S-260915-9002-V3_P1_INJ-07.cdf SHA-256 a251 2a9b ff79 7fd4

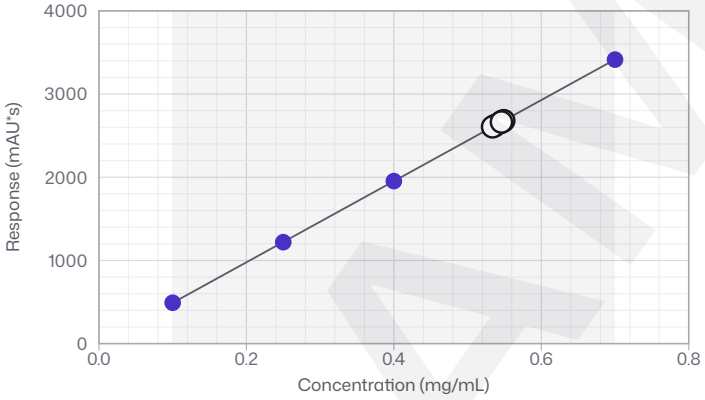
> Free base: mg of the peptide itself, without counter-ions or water. The reference standard content is assigned as free base. The salt form in the vial was not determined.

Reference standard

Standard	Tirzepatide reference standard RS-EX-TIRZ-01
Supplier, lot	Example supplier, EX-CAT-TZ, lot EX-RS-TIRZ-01
Grade	Secondary standard, qualified in house
Assigned content	88.9 % (free base), U 1.6 %; purity 99.1 %
Expiry	2027-05-01; qualification EX-QUAL-RS-TZ
Certificate	F7 EX-RS-TIRZ-01_certificate.pdf SHA-256 d237 3d3c bf10 9714

Calibration model

Model	linear, weighting none
Slope, intercept	4876.2, 2.4
R^2	0.99995
Calibrated range	0.100–0.700 mg/mL
Check standard	0.4012 found, 0.400 nominal: 100.3 % (98.0-102.0 %), passed
Standard used	RS-EX-TIRZ-01



Level	Conc. (mg/mL)	Response (mAU*s)
1	0.100	491.4
2	0.250	1219.5
3	0.400	1953.6
4	0.550	2686.5
5	0.700	3414.2

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	2672.8	0.5476 mg/mL	2.000	10.0	10.95
1	1	INJ-03	2656.8	0.5444 mg/mL	2.000	10.0	10.89
2	1	INJ-04	2621.4	0.5371 mg/mL	2.000	10.0	10.74
2	1	INJ-05	2605.8	0.5339 mg/mL	2.000	10.0	10.68
3	1	INJ-06	2680.1	0.5491 mg/mL	2.000	10.0	10.98
3	1	INJ-07	2664.1	0.5459 mg/mL	2.000	10.0	10.92

Results

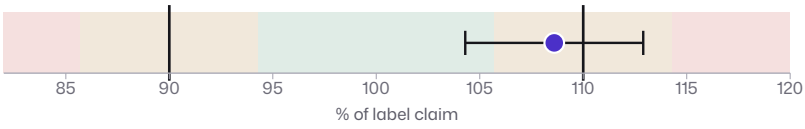
	mg per vial	Note
Vial 1	10.92 ± 0.44 mg/vial (k = 2)	2 injections
Vial 2	10.71 ± 0.43 mg/vial (k = 2)	2 injections
Vial 3	10.95 ± 0.44 mg/vial (k = 2)	2 injections
Mean	**10.86 ± 0.43 mg/vial (k = 2)**	n = 3 vials, SD 0.13 mg, RSD 1.2 %
Label claim client-supplied	10 mg per vial	**108.6 % of label claim** client-supplied

Example report · not a test result

Specification and conclusion

Specification	90.0–110.0 % of label claim
Source	HK reference specification: EX-SPEC-CONTENT v1: 90.0-110.0 % of label claim
Decision rule	`DR-GUARDED-U v1`, guarded acceptance, guard band w = 1 × U. 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 %.
Conclusion	**Inconclusive** (conditional pass)

Acceptance zones for content pct of label claim calculated



Result **108.6 % of label claim** ± 4.3 (U, k = 2)
Lower limit 90.0
Upper limit 110.0
Guard band w = 4.3
Conforms from 94.3 to 105.7
Does not conform below 85.7
Does not conform above 114.3
U converted: 0.43 mg/vial on a 10 mg claim = 4.30 percentage points.

conforms · guard band (inconclusive) · does not conform · limit · dot and whisker: result ± U

Lab notes

- Mean 108.6 % of label claim, U = 4.3 percentage points. The upper acceptance limit with the guard band is 105.7 %, and the upper rejection limit is 114.3 %. The value lies between them, so the result is inconclusive (conditional pass).

Bacterial endotoxins (kinetic chromogenic LAL)

`T5 EX-M-010 v1`

0.24 EU/mL · 0.48 EU/vial · 0.044 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	2026-09-17 12:00 UTC
Accreditation	Not accredited	Completed	2026-09-17 13:30 UTC
Compendial reference	USP <85>	Vials	3
Performed	In house, site `example-site`	Instruments	`INS-EX-READER1` Incubating microplate reader

Raw data files: `F6 S-260915-9002-V3_LAL_plate.csv` SHA-256 `0429 f788 a7e5 b3ad`

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 3, reconstituted in 2.000 mL LAL reagent water
Test dilution	1:20; 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 1:20.
LOQ	0.10 EU/mL (Lowest standard 0.005 EU/mL x dilution 20)

Standard curve

Endotoxin (EU/mL)	Response (onset time s)
5.0	608
0.50	1224
0.050	2385
0.005	4690

|r| = 0.9993 slope -0.2931, intercept 3.4797

Replicates and controls

	Result	Note	Control
Replicate 1	0.0121 EU/mL	test solution	
Replicate 2	0.0118 EU/mL	test solution	
Negative control	< 0.005 EU/mL		Passed
Positive product control	94 % recovery of 0.50 EU/mL	limits 50–200 %	Passed
Replicate CV	1.8 %	limit 25 %	Passed

Results

Result	Value	How it is calculated
Endotoxin per mL of the reconstituted vial	0.24 EU/mL (U not estimated for this method)	calculated mean test-solution result x dilution 20
Endotoxin per vial	0.48 EU/vial (U not stated: calculated from values without U)	calculated EU/mL x 2.000 mL reconstitution volume
Endotoxin per mg of peptide	0.044 EU/mg (U not stated: calculated from values without U)	calculated EU/vial / measured content of vial 3 (T3)

Mass used for EU/mg: measured content of the same vial, 10.95 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 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.

Vial-to-vial uniformity

T4 EX-M-003 v1

RSD 1.2 % across 3 vials — Conforms

Method	EX-M-003 v1 Peptide content per vial by RP-UHPLC-UV, external standard	Analysts	Example analyst A
Technique	Statistics on the per-vial results of T3	Technical review	Example reviewer
Validation	Validated (ICH Q2(R2)), report EX-VAL-003	Started	2026-09-17 08:00 UTC
Accreditation	Not accredited	Completed	2026-09-17 11:10 UTC
Performed	In house, site example-site	Vials	1, 2, 3
		Instruments	INS-EX-UHPLC1 UHPLC with diode-array detector

Raw data files: F8 S-260915-9002-V1_P1_INJ-02.cdf SHA-256 ab2c 099c 9425 9d26 F9 S-260915-9002-V1_P1_INJ-03.cdf SHA-256 6f87 2825 f923 6d40 F10 S-260915-9002-V2_P1_INJ-04.cdf SHA-256 b127 346e c761 70dc F11 S-260915-9002-V2_P1_INJ-05.cdf SHA-256 413e 68a5 0ea7 1104 F12 S-260915-9002-V3_P1_INJ-06.cdf SHA-256 51af 5132 ffed e05f F13 S-260915-9002-V3_P1_INJ-07.cdf SHA-256 a251 2a9b ff79 7fd4

Vial	Value
Vial 1	10.92 mg/vial
Vial 2	10.71 mg/vial
Vial 3	10.95 mg/vial

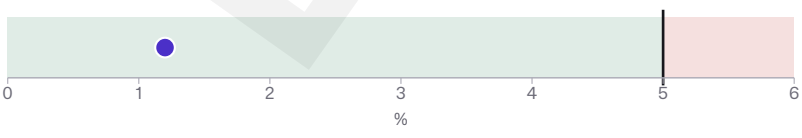
Source tests	T3
Parameter	net content mg
n	3
Mean	10.86
SD	0.13
RSD	1.2 %
Min to max	10.71 to 10.95

Statistics recalculated by the engine from the per-vial values of the source test before issue.

Specification and conclusion

Specification	≤ 5.0 %
Source	HK reference specification: EX-SPEC-UNIFORMITY v1: RSD of vial contents <= 5.0 %
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 rsd pct calculated



Result **1.2 %**
Upper limit 5.0
Guard band w = 0.0
Conforms at or below 5.0

conforms · guard band (inconclusive) · does not conform · limit · dot and whisker: result ± U

Example report · not a test result

Methods, instruments and materials

Methods

Method	Title and technique	Validation	Compendial reference	Accreditation
EX-M-004 v1 T1	Blind GLP-1 identity panel by LC-HRMS RP-UHPLC-ESI-QTOF, positive mode, extracted-ion screening of 4 candidates	Validated (ICH Q2(R2)), report EX-VAL-004	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, T4	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 T5	Bacterial endotoxins, kinetic chromogenic LAL Kinetic chromogenic LAL, 405 nm	Compendial method, verified in this lab, report EX-VAL-010	USP <85>	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

Reference standards

ID	Name and supplier	Lot	Assigned content	Expiry
RS-EX-TIRZ-01	Tirzepatide reference standard Example supplier	EX-RS-TIRZ-01	88.9 % (free base)	2027-05-01

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-260915-9002_receipt_all_units.jpg e1f5796c36ec8af2ebb0a5c304d288a8fa5f599f00cb9ce787bcb2adf50da982	photo	125 kB	2026-09-15 09:40 UTC	public
F2	S-260915-9002_V1_cap_fill.jpg 91eeb033918523c2a09c09ac2f0e6364f4a7c1b4dc45d234141873dcb9c30431	photo	133 kB	2026-09-15 09:41:10 UTC	public
F3	S-260915-9002-V1_LCMS_BLINDPANEL.mzML c5538edd5aa3ce1423f4f828945306126e63b0ee94617f267e6f8b7aca2fdf01	ms raw	140 kB	2026-09-16 09:35 UTC	private
F4	S-260915-9002_CAL_TIRZ.cdf a255894df7993bc06d6990f2fc74bff46f14430c368bacde827cd161efbc6703	calibration data	148 kB	2026-09-17 08:05 UTC	private
F5	S-260915-9002_BLANK_INJ-01.cdf b2d42e77fb3d69deb9609591a8fee947b5c2260285533414d1c5cfb48d8e6ffd	chromatography raw	156 kB	2026-09-17 08:40 UTC	private
F6	S-260915-9002-V3_LAL_plate.csv 0429f788a7e5b3ad512379b09e74a9e79bc6e51d69a7c8eb8f8640ca5592f392	plate reader raw	164 kB	2026-09-17 13:10 UTC	private
F7	EX-RS-TIRZ-01_certificate.pdf d2373d3cbf109714439d1a361de8843346b6f250b6c28ab3ba920953eff86e67	certificate	171 kB	2026-05-20 12:00 UTC	private
F8	S-260915-9002-V1_P1_INJ-02.cdf ab2c099c94259d263bb33de0d80b5a129e9149ab0a2b73cad125d3f19a1150fd	chromatography raw	179 kB	2026-09-17 09:02 UTC	private
F9	S-260915-9002-V1_P1_INJ-03.cdf 6f872825f9236d40529d098ad12c9299be10eee7ee3f38d7217a194856bb6e51	chromatography raw	187 kB	2026-09-17 09:22 UTC	private
F10	S-260915-9002-V2_P1_INJ-04.cdf b127346ec76170dca22ba21297957b9f5ebb0a66ad92bd1a1cdf2b97afb95422	chromatography raw	195 kB	2026-09-17 09:42 UTC	private

Example report · not a test result

ID	File name and SHA-256	Kind	Size	Created	Visibility
F11	S-260915-9002-V2_P1_INJ-05.cdf 413e68a50ea71104c18f43411ffd4194f1691a264644d5c78e12ee4364c28ae8	chromatography raw	202 kB	2026-09-17 10:02 UTC	private
F12	S-260915-9002-V3_P1_INJ-06.cdf 51af5132ffede05fbf62ab836cfc7c445213bb5f77f6bb3da7396023a71642b4	chromatography raw	210 kB	2026-09-17 10:22 UTC	private
F13	S-260915-9002-V3_P1_INJ-07.cdf a2512a9bff797fd4e5cd2e221acb008b3245f94b9914f72672077cf3c3d50b24	chromatography raw	218 kB	2026-09-17 10:42 UTC	private

Interpretations, deviations and notes

Interpretation (opinion) OP-1

The impurity at RRT 0.973 is 15.995 Da heavier than tirzepatide. This is consistent with a single oxidation, which is a common storage or handling degradant. This is an interpretation, not a measured identity.

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

Deviations, additions and exclusions

No report-level deviations. Deviations of single tests are listed in their sections.

Example report · not a test result

Authorisation and verification

Approvals

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

Person	Role	Date and time	Meaning
Example reviewer	Technical reviewer	2026-09-18 14:10 UTC	Technical review completed
Example approver	Quality manager	2026-09-21 08:40 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 0-9W4T2H6N reviewed 2026-09-14 08:30 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-VSWMV6** Version 1
Access key	**QVYKR-Q1PDV-F4BY2-XCQ5W-NQPGGK**
Issued	2026-09-25 20:10:09 UTC
Record SHA-256	8559714249ccac75fa13c95c4dd15d163f6a587234be9b9969eb367530c7368d
Signature (Ed25519)	a-GVaPrCGNda-MrpOWnxSYU5hrAt62OVaLBhdRtDeeR yxqqE98OSi2JBBh8OuciRbjebeQrCkfapPhtRRT_XBw
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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4. Compare the lot, cap, crimp and fill on page 2 with your own vial.

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Version history

Version	COA ID	Issued	Reason
1	HK-260925-VSWMV6	2026-09-25 20:10:09 UTC	First issue

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

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End of report.