ANALYTON LABS

AN-2026-00014

Issued 2026-08-01

Certificate of analysis

BATCH ID AMENDED 2026-10-29

REPORT FIELD OMITTED 2026-10-29

Issued by ANALYTON LABS, analytical testing laboratory, under ANALYTON GC 1.1. Relates only to the sample as received and described below.

Client	Molequa
Sample as described	Tirzepatide, lyophilised powder, vial labelled 5 mg
Batch as marked	MQ-TIRZEPATIDE-202609
Matrix	Research peptide

Sample received	2026-07-25
Analysis	2026-07-26 to 2026-07-31
Date of issue	2026-08-01
Determinations performed	19

CONFORMS TO SPECIFICATION

All 18 determinations judged against a specification are within it. 2 further determinations are reported without a specification.

SUMMARY OF RESULTS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Appearance	Visual	**White to off-white lyophilised cake, free of visible particles**	White to off-white powder or cake PASS
Identity	LC-HRMS (ESI+), USP <621> principles	**Deconvoluted monoisotopic mass 4810.529 Da, deviation 0.8 ppm (0.004 Da); observed m/z 1604.516 (3+), 1203.638 (4+), 963.112 (5+); charge envelope 3+ to 6+**	Theoretical monoisotopic 4810.525 Da from C225H348N48O68 (average 4813.5 Da); expected m/z 1604.516 (3+), 1203.638 (4+), 963.112 (5+); deviation <= 10 ppm PASS
Purity	RP-HPLC, C18, 214 nm, area %	**99.25 ± 0.20 % (k = 2)**	>= 99.0 % PASS
Related substances	RP-HPLC, 214 nm; LOD 0.01 %, LOQ 0.03 %, reporting threshold 0.05 %	**Largest single impurity 0.21 % at RRT 1.03 (± 0.02 %); total impurities 0.75 %, i.e. 0.038 mg per vial**	Single <= 0.5 %, total <= 1.0 % PASS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Impurity profile	RP-HPLC with LC-HRMS assignment	**RRT 0.93, 0.12 %, -18 Da (Asp9 or Asp15 succinimide); RRT 0.97, 0.17 %, same mass (isoAsp9 or isoAsp15); RRT 1.03, 0.21 %, +0.98 Da (deamidation of Gln19 or Gln24); RRT 1.06, 0.09 %, -28.03 Da (C18 diacid analogue, acyl chain short by C2H4); RRT 1.12, 0.16 %, +16 Da (Trp25 or Tyr oxidation)**	Peaks above 0.05 % reported (ICH Q3B)
Net peptide content	Amino acid analysis after acid hydrolysis (AAA), eight stable residues	**94.80 ± 1.3 % w/w (k = 2)**	>= 90 % PASS
Fill weight	Gravimetric, two vials	**5.19 ± 0.05 mg (second vial 5.15 mg, difference 0.8 %)**	Labelled 5 mg REPORT ONLY
Peptide per vial	Calculated from fill weight and net peptide content	**4.92 mg per vial labelled 5 mg, i.e. 98.4 % of label**	95 to 105 % of label PASS
Counter-ion content	Ion chromatography (anion), suppressed conductivity	**Acetate 2.40 % w/w (± 0.15 %), i.e. 0.12 mg per vial, 1.9 mol per mol at two basic sites (Tyr1 N-terminus and Lys16; Lys20 carries the acyl chain); trifluoroacetate < 20 ppm (LOQ 20 ppm); chloride and phosphate < 20 ppm**	Acetate <= 5.0 %; trifluoroacetate <= 1000 ppm PASS
Water content	Coulometric Karl Fischer, USP <921>	**2.60 ± 0.15 % w/w (k = 2), i.e. 0.13 mg per vial**	<= 5.0 % PASS
Mass balance	Peptide + counter-ion + water	**94.80 + 2.40 + 2.60 = 99.80 % (± 1.3 %)**	Close to 100 % PASS
pH	Potentiometric, 10 mg/ml in water	**6.8 (acidic peptide, pI 4.4, unbuffered)**	6.0 to 7.5 PASS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Solubility	Visual, 10 mg/ml and 1 mg/ml	**>= 10 mg/ml in water and in bacteriostatic water; clear, colourless, free of particles within 60 s (lipidated peptide wets slowly); no opalescence after 24 h at 2 to 8 °C**	Clear solution PASS
Bacterial endotoxins	Kinetic chromogenic LAL, USP <85>	**< 0.05 EU/mg (< 0.25 EU per vial; LOQ 0.005 EU/mg)**	<= 1.0 EU/mg PASS
Sterility	Membrane filtration, USP <71>; fluid thioglycollate 30 to 35 °C and soya bean casein digest 20 to 25 °C	**No growth after 14 days, 2 vials**	No growth PASS
Microbial enumeration	Plate count, USP <61>; specified organisms, USP <62>	**TAMC < 10 CFU/g, TYMC < 10 CFU/g; Escherichia coli, Salmonella, Staphylococcus aureus and Pseudomonas aeruginosa absent in 1 g**	TAMC <= 1000 CFU/g, TYMC <= 100 CFU/g; specified organisms absent PASS
Residual solvents	Headspace GC, USP <467>	**Acetonitrile 38 ppm; N,N-dimethylformamide, methanol, dichloromethane, diethyl ether, diisopropyl ether, tert-butyl methyl ether and piperidine each < 10 ppm (LOQ 10 ppm)**	ICH Q3C: acetonitrile <= 410, DMF <= 880, methanol <= 3000, dichloromethane <= 600, ethers <= 5000 ppm PASS
Elemental impurities	ICP-MS after microwave digestion (HNO3/H2O2), USP <233>	**Cd, Pb, As, Hg < 0.05 µg/g; Co, V, Ni < 0.10 µg/g, all below LOQ**	ICH Q3D(R2) Class 1 and 2A, parenteral PDE per 5 mg daily: Cd 400, Pb 1000, As 3000, Hg 600, Co 1000, V 2000, Ni 4000 µg/g PASS
Chiral purity (D-amino acids)	Acid hydrolysis (6 M DCl in D2O, 110 °C, 24 h; Trp after alkaline hydrolysis), Marfey's derivatisation (FDAA), LC-MS	**D-Tyr 0.05 %, D-Ser 0.05 %, D-Glu (Glu + Gln) 0.04 %, D-Phe 0.04 %, D-Thr 0.03 %, D-Asp 0.03 %, D-Ile 0.02 %, D-Leu 0.02 %, others < 0.02 %; Aib and Gly achiral; sum of D-forms 0.28 %**	Each D-amino acid <= 0.2 %, sum of D-forms <= 0.5 % PASS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Compound screening	LC-HRMS full scan m/z 100 to 2000, both polarities, against reference standards	**Fentanyl and analogues, semaglutide, liraglutide, retatrutide, GLP-1 (7-37), GIP (1-42), cagrilintide, protected intermediates (tBu, Boc, Trt, Pbf, Fmoc, protected acyl chain) and free amino acids: none above 0.05 % of area**	Nothing above 0.05 % PASS

Labelled 5 mg / **4.92 mg peptide** / 98.4 % of label

Labelled 5 mg; the container held 5.19 mg of powder when weighed, of which 94.8 % w/w is peptide. The remainder is counter-ion, water and residue, which a purity figure at one wavelength never sees.



SIGNATURE

NAME O. Noga

ROLE Head Laboratory Technician

DATE 2026-08-01



The sample, and what is known about it

Sample as described	Tirzepatide, lyophilised powder, vial labelled 5 mg
Batch as marked	MQ-TIRZEPATIDE-202609
Matrix	Research peptide
Received	2026-07-25
Analysis	2026-07-26 to 2026-07-31
Condition on receipt	Seal intact, closure unmarked, white to off-white lyophilised cake, no visible particles
Storage before analysis	Minus 20 degrees Celsius, desiccated, dark, until first portion taken

WHAT THE DESCRIPTION IS, AND IS NOT

Everything in the table above is a description of what arrived, taken from the container and from the submission. None of it is a finding. ANALYTON does not verify that a marking on a container is true, and a batch number on a vial is a claim by whoever printed the label.

The sample travels under its submission reference rather than under the client's name, so the laboratory performing a determination does not learn who submitted it. That is a confidentiality measure and it is also a bias control: an analyst who does not know whose material this is cannot be influenced by it.

WHAT A CERTIFICATE COVERS

This certificate relates to the sample as received and to nothing else. It does not establish that other material bearing the same description, the same batch marking or the same label is the material that was tested. A certificate travels more easily than the material it describes, and the commonest misuse of one in this market is a genuine certificate attached to a different batch.

Where a determination was not performed, it is listed on this report with the reason, whether it was never ordered or was ordered and could not be run. The absence of a result has to be legible as an absence, rather than mistaken for a clean one.

Identity by liquid chromatography mass spectrometry

PRINCIPLE

The sample is separated by reversed-phase chromatography and the eluent is ionised by electrospray at atmospheric pressure. Peptides ionise as a series of multiply protonated species rather than as a single ion, so the measurement is not one mass but a charge envelope, and each member of that envelope has to agree with the same neutral mass before the identification stands.

WHAT THE NUMBER MEANS

Whether the compound present is the compound named. The observed monoisotopic mass is compared against the mass computed from the stated sequence or formula, and the deviation is reported in parts per million rather than in daltons, because a fixed tolerance in daltons is loose at low mass and impossibly tight at high mass.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Mass accuracy, sample ions	within 5 ppm of theoretical	0.8 ppm
Charge states agreeing on one neutral mass	at least two	4 (3+ to 6+)
Isotope spacing	consistent with the assigned charge	consistent with the assigned charge
Signal to noise of the assigned ion	at least 10 to 1	640 to 1

HOW IT IS REPORTED

Reported as the observed and theoretical masses with the deviation in parts per million. An identification is never reported on retention time alone: a retention time is a property of a method, not of a molecule, and a co-eluting compound of different mass would carry the same one.

IDENTITY · PASS

Deconvoluted monoisotopic mass 4810.529 Da, deviation 0.8 ppm (0.004 Da); observed m/z 1604.516 (3+), 1203.638 (4+), 963.112 (5+); charge envelope 3+ to 6+

Against Theoretical monoisotopic 4810.525 Da from C225H348N48O68 (average 4813.5 Da); expected m/z 1604.516 (3+), 1203.638 (4+), 963.112 (5+); deviation <= 10 ppm

What this does not establish. Identity establishes that the compound present is the one named. It does not establish how much of it is there. A sample can be correctly identified and still be mostly something else by mass.

Chromatographic purity by reversed-phase HPLC

PRINCIPLE

The sample is separated on a C18 stationary phase under a water and acetonitrile gradient, both modified with trifluoroacetic acid, and the eluent is monitored by ultraviolet absorbance at 214 nanometres, where the peptide bond itself absorbs. Detection at 214 rather than 280 is deliberate: 280 sees only aromatic residues, so a peptide without tryptophan, tyrosine or phenylalanine is close to invisible at that wavelength.

WHAT THE NUMBER MEANS

The proportion of the detected peak area attributable to the main component, expressed as a percentage of total integrated area. It is an area normalisation, not a mass balance, and it is bounded by what the detector can see.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Resolution between the main peak and its nearest neighbour	not less than 1.5	2.0
Tailing factor of the main peak	not more than 2.0	1.1
Theoretical plates	not fewer than 2000	79,800 (apparent, gradient)
Relative standard deviation of replicate injections	not more than 2.0 per cent	0.5 % (6 injections)
Baseline drift across the gradient	within the integration threshold	1.5 mAU over the gradient

HOW IT IS REPORTED

Reported as a percentage of total integrated area, with the integration threshold stated. Peaks below the threshold are not integrated and are not counted against purity, which is why the threshold is on the report rather than left to be assumed.

PURITY · PASS

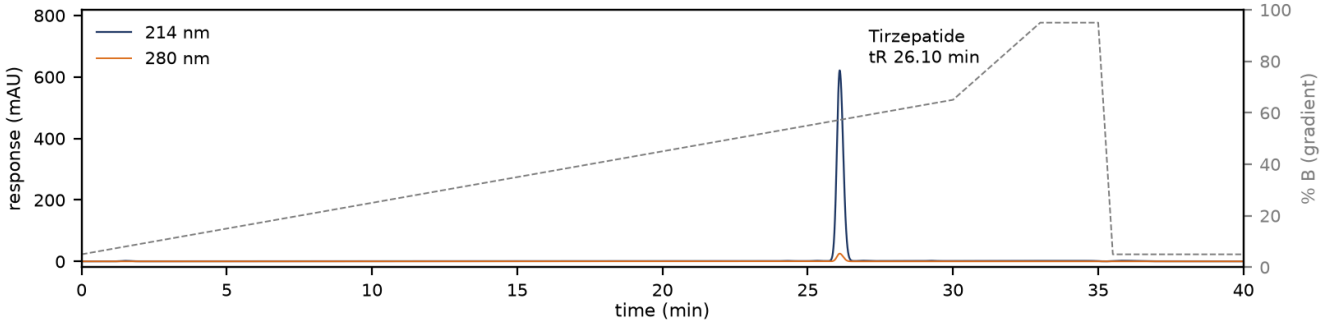
99.25 ± 0.20 % (k = 2)

Against >= 99.0 %

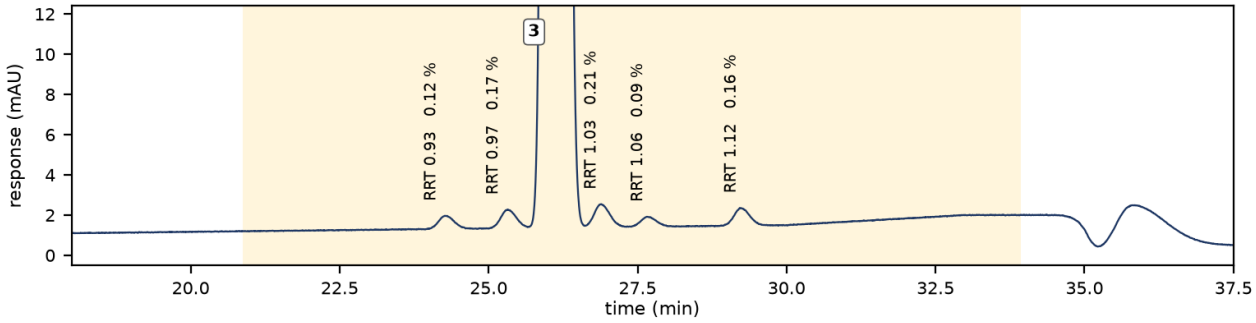
Tirzepatide 5 mg · RP-HPLC purity, 214 nm

Column C18, 4.6 × 150 mm, 3 µm, 40 °C; flow 1.0 ml/min; A: 0.05 % TFA in water; B: 0.05 % TFA in acetonitrile; gradient 5 to 65 % B in 30 min, 65 to 95 % B by 33 min, 95 % B to 35 min, return to 5 % B, equilibration to 40 min; injection 10 µl, 1.0 mg/ml in water (10 µg on column).

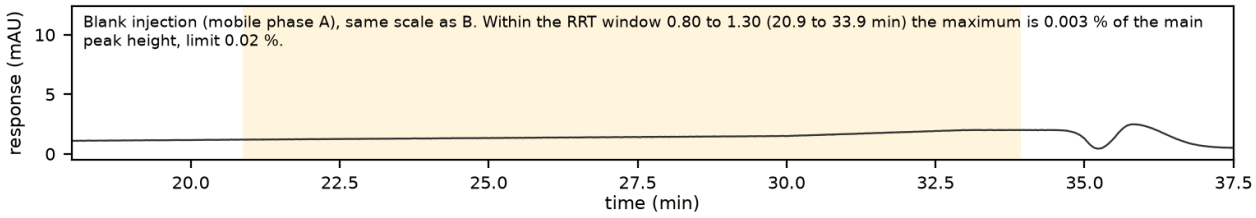
A. Full trace 0 to 40 min, full scale



B. Expanded view 0 to 2 % of the main peak height (12.4 mAU); main peak Tirzepatide tR 26.10 min off scale; impurities above the 0.05 % reporting threshold, numbered as in the table; yellow band = RRT window 0.80 to 1.30



C. Blank injection before the sequence



D. Peak table and system suitability

Peak	tR (min)	RRT	Area (%)	Height (mAU)	Mass shift	Assignment
1	24.27	0.93	0.12	0.65	−18 Da	Asp9/Asp15 succinimide (dehydration)
2	25.32	0.97	0.17	0.92	same mass	isoAsp9 or isoAsp15 (Asp isomerisation)
3	26.10	1.00	99.25	620		Tirzepatide (main peak)
4	26.88	1.03	0.21	1.14	+0.98 Da	Gln19 or Gln24 deamidation
5	27.67	1.06	0.09	0.49	−28.03 Da	C18 diacid analogue (acyl chain short by C2H4)
6	29.23	1.12	0.16	0.87	+16 Da	Trp25 or Tyr oxidation

Purity (main peak area of all peaks): 99.25 % · total impurities 0.75 % · largest impurity 0.21 % at RRT 1.03

System suitability (USP <621>): resolution main peak / RRT 0.97 = 2.0 (≥ 1.5); tailing factor T = 1.1 (0.8 to 1.5); theoretical plates N = 79,800 (≥ 5,000, apparent in gradient elution, peak width at half height 0.22 min); S/N at 0.03 % = 14 (≥ 10); area RSD of 6 standard injections = 0.5 % (≤ 2.0 %).

Integration: reporting threshold 0.05 %, LOD 0.01 %, LOQ 0.03 %; noise 0.030 mAU peak to peak within ± 1 min of the main peak; baseline drift 1.5 mAU over the gradient; system peaks at t0 1.5 min and at the gradient return at 35.8 min are also present in the blank and are not integrated.

Wavelength 214 nm as primary (peptide bond, also detects fragments without aromatic residues), 280 nm only as a control trace with a weak Tyr/Phe/Trp signal. Main peak 280/214 response ratio 0.041.

RP-HPLC RECORD OF THE SAMPLE, SEQUENCE OF 2026-07-27: 214 NM WITH 280 NM CONTROL TRACE, C18 4.6 × 150 MM 3 MM, 40 °C, 0.05 % TFA IN WATER AND ACETONITRILE, 5 TO 65 % B IN 30 MIN; FULL TRACE, EXPANDED VIEW, BLANK INJECTION AND PEAK

What this does not establish. Chromatographic purity is the share of detected peak area at one wavelength. It cannot see what does not absorb there, so counter-ion, water and inorganic residue are invisible to it. It is not a statement of how much peptide is in the container.

Counter-ion content

PRINCIPLE

The sample is dissolved and its anions are separated on a hydroxide-selective column with suppressed conductivity detection, which removes the eluent contribution and leaves the trifluoroacetate peak quantifiable against calibrated standards. Where the matrix interferes, the determination is run by LC-MS in negative ionisation, monitoring the trifluoroacetate ion at mass 113.

WHAT THE NUMBER MEANS

How much of the delivered mass is counter-ion rather than peptide. Trifluoroacetate binds to every protonated basic site during reversed-phase purification and survives lyophilisation, typically accounting for 10 to 25 per cent of the mass in the vial at 114 daltons per counter-ion. It does not absorb at 214 nm and is not retained on a C18 column, so a purity chromatogram never sees it.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Calibration linearity across the working range	coefficient of determination at least 0.999	0.9998
Resolution from the nearest eluting anion	not less than 1.5	3.4, acetate from formate
Recovery of a spiked trifluoroacetate standard	95 to 105 per cent	99.3 per cent
Replicate agreement	within 2 per cent relative	0.6 per cent relative

HOW IT IS REPORTED

Reported as per cent weight for weight and as milligrams per labelled unit, with the counter-ion named. It is one of the two contributions, with water, that separate a purity percentage from a mass of peptide, and it is read together with net peptide content rather than on its own.

COUNTER-ION CONTENT · PASS

Acetate 2.40 % w/w (± 0.15 %), i.e. 0.12 mg per vial, 1.9 mol per mol at two basic sites (Tyr1 N-terminus and Lys16; Lys20 carries the acyl chain); trifluoroacetate < 20 ppm (LOQ 20 ppm); chloride and phosphate < 20 ppm

Against Acetate <= 5.0 %; trifluoroacetate <= 1000 ppm

What this does not establish. Counter-ion content states how much of the vial mass is salt rather than peptide. It does not establish that the remaining mass is the named peptide, and it does not say whether the counter-ion has affected the stability of the material. Free trifluoroacetic acid present as a volatile residue is a residual solvents question and is not covered here.

Water content

PRINCIPLE

Water in the sample reacts stoichiometrically with iodine generated coulometrically in the titration cell, and the charge passed gives the mass of water directly. The coulometric form is used rather than the volumetric because the quantities here are small.

WHAT THE NUMBER MEANS

The mass of water in the powder as received, as a percentage. Lyophilised peptides are hygroscopic and take up water from the air within seconds of a vial being opened, so this figure describes the container at receipt and not after it has been handled.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Cell blank drift	stable before the determination begins	stable at 0.8 micrograms per minute
Recovery of a water standard	97.5 to 102.5 per cent	99.6 per cent
Replicate agreement	within 0.2 per cent absolute	0.05 per cent absolute

HOW IT IS REPORTED

Reported as per cent weight for weight, with the number of replicate determinations. Water content is one of the two contributions, with counter-ion, that separate a purity percentage from a mass of peptide.

> WATER CONTENT · PASS
>
> **2.60 ± 0.15 % w/w (k = 2), i.e. 0.13 mg per vial**
>
> Against <= 5.0 %

What this does not establish. Water content describes the powder as received. It moves with handling and storage, and a figure taken on the day of receipt does not describe the container after it has been opened.

Bacterial endotoxins

PRINCIPLE

Lysate from the amoebocytes of the horseshoe crab is activated by bacterial endotoxin through a protease cascade, which cleaves a chromogenic substrate. The rate at which colour develops is proportional to endotoxin concentration, and the onset time is read against a standard curve prepared from control standard endotoxin.

WHAT THE NUMBER MEANS

Endotoxin concentration in endotoxin units per milligram. Endotoxin is a fragment of the outer membrane of gram-negative bacteria. It survives autoclaving, it is not removed by sterile filtration, and it is pyrogenic in the absence of any living organism.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Standard curve correlation coefficient	not less than 0.980 in absolute value	0.9992
Positive product control recovery	50 to 200 per cent	96 %
Negative control	below the lowest standard	no onset
Dilution used	at or below the maximum valid dilution	1 in 20, below MVD

HOW IT IS REPORTED

Reported in endotoxin units per milligram at the dilution used, with the maximum valid dilution stated. A result obtained beyond the maximum valid dilution is not reportable, because the dilution itself would have carried the endotoxin below the sensitivity of the assay.

BACTERIAL ENDOTOXINS · PASS

< 0.05 EU/mg (< 0.25 EU per vial; LOQ 0.005 EU/mg)

Against <= 1.0 EU/mg

What this does not establish. Bacterial endotoxin is not sterility. A sample can be free of endotoxin and carry viable organisms, and it can be sterile and still pyrogenic. The two are separate determinations because they are separate properties.

Sterility

PRINCIPLE

The contents are transferred under aseptic conditions to fluid thioglycollate medium and to soya bean casein digest medium, and incubated for fourteen days at the temperatures each medium requires. Growth in either medium is a failure.

WHAT THE NUMBER MEANS

Whether the units tested were free of viable organisms recoverable under those conditions. The determination applies to the units opened and to nothing else. A batch is not made sterile by a sterility test, and the test cannot be extrapolated to a container that was not sampled.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Growth promotion of each medium	confirmed with the compendial challenge organisms	all media passed
Method suitability against the product	confirmed, no inhibition	growth within 3 days with product present
Negative control	no growth for the full incubation	no growth
Incubation	not fewer than 14 days	14 days

HOW IT IS REPORTED

Reported as no growth or growth observed, with the incubation period completed. Sterility is not pyrogenicity: a preparation can be sterile and still cause fever, which is what the endotoxin determination is for.

> STERILITY · PASS
>
> **No growth after 14 days, 2 vials**
>
> Against No growth

What this does not establish. Sterility applies to the units tested, not to the batch they came from. It cannot be extrapolated to a container that was not sampled, and it is not a statement about pyrogens.

Microbial enumeration

PRINCIPLE

A prepared portion is plated onto soya bean casein digest agar for total aerobic microbial count and onto Sabouraud dextrose agar for total combined yeasts and moulds, and colonies are counted after incubation.

WHAT THE NUMBER MEANS

How many organisms grow under the stated conditions on the stated media, as colony forming units per gram. Organisms that will not grow on those media at those temperatures are not counted, and are not reported as absent.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Growth promotion of each medium	confirmed	all media passed
Method suitability against the product	recovery within a factor of two	recovery 78 to 112 % of the inoculum
Negative control plates	no growth	no growth

HOW IT IS REPORTED

Reported as colony forming units per gram for each count, with the specified organisms tested for separately where those were ordered. Enumeration is not sterility and does not substitute for it.

MICROBIAL ENUMERATION · PASS

TAMC < 10 CFU/g, TYMC < 10 CFU/g; Escherichia coli, Salmonella, Staphylococcus aureus and Pseudomonas aeruginosa absent in 1 g

Against TAMC <= 1000 CFU/g, TYMC <= 100 CFU/g; specified organisms absent

What this does not establish. Enumeration counts what grows under the stated conditions on the stated media. It is not sterility, and an organism that does not grow under those conditions is not counted and is not reported as absent.

Residual solvents

PRINCIPLE

A weighed portion is equilibrated in a sealed vial and the vapour above the sample is sampled and separated by gas chromatography, with detection by mass spectrometry or flame ionisation. Sampling the headspace rather than the solution keeps involatile matrix out of the instrument.

WHAT THE NUMBER MEANS

The concentration of each solvent in the panel applied. ICH Q3C sorts solvents into three classes. Class 1 solvents such as benzene are to be avoided and are limited at parts per million. Class 2 are restricted and include acetonitrile, dichloromethane and dimethylformamide, all of which are routine in peptide synthesis. Class 3 carry a default limit of 5000 parts per million.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Resolution between the two closest eluting solvents	not less than 1.0	3.6, acetonitrile from dichloromethane
Signal to noise at the limit of quantitation	not less than 10 to 1	48 to 1 at the LOQ
Repeatability of the standard	not more than 15 per cent relative standard deviation	4.2 %
System blank	no interfering peak at any target retention time	no interfering peak

HOW IT IS REPORTED

Reported per solvent against its ICH Q3C limit. A solvent not in the panel was not looked for and its absence from this report is not evidence of its absence from the sample.

RESIDUAL SOLVENTS · PASS

Acetonitrile 38 ppm; N,N-dimethylformamide, methanol, dichloromethane, diethyl ether, diisopropyl ether, tert-butyl methyl ether and piperidine each < 10 ppm (LOQ 10 ppm)

Against ICH Q3C: acetonitrile <= 410, DMF <= 880, methanol <= 3000, dichloromethane <= 600, ethers <= 5000 ppm

What this does not establish. Residual solvents are reported for the solvents in the panel, at the limits stated. A solvent not in the panel was not looked for, and its absence from this report is not evidence of its absence from the sample.

Elemental impurities by ICP-MS

PRINCIPLE

The sample is digested in acid under microwave pressure and introduced into an argon plasma at approximately 7000 kelvin, which atomises and ionises the elements present. Ions are separated by mass to charge in a quadrupole and counted individually, which is what puts the technique at parts per billion.

WHAT THE NUMBER MEANS

The concentration of each element in the panel applied. An element outside the panel is not reported as absent, because it was not sought. Class 1 elements are cadmium, lead, arsenic and mercury, which have no acceptable role in a preparation and are limited on toxicity alone.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Internal standard recovery	80 to 120 per cent	97 %
Spike recovery in matrix	70 to 150 per cent	92 to 106 %
Calibration correlation coefficient	not less than 0.995	0.9996
Digestion blank	below the reporting limit for every element	below LOQ
Drift check across the sequence	within 20 per cent	3 %

HOW IT IS REPORTED

Reported per element against the permitted daily exposure of ICH Q3D for the intended route, with the limit of quantitation stated for each. A result below the limit of quantitation is reported as such and is not reported as zero.

> ELEMENTAL IMPURITIES · PASS
>
> **Cd, Pb, As, Hg < 0.05 µg/g; Co, V, Ni < 0.10 µg/g, all below LOQ**
>
> Against ICH Q3D(R2) Class 1 and 2A, parenteral PDE per 5 mg daily: Cd 400, Pb 1000, As 3000, Hg 600, Co 1000, V 2000, Ni 4000 µg/g

What this does not establish. Elemental impurities are reported for the elements in the panel applied. An element outside that panel is not reported as absent, because it was not sought.

Compound screening

PRINCIPLE

The sample is acquired in both positive and negative ionisation and the detected features are compared against reference standards held by the laboratory and against a spectral library, with confirmation by retention time and fragmentation where a standard is available.

WHAT THE NUMBER MEANS

Which compounds from the reference set are present. The result is bounded by the standards held on the day the screen was run, which is a real and stated limit rather than a general statement about what the sample contains.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Reference standards injected in the same sequence	confirmed for every reported identification	42 injected in the same sequence
Mass accuracy	within 5 ppm	within 3 ppm
Both polarities acquired	confirmed	acquired
Solvent blank between injections	no carryover above the reporting threshold	no carry-over above 0.01 %

HOW IT IS REPORTED

Reported as identified, tentatively identified, or not detected, per compound. A tentative identification is one made on accurate mass and fragmentation without a reference standard in the same sequence, and it is labelled as tentative for exactly that reason.

COMPOUND SCREENING · PASS

Fentanyl and analogues, semaglutide, liraglutide, retatrutide, GLP-1 (7-37), GIP (1-42), cagrilintide, protected intermediates (tBu, Boc, Trt, Pbf, Fmoc, protected acyl chain) and free amino acids: none above 0.05 % of area

Against Nothing above 0.05 %

What this does not establish. A screen is bounded by the reference standards held on the day it was run. A compound for which no standard was available cannot be identified by it, and its absence from the result is not evidence of its absence from the sample.

Controls carried in the same sequence

Blank	Solvent blank (mobile phase A) injected before the sequence; no peak above 0.02 % of the main peak within RRT 0.80 to 1.30 (maximum 0.003 %)
Reference standard	In-house reference standard RS-TZP-01 (purity assigned against a primary standard, stored at -20 °C) injected at the start and end of the sequence; area difference 0.3 %, retention time within 0.1 min; control sample from the previous batch within 0.2 % of its value

A result acquired without a blank cannot separate a peak that came from the sample from a peak that came from the system: solvent, column bleed, a carryover from the previous injection and a contaminated vial all produce peaks, and all of them are invisible until something is injected that contains nothing.

A result acquired without a reference standard in the same sequence is a retention time rather than an identification. Retention is a property of a method on a day, and it moves with column age, mobile phase batch and temperature. A standard run alongside the sample is what turns a number on an axis into a name.

WHY THIS IS ON THE REPORT AT ALL

It is the part of an analysis that certificates normally omit, and the part an analyst asks about first. A reader who knows to ask for it should not have to, and a reader who does not know to ask is better served by seeing it than by not knowing it was missing.

What these results do not establish

Each determination on this report answers one question. The limits below are the questions it does not answer, and every one of them is a mistake made routinely and in good faith by someone reading a certificate.

Identity
Identity establishes that the compound present is the one named. It does not establish how much of it is there. A sample can be correctly identified and still be mostly something else by mass.

Purity
Chromatographic purity is the share of detected peak area at one wavelength. It cannot see what does not absorb there, so counter-ion, water and inorganic residue are invisible to it. It is not a statement of how much peptide is in the container.

Counter-ion content
Counter-ion content states how much of the vial mass is salt rather than peptide. It does not establish that the remaining mass is the named peptide, and it does not say whether the counter-ion has affected the stability of the material. Free trifluoroacetic acid present as a volatile residue is a residual solvents question and is not covered here.

Water content
Water content describes the powder as received. It moves with handling and storage, and a figure taken on the day of receipt does not describe the container after it has been opened.

Bacterial endotoxins
Bacterial endotoxin is not sterility. A sample can be free of endotoxin and carry viable organisms, and it can be sterile and still pyrogenic. The two are separate determinations because they are separate properties.

Sterility
Sterility applies to the units tested, not to the batch they came from. It cannot be extrapolated to a container that was not sampled, and it is not a statement about pyrogens.

Microbial enumeration
Enumeration counts what grows under the stated conditions on the stated media. It is not sterility, and an organism that does not grow under those conditions is not counted and is not reported as absent.

Residual solvents
Residual solvents are reported for the solvents in the panel, at the limits stated. A solvent not in the panel was not looked for, and its absence from this report is not evidence of its absence from the sample.

Elemental impurities
Elemental impurities are reported for the elements in the panel applied. An element outside that panel is not reported as absent, because it was not sought.

Compound screening
A screen is bounded by the reference standards held on the day it was run. A compound for which no standard was available cannot be identified by it, and its absence from the result is not evidence of its absence from the sample.

NOT PERFORMED

Biological activity	receptor binding was not requested
Aggregates by SEC-HPLC	not requested
Stability after reconstitution, osmolality after reconstitution and sub-visible particles	the container was not presented for reconstitution studies
Microbiological quality after opening	outside the scope of a certificate on a sealed container

MS/MS localisation of the acyl chain	the position at Lys20 follows from the mass and the retention match with the standard, not from fragmentation

Verify this certificate against the register

SCAN TO VERIFY

Scan the code, or open `https://analyton.com/verify/` and enter the report number with this key:

D4N4EZDVQM

The register returns every result on this report, the date of issue and the current status. It never discloses the client, so a buyer can check a certificate without needing anything from the seller and without the seller learning who checked.

Where a copy in circulation differs from the register, the register governs. It is the issuing laboratory's own copy, and a file can be edited by anyone holding a reader. The register also carries the SHA-256 of this file exactly as it was issued, so a copy can be checked byte for byte rather than trusted. A document cannot carry its own fingerprint, which is why that lives in the register and not on this page.