ANALYTON LABS

**AN-2026-00027**

Issued 2026-10-28

# Certificate of analysis

Issued by ANALYTON LABS, analytical testing laboratory, under ANALYTON GC 1.1.

BATCH ID AMENDED 2026-10-29
REPORT FIELD OMITTED 2026-10-29

| | |
|---|---|
| Client | Molequa |
| Sample | Semax, lyophilised powder, vial labelled 10 mg |
| Batch number | MQ-SEMAX-202609 |
| Client lot reference | MQ-SEMAX-202609, as declared by the client |
| Matrix | Research peptide |

| | |
|---|---|
| Supersedes | AN-2026-00009 |
| Sample received | 2026-09-08 |
| Date of issue | 2026-10-28 |
| Determinations performed | 20 |

## SUMMARY OF RESULTS

| DETERMINATION | METHOD | RESULT | SPECIFICATION |
|---|---|---|---|
| **Appearance** | Visual | **White to off-white powder** | White to off-white powder |
| **Purity** | RP-HPLC, C18, 214 nm (280 nm control trace), area % | **99.77 ± 0.20 % (k = 2)** | >= 98.0 % |
| **Related substances** | RP-HPLC, 214 nm; LOD 0.01 %, LOQ 0.03 %, reporting threshold 0.05 % | **Largest single impurity 0.23 % at RRT 0.88 (± 0.03 %); total impurities 0.23 %, i.e. 0.026 mg per vial** | Single <= 1.0 %, total <= 2.0 % |
| **Impurity profile** | RP-HPLC with LC-HRMS assignment | **RRT 0.88, 0.23 %, +16 Da (Met sulfoxide)** | Peaks above 0.05 % reported (ICH Q3B) |
| **Net peptide content** | Assay | **95.59 ± 1.2 % w/w (k = 2)** | — |
| **Fill weight** | Gravimetric | **12.03 ± 0.05 mg** | Labelled 10 mg |
| **Peptide per vial** | Calculated from fill weight and net peptide content | **11.50 mg per vial labelled 10 mg, i.e. 115.0 % of label** | 95 to 105 % of label |
| **Vial-to-vial consistency** | Gravimetric, two vials of the batch | **12.03 and 12.33 mg, difference 2.5 %; purity of both within 0.1 %** | <= 5 % |
| **Counter-ion content** | Ion chromatography, suppressed conductivity | **Acetate 1.32 % w/w (± 0.08 %), i.e. 0.16 mg per vial** | <= 15.0 % |
| **Trifluoroacetate** | Ion chromatography, LOQ 20 ppm | **Not detected** | <= 0.5 % |

| DETERMINATION | METHOD | RESULT | SPECIFICATION |
|---|---|---|---|
| **Water content** | Coulometric Karl Fischer, USP <921> | **2.86 ± 0.14 % w/w (k = 2), i.e. 0.34 mg per vial** | <= 8.0 % |
| **Mass balance** | Peptide + counter-ion + water | **95.59 + 1.32 + 2.86 = 99.77 % (± 1.3 %)** | Close to 100 % |
| **pH** | Potentiometric, 10 mg/ml in water | **5.2** | 4.4 to 6.0 |
| **Solubility** | Visual, 10 mg/ml and 1 mg/ml | **>= 10 mg/ml in water and in bacteriostatic water; clear, colourless, free of particles within 30 s** | Clear solution |
| **Bacterial endotoxins** | Kinetic chromogenic LAL, USP <85> | **< 0.05 EU/mg (< 0.60 EU per vial)** | <= 10 EU/mg |
| **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 |
| **Microbial enumeration** | Plate method, USP <61> and <62> | **TAMC < 10 CFU/g, TYMC < 10 CFU/g; E. coli, Salmonella, S. aureus and P. aeruginosa absent in 1 g** | TAMC <= 1000 CFU/g, TYMC <= 100 CFU/g, specified organisms absent |
| **Residual solvents** | Headspace GC, USP <467> | **Acetonitrile 45 ppm; N,N-dimethylformamide, methanol, dichloromethane, diethyl ether, diisopropyl ether and piperidine each < 10 ppm (LOQ 10 ppm)** | ICH Q3C: acetonitrile <= 410, DMF <= 880, methanol <= 3000, dichloromethane <= 600, ethers <= 5000 ppm |
| **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 |
| **Chiral purity (D-amino acids)** | Acid hydrolysis (6 M DCl in D2O, 110 °C, 24 h), Marfey's derivatisation (FDAA), LC-MS | **D-His 0.10 %, D-Phe 0.06 %, D-Glu 0.05 %, others < 0.05 %; Gly achiral; sum of D-forms 0.25 %** | Each D-amino acid <= 0.2 %, sum of D-forms <= 0.5 % |
| **Compound screening** | LC-HRMS full scan, m/z 100 to 2000, against library: fentanyl and analogues, Selank, protected intermediates (tBu, Boc, Trt, Pbf, Fmoc), free amino acids | **None detected above 0.05 % area** | No foreign compound above 0.05 % area |

Labelled 10 mg / **11.50 mg peptide** / 115.0 % of label

Labelled 10 mg; the container held 12.03 mg of powder when weighed, of which 95.59 % w/w is peptide.



SIGNATURE

NAME O. Noga

ROLE Head Laboratory Technician

DATE 2026-10-28



## The sample

| | |
|---|---|
| Sample | Semax, lyophilised powder, vial labelled 10 mg |
| Batch number | MQ-SEMAX-202609 |
| Client lot reference | MQ-SEMAX-202609, as declared by the client |
| Matrix | Research peptide |
| Received | 2026-09-08 |

## 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.

SYSTEM SUITABILITY APPLIED

| CRITERION | REQUIREMENT | ACHIEVED |
|---|---|---|
| Resolution between the main peak and its nearest neighbour | not less than 1.5 | 7.4 (main peak against RRT 0.88) |
| Tailing factor of the main peak | not more than 2.0 | 1.1 |
| Theoretical plates | not fewer than 2000 | 59 900 (apparent, gradient) |
| Relative standard deviation of replicate injections | not more than 2.0 per cent | 0.6 per cent, 6 injections |

PURITY

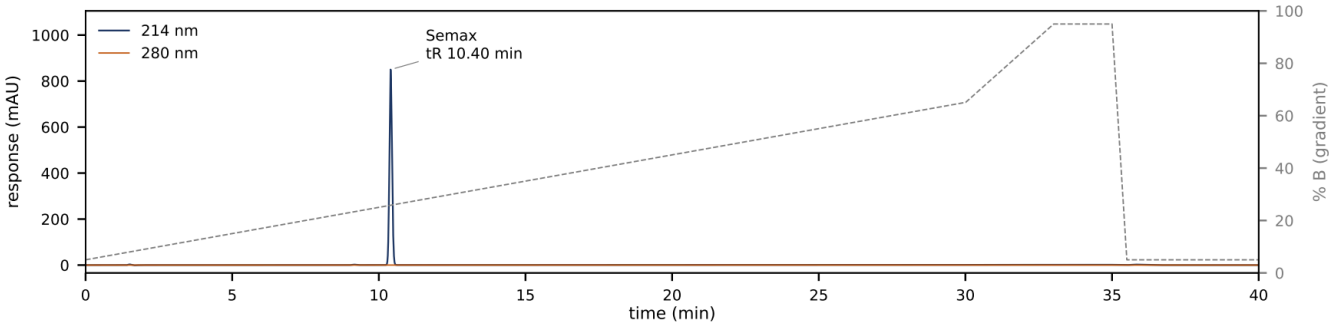
**99.77 ± 0.20 % (k = 2)**

Against >= 98.0 %

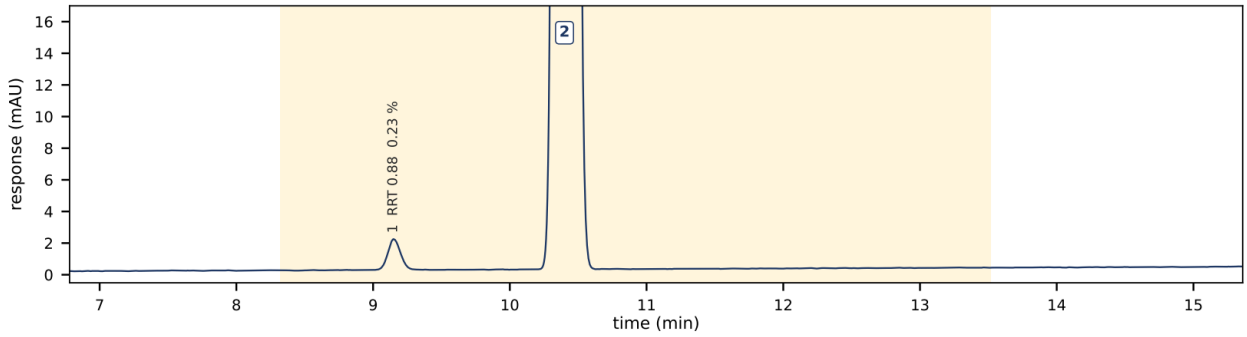
# Semax 10 mg · RP-HPLC purity, 214 nm

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).

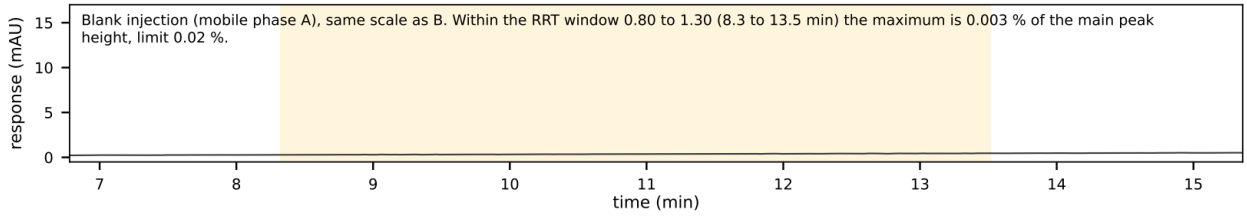
### A. Full trace 0 to 40 min, full scale




### B. Expanded view 0 to 2 % of the main peak height (17.0 mAU); main peak Semax tR 10.40 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 | 9.15 | 0.88 | 0.23 | 1.96 | +16 Da | Met oxidation to sulfoxide (1× Met) |
| 2 | 10.40 | 1.00 | 99.77 | 850 | | Semax (main peak) |

Purity (main peak area of all peaks): 99.77 % · total impurities 0.23 % · largest impurity 0.23 % at RRT 0.88

System suitability (USP <621>): resolution main peak / RRT 0.88 = 7.4 (≥ 1.5); tailing factor T = 1.1 (0.8 to 1.5); theoretical plates N = 59,900 (≥ 5,000, apparent in gradient elution, peak width at half height 0.10 min); S/N at 0.03 % = 13 (≥ 10); area RSD of 6 standard injections = 0.6 % (≤ 2.0 %).

Integration: reporting threshold 0.05 %, LOD 0.01 %, LOQ 0.03 %; noise 0.039 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 signal. Main peak 280/214 response ratio 0.000.

RP-HPLC CHROMATOGRAM AT 214 NM: FULL TRACE, EXPANDED VIEW, BLANK INJECTION AND PEAK TABLE

## 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.

SYSTEM SUITABILITY APPLIED

| | |
|---|---|
| Cell blank drift | stable before the determination begins |
| Recovery of a water standard | 97.5 to 102.5 per cent |
| Replicate agreement | within 0.2 per cent absolute |

WATER CONTENT

**2.86 ± 0.14 % w/w (k = 2), i.e. 0.34 mg per vial**

Against <= 8.0 %

## 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.

SYSTEM SUITABILITY APPLIED

| CRITERION | REQUIREMENT | ACHIEVED |
|---|---|---|
| Positive product control recovery | 50 to 200 per cent | 97 per cent |

BACTERIAL ENDOTOXINS

**< 0.05 EU/mg (< 0.60 EU per vial)**

Against <= 10 EU/mg

## 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.

SYSTEM SUITABILITY APPLIED

| CRITERION | REQUIREMENT | ACHIEVED |
|---|---|---|
| Incubation | not fewer than 14 days | 14 days |

STERILITY

**No growth after 14 days, 2 vials**

Against No growth

## 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.

SYSTEM SUITABILITY APPLIED

| | |
|---|---|
| Growth promotion of each medium | confirmed |
| Method suitability against the product | recovery within a factor of two |
| Negative control plates | no growth |

MICROBIAL ENUMERATION

**TAMC < 10 CFU/g, TYMC < 10 CFU/g; E. coli, Salmonella, S. aureus and P. aeruginosa absent in 1 g**

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

SYSTEM SUITABILITY APPLIED

| | |
|---|---|
| Resolution between the two closest eluting solvents | not less than 1.0 |
| Signal to noise at the limit of quantitation | not less than 10 to 1 |
| Repeatability of the standard | not more than 15 per cent relative standard deviation |
| System blank | no interfering peak at any target retention time |

RESIDUAL SOLVENTS

**Acetonitrile 45 ppm; N,N-dimethylformamide, methanol, dichloromethane, diethyl ether, diisopropyl ether and piperidine each < 10 ppm (LOQ 10 ppm)**

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

## 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.

SYSTEM SUITABILITY APPLIED

| | |
|---|---|
| Internal standard recovery | 80 to 120 per cent |
| Spike recovery in matrix | 70 to 150 per cent |
| Calibration correlation coefficient | not less than 0.995 |
| Digestion blank | below the reporting limit for every element |
| Drift check across the sequence | within 20 per cent |

ELEMENTAL IMPURITIES

**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

## 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.

SYSTEM SUITABILITY APPLIED

| | |
|---|---|
| Reference standards injected in the same sequence | confirmed for every reported identification |
| Mass accuracy | within 5 ppm |
| Both polarities acquired | confirmed |
| Solvent blank between injections | no carryover above the reporting threshold |

COMPOUND SCREENING

**None detected above 0.05 % area**

Against No foreign compound above 0.05 % area

## 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 |
| Reference standard | In-house reference standard RS-SEM-01 (purity assigned against a primary standard, stored at -20 °C) injected at the start and end of the sequence; area difference 0.4 %, retention time within 0.1 min |

## 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:

**W36PAK7RJK**

The register returns every result on this report, the date of issue and the current status.

END OF REPORT