# Certificate of Analysis

LIQUILABS
Analytical services

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Verify Results Online

## Sample Identification

| | |
|---|---|
| **Sample Name** | Cartalax 40 mg |
| **Batch Number** | GF-CARTA40-B241 |
| **Date Published** | 2026-11-10 15:07 |

# Results for LYO-1254

| Peptides | Result | Unit | Uncertainty | Acceptable Range |
|---|---|---|---|---|
| Cartalax Assay<br>Peptide Screening 0.1% TFA | 42.3 | *mg* | [± 0.2] | |
| Cartalax Purity<br>Peptide Screening 0.1% TFA | > 99.8 | *%* | | |
| Cartalax Identification by Spectrum (FTIR)<br>Peptide Screening 0.1% TFA | 997 | | [± 5] | |
| Cartalax Identification by RT<br>Peptide Screening 0.1% TFA | 0.990 | | [± 0.005] | |

| Microbiology | Result | Unit | Uncertainty | Acceptable Range |
|---|---|---|---|---|
| Total Aerobic Microbial Count<br>USP <61>/Eur. Ph. 2.6.12. Plate Count Method | 0 | *CFU/g* | [± ] | 0 - 1000 |
| Total Yeast and Mold Count<br>USP <61>/Eur. Ph. 2.6.12. Plate Count Method | 0 | *CFU/g* | [± ] | 0 - 100 |
| Bacterial Endotoxin Chromgenic<br>USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test | 0.004 | *EU/mg* | [± 0] | 0 - 0.5 |

| Elemental Impurities | Result | Unit | Uncertainty | Acceptable Range |
|---|---|---|---|---|
| Arsenic<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 1.5 |
| Cadmium<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 0.5 |
| Quicksilver<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 1.5 |
| Lead<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 1.5 |
| Nickel<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 25 |
| Vanadium<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 25 |
| Cobalt<br>Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20 | < 0.001 | *ppm* | | 0 - 25 |

| Mass Spectrometry | Result | Unit | Uncertainty | Acceptable Range |
|---|---|---|---|---|
| Molecular Ion Mass Identification (MS Deconvolution)<br>Mass Spectrometry Identity | 333 | *Da* | [± 1] | |

| Counter Ion Analysis | Result | Unit | Uncertainty | Acceptable Range |
|---|---|---|---|---|
| Acetate<br>Counter Ion Analysis | 11.82 | *ppm* | [± 0.24] | |
| Bromide<br>Counter Ion Analysis | 0.15 | *ppm* | [± 0] | |
| Chloride<br>Counter Ion Analysis | 0.29 | *ppm* | [± 0.01] | |
| Fluoride<br>Counter Ion Analysis | 0.00 | *ppm* | [± ] | |
| Nitrate<br>Counter Ion Analysis | 0.24 | *ppm* | [± 0] | |
| Phosphate<br>Counter Ion Analysis | 0.41 | *ppm* | [± 0.01] | |
| Sulphate<br>Counter Ion Analysis | 0.00 | *ppm* | [± ] | |
| TFA<br>Counter Ion Analysis | 24.11 | *ppm* | [± 0.48] | |

| Excipients | Result | Unit | Uncertainty | Acceptable Range |
|---|---|---|---|---|
| Mannitol | 120.82 | *mg* | [± 2.42] | |



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| LIQUILABS Analytical services | Method Specification | |
|---|---|---|
| Determination of identity, content and purity of Cartalax | | |
| *Document number* CTX_008_2026_P | *Superseded document* - | *Number of pages* 4 |

# 1. Content Assesment

## 1.1. Instrumentation

| Module | Name | Serial Number |
|---|---|---|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit | Shimadzu DGU-403 | NA |
| Pump | Shimadzu LC-40B XR | L22146350580 |
| Autosampler | Shimadzu SIL-40C XR | L22216351622 |
| Colum Thermostat | Shimadzu CTO-40S | L22236351602 |
| PDA Detector | Shimadzu SPD-M40 | L22276352808 |
| SQ MS Detector | Shimadzu LCMS-2050 | O12476200760 |

## 1.2. Chromatographic conditions

| Chromatographic conditions | |
|---|---|
| Eluent A | 10 mM Ammonium Formate in ACN (HPLC, Gradient Grade) |
| Eluent B | 10 mM Ammonium Formate in Water (HPLC, Gradient Grade) |
| Flow rate | 0.6 mL/min |
| Program | Gradient elution |
| Injection volume | 2 µL |
| Colum Temperature | 40°C |
| Column | Merck SeQuant ZIC-HILIC 150x2.1mm 3.5µm |
| Detection wavelength | 225nm |

| Gradient Program | | |
|---|---|---|
| Time [min] | A [%] | B [%] |
| 2 | 100 | 0 |
| 18 | 5 | 95 |
| 20 | 5 | 95 |
| 22 | 100 | 0 |
| 30 | end | |





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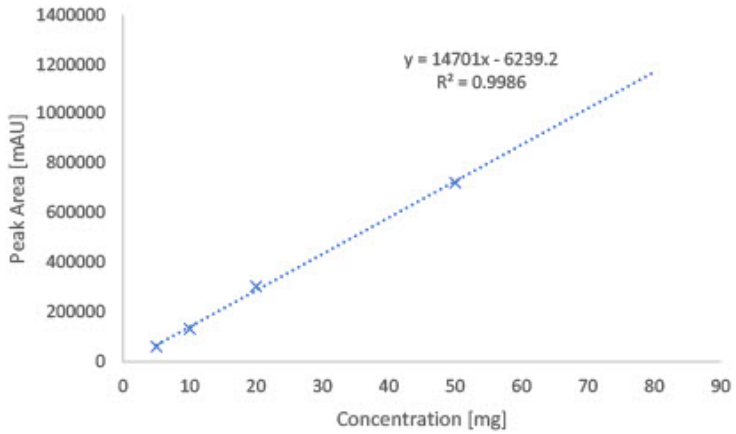
### 1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (LCMS Grade). 100 µL of sample was transferred to HPLC vial and diluted by 900 µL water (LCMS Grade) and submitted for analysis.

### 1.4. Calibration curve

| Calibration curve detail | |
|---|---|
| Quantitative method | External Standard |
| Calibration Type | Linear |
| Number of calibration points | 4 |
| Force through Zero | Disabled |
| Weighting Method | None |




2



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# 2. Purity assessment

## 2.1 Instrumentation

| Module | Name | Serial Number |
|---|---|---|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit | Shimadzu DGU-403 | NA |
| Pump | Shimadzu LC-40B XR | L22146350580 |
| Autosampler | Shimadzu SIL-40C XR | L22216351622 |
| Colum Thermostat | Shimadzu CTO-40S | L22236351602 |
| PDA Detector | Shimadzu SPD-M40 | L22276352808 |
| SQ MS Detector | Shimadzu LCMS-2050 | O12476200760 |

## 2.2 Chromatographic conditions

| Chromatographic conditions | |
|---|---|
| Eluent A | 10 mM Ammonium Formate in ACN (HPLC, Gradient Grade) |
| Eluent B | 10 mM Ammonium Formate in Water (HPLC, Gradient Grade) |
| Flow rate | 0.6 mL/min |
| Program | Gradient elution |
| Injection volume | 2 µL |
| Colum Temperature | 40°C |
| Column | Merck SeQuant ZIC-HILIC 150x2.1mm 3.5µm |
| Detection wavelength | 225nm |

| Gradient Program | | |
|---|---|---|
| Time [min] | A [%] | B [%] |
| 2 | 100 | 0 |
| 18 | 5 | 95 |
| 20 | 5 | 95 |
| 22 | 100 | 0 |
| 30 | end | |

## 2.3 Purity assesment

Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelenght of 225 nm.



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# 3. Identity Assessment

## 3.1 Instrumentation

| Module | Name | Serial Number |
|---|---|---|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit | Shimadzu DGU-403 | NA |
| Pump | Shimadzu LC-40B XR | L22146350580 |
| Autosampler | Shimadzu SIL-40C XR | L22216351622 |
| Colum Thermostat | Shimadzu CTO-40S | L22236351602 |
| PDA Detector | Shimadzu SPD-M40 | L22276352808 |
| SQ MS Detector | Shimadzu LCMS-2050 | O12476200760 |

## 3.2 Chromatographic conditions

| Chromatographic conditions | |
|---|---|
| Eluent A | 10 mM Ammonium Formate in ACN (HPLC, Gradient Grade) |
| Eluent B | 10 mM Ammonium Formate in Water (HPLC, Gradient Grade) |
| Flow rate | 0.6 mL/min |
| Program | Gradient elution |
| Injection volume | 2 µL |
| Colum Temperature | 40°C |
| Column | Merck SeQuant ZIC-HILIC 150x2.1mm 3.5µm |
| Detection w | MS 155-2000 Da |

| Gradient Program | | |
|---|---|---|
| Time [min] | A [%] | B [%] |
| 2 | 100 | 0 |
| 18 | 5 | 95 |
| 20 | 5 | 95 |
| 22 | 100 | 0 |
| 30 | end | |

## 3.3 Molecular Ion Mass evaluation

Molecular ion mass was determined by deconvolution of multiply charged ESI-MS spectra to calculate the average neutral (zero-charge) molecular mass by equation:

$$M(neutral) = (z_i((mz_i) - H)) - ME$$

Where:
$mz_i$ - Measured mass of charged particle
$z_i$ - charge
H - proton mass (1.0076 Da)
ME – mass error



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# Analysis Report

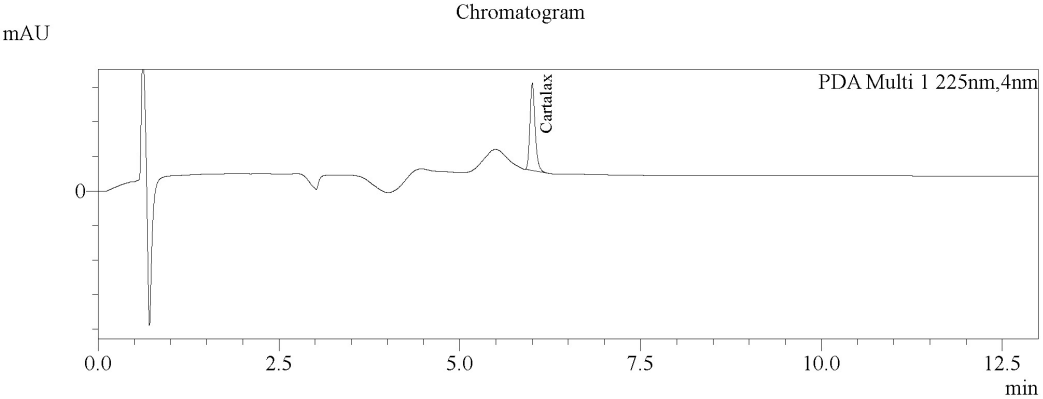
LIQUILABS Analytical services

## Analysis of quantity of active ingredient by UHPLC with MS detection

Sample Information

| | |
|---|---|
| Injection Volume | : 2 |
| Data File | : LYO-1254__001.lcd |
| Method File | : Peptides HILIC_A.lcm |
| Date Acquired | : 11/2/2026 2:01:59 PM |

Chromatogram




Peak Table

PDA Ch1 225nm

| Peak# | Name | Ret. Time | Area | Area% | Conc. | Unit |
|---|---|---|---|---|---|---|
| 1 | Cartalax | 6.003 | 615241 | 100.000 | 42.275 | mg |
| Total | | | 615241 | 100.000 | | |

Peak Table



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# Analysis Report

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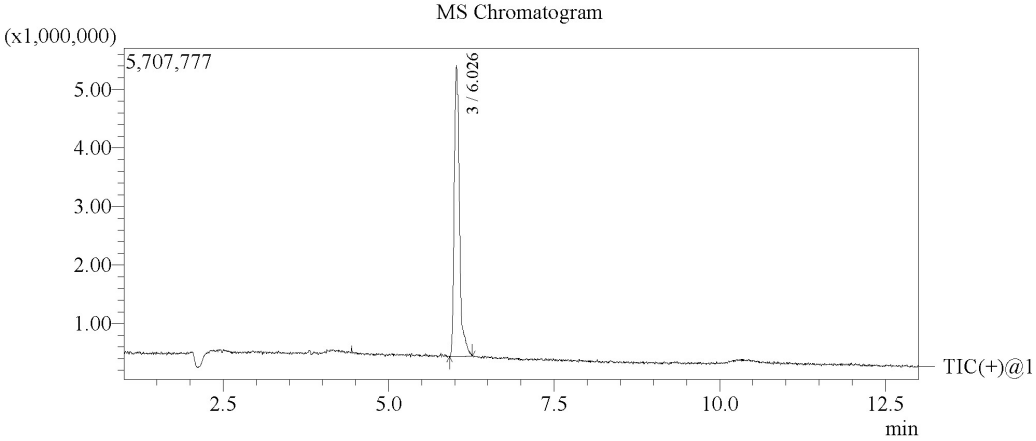
## Identification of active ingredient by UHPLC Mass Spectrometr

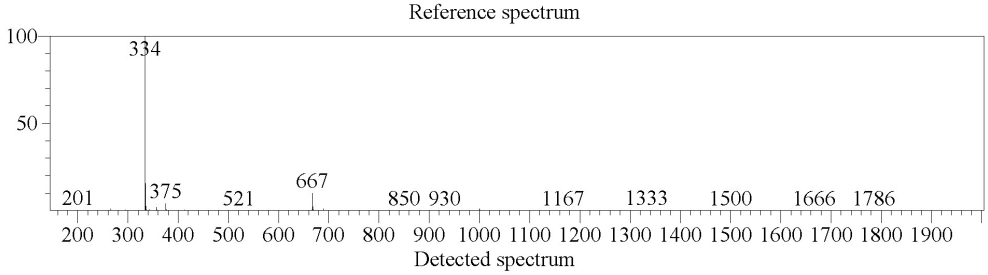
MS Chromatogram




Library Search

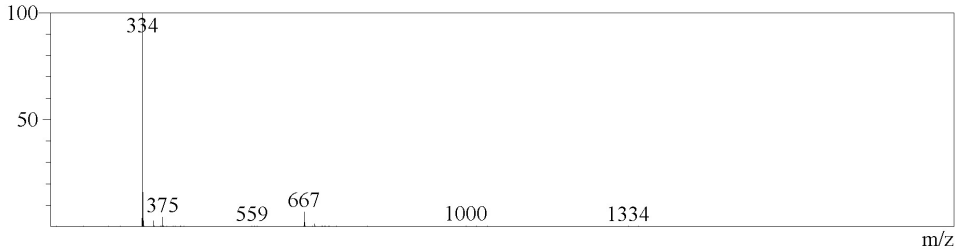
Base Peak: 334(865497)
Scan Range: 155.00 - 2000.00 Porality: Positive

Reference spectrum




Detected spectrum

Library: Peptide HILIC.lib
Formula: C12H19N3O8 CAS: 85806-95-7 Mol.Weight: 333(0!=)
Compound Name: Cartalax



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# Analysis Report

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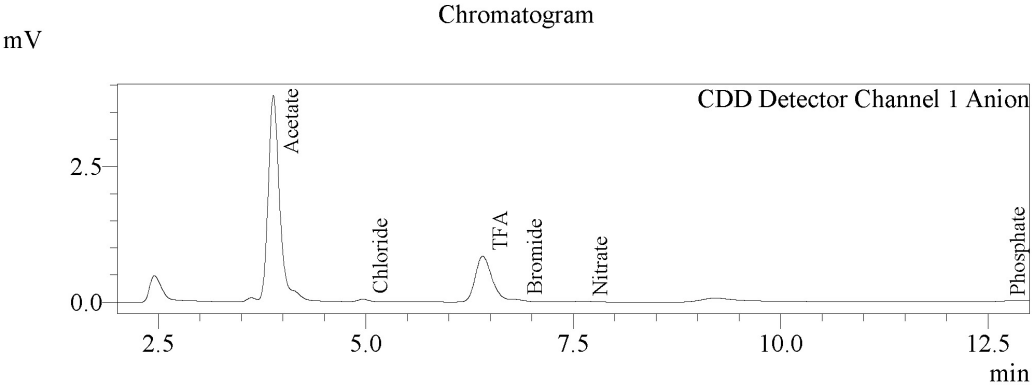
Analytical services

## Determination of anions and cations in peptide sample

Sample Information

| | |
|---|---|
| Injection Volume | : 10 |
| Data File | : LYO-1254__003.lcd |
| Method File | : Anions+Cations.lcm |
| Date Acquired | : 11/3/2026 5:14:46 PM |

Chromatogram




Peak Table

CDD Detector Channel 1 Anion

| Name | Ret. Time | Area | Conc. | Unit |
|---|---|---|---|---|
| Acetate | 3.883 | 35825 | 11.822 | ppm |
| Chloride | 4.963 | 411 | 0.295 | ppm |
| TFA | 6.407 | 12426 | 24.115 | ppm |
| Bromide | 6.827 | 70 | 0.147 | ppm |
| Nitrate | 7.610 | 230 | 0.241 | ppm |
| Phosphate | 12.853 | 644 | 0.408 | ppm |
| | | 49606 | | |



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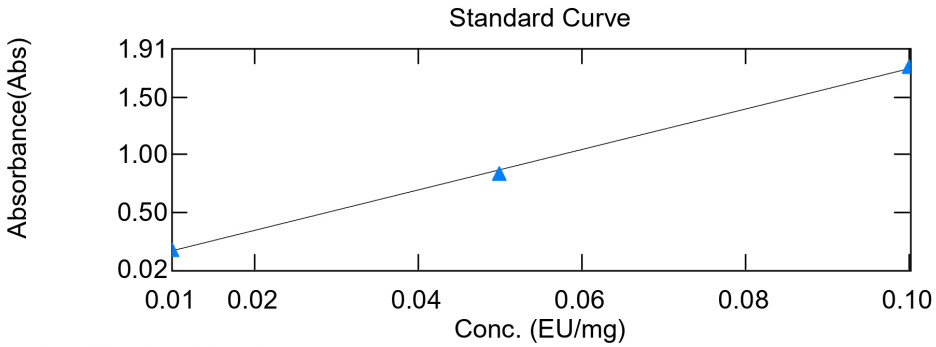
# Endotoxin Determination Report

File Information
Filename: C:\UVVis-Data\Data\File_261102_102508.vqud
Date/Time: 11/02/2026 11:13:25 AM

Instrument Information
Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12536253123)




y = 17.4393 x - 5.62824e-004
r2 = 0.99905

| | Sample Name | Conc | Raw_WL545.0 | Dilution Rate |
|---|---|---|---|---|
| 1 | LYO-1225 | 3.258 | 1.4198 | 40.00 |
| 2 | LYO-1226 | 0.098 | 0.0845 | 20.00 |
| 3 | LYO-1174 | 0.492 | 0.4285 | 20.00 |
| 4 | LYO-1175 | 0.162 | 0.1403 | 20.00 |
| 5 | LYO-1176 | 0.093 | 0.0806 | 20.00 |
| 6 | LYO-1177 | 0.108 | 0.0934 | 20.00 |
| 7 | LYO-1178 | 0.114 | 0.0987 | 20.00 |
| 8 | LYO-1179 | 0.116 | 0.1004 | 20.00 |
| 9 | LYO-1251 | 0.101 | 0.0876 | 20.00 |
| 10 | LYO-1252 | 0.441 | 0.3839 | 20.00 |
| 11 | LYO-1253 | 0.105 | 0.0907 | 20.00 |
| 12 | LYO-1254 | 0.147 | 0.1279 | 20.00 |
| 13 | LYO-1224 | 0.095 | 0.0823 | 20.00 |
| 14 | RAW-0013 | 0.127 | 0.1098 | 20.00 |
| 15 | RAW-0014 | 0.167 | 0.1452 | 20.00 |
| 16 | LIQ-0101 | 0.004 | 0.0759 | 1.00 |
| 17 | LIQ-0102 | 0.014 | 0.2467 | 1.00 |
| 18 | LIQ-0103 | 0.009 | 0.1590 | 1.00 |
| 19 | LIQ-0104 | 0.006 | 0.1026 | 1.00 |
| 20 | LIQ-0105 | 0.006 | 0.1044 | 1.00 |



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| LIQUILABS Analytical services | Method Specification | |
|---|---|---|
| Determination of bioburden of lyophilized samples | | |
| *Document number* MIC_001_2025 | *Superseded document* - | *Number of pages* 2 |

# 1. Instrumentation and chemicals

## 1.1. Instruments used

- Sterile Syringe 2mL Luer
- Sterile needles
- Ready made PCA Plate ROTI Aquatest
- Ready made Sab4 Plate ROTI Aquatest

## 1.2. Chemicals

Sterile physiological solution (0.9% NaCl)

# 2. Sample preparation and innoculation

## 2.1 Sample preparation

1. Fresh sterile needle and syringe was used for measuring exactly 2 mL of sterile physiological solution.
2. Needle was changed and by new needle rubber top of peptide containter was penetrated and 2 mL of sterile physiological solution was dispensed.
3. Content of container was completely dissolved and left for 5 minutes to settle potentially created bubbles.
4. This procedure is repeated for two vials.

## 2.2 Total Aerobic microbial count innoculation and cultivation

1. By sterile needle 1 mL of solution was filled into the sterile syringe.
2. Needle was placed above the flame for few seconds to sterilze.
3. Consequently 1 mL of solution was poured into the ready to use sterile petri dish filled with PCA agar and petri dish was closed.
4. Proces was repeated for two petri dishes.
5. With sterile needle, 1 mL of sterile physiological solution was filled into the sterile needle and was innoculated onto one sterile petri dish filled with PCA agar as negative control sample.
6. Samples and negative control sample were placed in incubator at temperature 37°C for 120h.



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### 2.3 Total Yeast and Mold count innoculation and cultivation

1. By sterile needle 1 mL of solution was filled into the sterile syringe.
2. Needle was placed above the flame for few seconds to sterilze.
3. Consequently 1 mL of solution was poured into the ready to use sterile petri dish filled with Sab4 agar and petri dish was closed.
4. Proces was repeated for two petri dishes.
5. With sterile needle, 1 mL of sterile physiological solution was filled into the sterile needle and was innoculated onto one sterile petri dish filled with Sab4 agar as negative control sample.
6. Samples and negative control sample were placed in incubator at temperature 25°C for 72h.

## 3. Evaluation of results

After incubation time, colonies are counted as cfu (colonies forming units) and result per 1g of sample is determined as:

$$CFU_{avg} = \frac{\sum CFU_n}{n}$$

$$CFU_{avg} = average\ CFU\ counted\ form\ n\ innoculations$$
$$CFU_n = CFU\ counted\ per\ innoculation$$
$$n = number\ of\ innoculations$$

$$CFU\ per\ gram = \frac{CFU_{avg}}{m_s} * DF$$

$$CFU_{avg} = Average\ CFU\ counted\ from\ n\ innoculations$$
$$m_s = mass\ of\ sample\ (mg)$$
$$DF = Dilution\ factor$$

If negative control sample is evaluated as positive, process have to be repeated due to possible contamination in the process of innoculation or incubation.



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**Responsibles**



**Mr. Ján Galbavý**
*CEO*

Analysis results relate only to the samples tested.
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