

Certificate of Analysis



Grail Formula B.V.

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Sample Identification

Sample Name	Tesamorelin 10 mg + Ipamorelin 3 mg
Batch Number	GF-TESAIPA10/3-B243
Date Published	2026-10-11 08:38

Results for LYO-1002

Peptides	Result	Unit	Uncertainty	Acceptable Range
Ipamorelin Assay Peptide Screening 0.1% TFA	3.50	mg	[± 0.02]	
Tesamorelin Assay Peptide Screening 0.1% TFA	10.17	mg	[± 0.05]	
Ipamorelin Purity Peptide Screening 0.1% TFA	> 99.8	%		
Tesamorelin Purity Peptide Screening 0.1% TFA	99.1	%	[± 0.5]	
Ipamorelin Identification by RT Peptide Screening 0.1% TFA	0.996		[± 0.005]	
Tesamorelin Identification by RT Peptide Screening 0.1% TFA	0.998		[± 0.005]	
Microbiology	Result	Unit	Uncertainty	Acceptable Range
Total Aerobic Microbial Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	0	CFU/g	[±]	0 - 1000
Total Yeast and Mold Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	0	CFU/g	[±]	0 - 100
Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	0.007	EU/mg	[± 0]	0 - 0.5
Elemental Impurities	Result	Unit	Uncertainty	Acceptable Range
Arsenic Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 1.5
Cadmium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 0.5
Quicksilver Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 1.5
Lead Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 1.5
Nickel Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 25
Vanadium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 25
Cobalt 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 (Ipamorelin) Mass Spectrometry Identity	711	Da	[± 1]	
Molecular Ion Mass Identification (Tesamorelin) Mass Spectrometry Identity	5135	Da	[± 1]	

	Method Specification	
Determination of identity, content and purity of Ipamorelin		
<i>Document number</i> IPA_008_2026	<i>Superseded document</i> -	<i>Number of pages</i> 4

1. Content Assessment

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	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

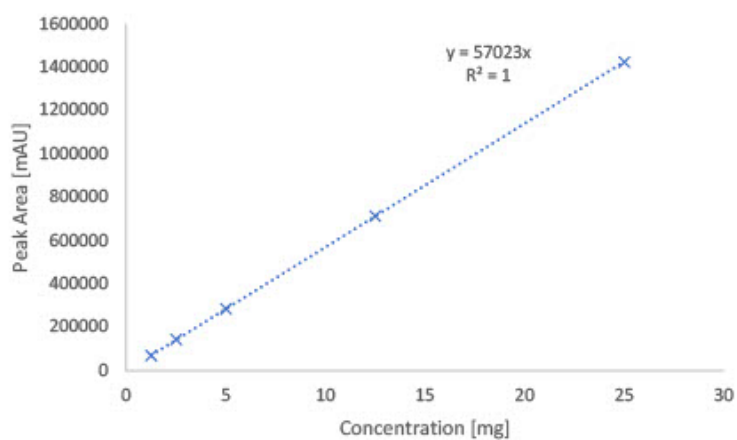
Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

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	5
Force through Zero	Enabled
Weighting Method	None



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	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	225nm

Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	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.

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
Column Thermostat	Shimadzu CTO-40S	L22236351602
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SQ MS Detector	Shimadzu LCMS-2050	O12476200760

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Chromatographic conditions	
Eluent A	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Column Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection	MS 220-2000 Da

Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	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:

$$M(\text{neutral}) = (z_i((mz_i) - H)) - ME$$

Where:

mz_i - Measured mass of charged particle

z_i - charge

H - proton mass (1.0076 Da)

ME - mass error

	Method Specification		
Determination of identity, content and purity of Tesamorelin			
<i>Document number</i> TESA_008_2026	<i>Superseded document</i> -	<i>Number of pages</i> 4	

1. Content Assessment

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
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Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

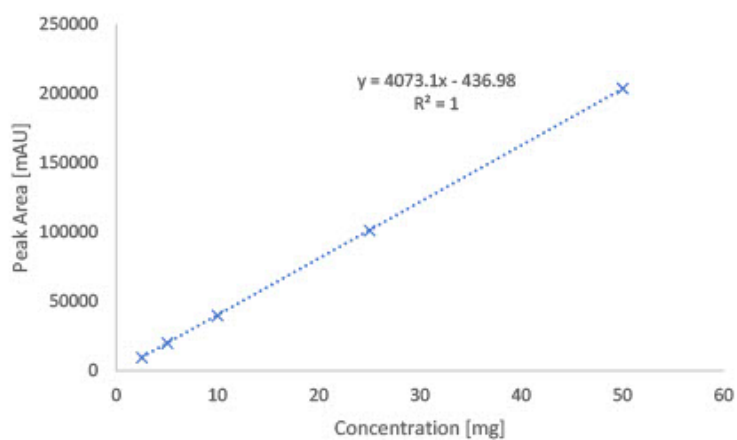
Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

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	5
Force through Zero	Enabled
Weighting Method	None



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
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Gradient Program		
Time [min]	A [%]	B [%]
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14	5	95
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15.01	98	2
19	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.

3. Identity Assessment

3.1 Instrumentation

Module	Name	Serial Number
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Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Column Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
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15	5	95
15.01	98	2
19	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:

$$M(\text{neutral}) = (z_i((mz_i) - H)) - ME$$

Where:

mz_i - Measured mass of charged particle

z_i - charge

H - proton mass (1.0076 Da)

ME - mass error

Analysis Report

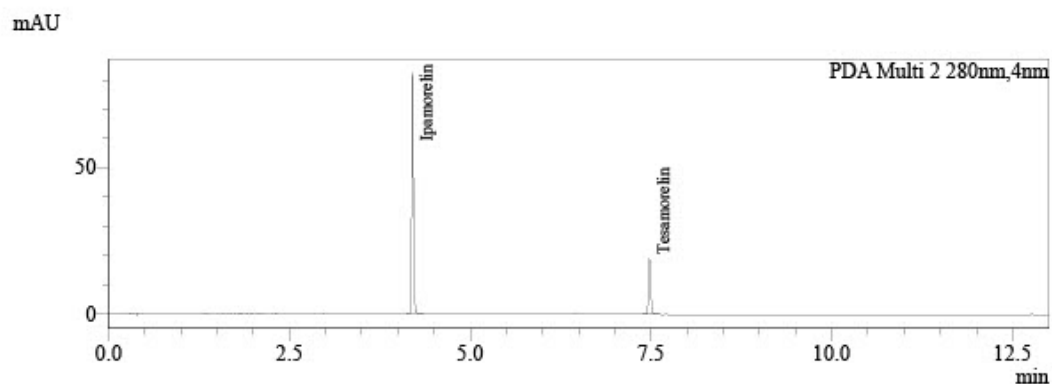
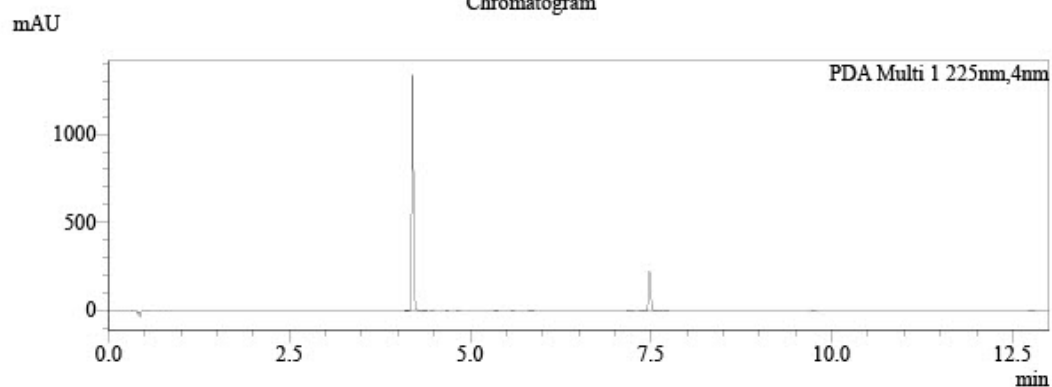


Analysis of quantity of active ingredient by UHPLC with MS detection

Sample Information

Injection Volume : 2
Data File : LYO-1002_018.lcd
Method File : Peptide Screening_DFA_Group B.lcm
Date Acquired : 9/29/2026 5:42:31 PM

Chromatogram



Peak Table

Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
1		4.110	297	0.010	0.000	
2		4.143	317	0.011	0.000	
3		4.202	2338228	82.535	0.000	
4		4.374	101	0.004	0.000	
5		4.468	383	0.014	0.000	
6		4.681	262	0.009	0.000	
7		4.824	303	0.011	0.000	
8		5.358	1034	0.037	0.000	
9		5.584	119	0.004	0.000	
10		5.844	1427	0.050	0.000	
11		7.218	814	0.029	0.000	
12		7.352	586	0.021	0.000	
13		7.479	486391	17.169	0.000	
14		7.709	1016	0.036	0.000	
15		9.747	381	0.013	0.000	
16		12.766	1358	0.048	0.000	

Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
Total			2833016	100.000		

Peak Table

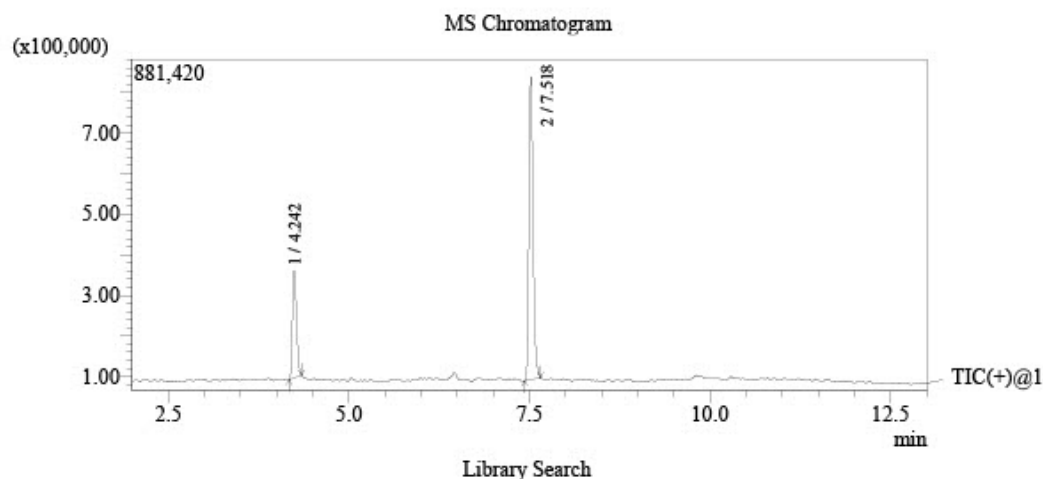
PDA Ch2 280nm

Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
1	Ipamorelin	4.202	139699	76.871	3.504	mg
2	Tesamorelin	7.479	40976	22.548	10.167	mg
3		14.223	1056	0.581	0.000	
Total			181731	100.000		

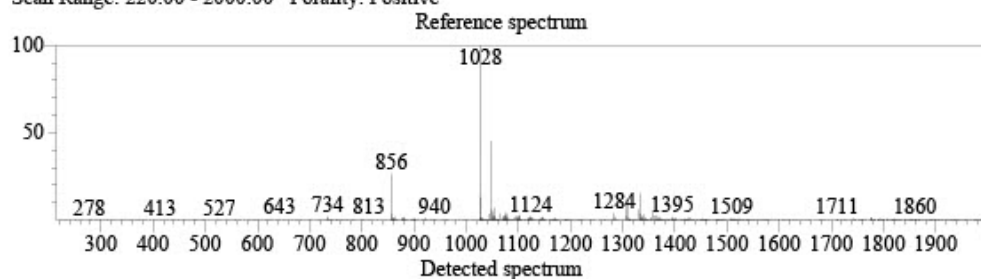
Analysis Report



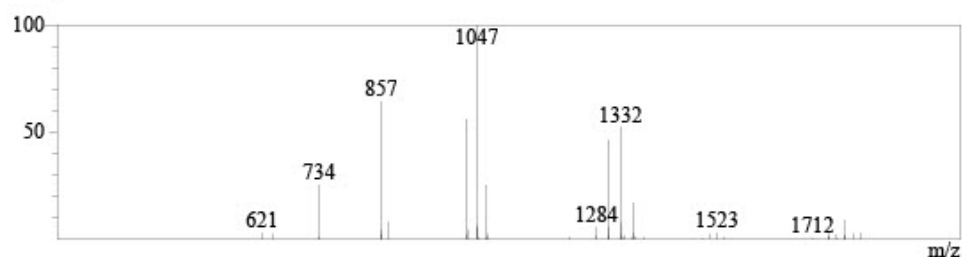
Identification of active ingredient by UHPLC Mass Spectrometry



Base Peak: 1028(145583)
Scan Range: 220.00 - 2000.00 Polarity: Positive



Library: Peptide Screening DFA.lib
Formula: C₂₂H₃₆N₇O₆S CAS: 218949-48-5 Mol.Weight: 5135(0!=)
Compound Name: Tesamorelin



Endotoxin Determination Report

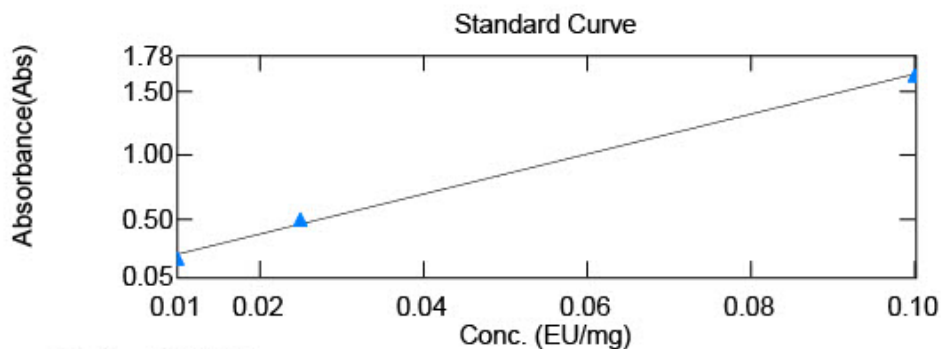


File Information

Filename: C:\UVVis-Data\Data\File_260930_145842.vqud
Date/Time: 09/30/2026 03:59:11 PM

Instrument Information

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



$$y = 15.7052x + 0.0656609$$
$$r^2 = 0.99825$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-1014	0.055	0.1088	20.00
2	LYO-1015	0.019	0.0804	20.00
3	LYO-1016	0.113	0.1547	20.00
4	LYO-1017	2.333	0.9816	40.00
5	LYO-1018	1.396	1.1619	20.00
6	LYO-1022	0.077	0.1259	20.00
7	LYO-1023	0.073	0.1231	20.00
8	LYO-1028	0.025	0.0851	20.00
9	LYO-1032	0.070	0.1206	20.00
10	LYO-1033	0.023	0.0839	20.00
11	LYO-1034	0.023	0.0838	20.00
12	LYO-1019	4.611	0.9709	80.00
13	LYO-1020	0.043	0.0995	20.00
14	LYO-1021	0.020	0.0816	20.00
15	LYO-1000	0.021	0.0818	20.00
16	LYO-1001	0.023	0.0841	20.00
17	LYO-1002	0.036	0.0943	20.00
18	LYO-1003	0.029	0.0884	20.00
19	LYO-1004	0.022	0.0832	20.00
20	LYO-1005	0.018	0.0797	20.00

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
21	LYO-1006	1.201	1.0090	20.00
22	LYO-1007	0.690	0.6079	20.00
23	LYO-1008	0.040	0.0968	20.00
24	LYO-1009	1.688	0.7283	40.00
25	LYO-1010	0.024	0.0846	20.00
26	LYO-1011	35.865	0.7697	800.00
27	LYO-1036	1.937	0.8261	40.00
28	LIQ-0077	0.002	0.0989	1.00
29	LIQ-0078	0.002	0.0965	1.00
30	LIQ-0079	0.002	0.0938	1.00
31	LIQ-0080	0.003	0.1202	1.00
32	LIQ-0081	0.002	0.1005	1.00
33	LIQ-0082	0.003	0.1160	1.00

 LIQUILABS Analytical services	Method Specification	
Determination of bioburden of lyophilized samples		
<i>Document number</i> MIC_001_2025	<i>Superseded document</i> -	<i>Number of pages</i> 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 inoculation

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 container 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 inoculation 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 sterilize.
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 inoculated 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.

2.3 Total Yeast and Mold count inoculation 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 sterilize.
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 inoculated 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 inoculations

CFU_n = CFU counted per inoculation

n = number of inoculations

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

CFU_{avg} = Average CFU counted from n inoculations

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 inoculation or incubation.

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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