

# Certificate of Analysis

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[Verify Results Online](#)

## Sample Identification

<b>Sample Name</b>	Tesamorelin/Ipamorelin 10mg/3mg
<b>Batch Number</b>	GF-TESAIPA10/3-B242
<b>Date Published</b>	2026-06-22 17:34

## Results for LYO-0241

Peptides	Result	Unit	Uncertainty	Acceptable Range
Ipamorelin Assay Peptide Screening 0.1% TFA	3.57	mg	[± 0.02]	
Tesamorelin Assay Peptide Screening 0.1% TFA	10.90	mg	[± 0.05]	
Ipamorelin Purity Peptide Screening 0.1% TFA	> 99.8	%		
Tesamorelin Purity Peptide Screening 0.1% TFA	99.7	%	[± 0.5]	
Ipamorelin Identification by RT Peptide Screening 0.1% TFA	0.992		[± 0.005]	
Tesamorelin Identification by RT Peptide Screening 0.1% TFA	0.991		[± 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	0.014	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	993	Da	[± 1]	
Molecular Ion Mass Identification (Tesamorelin) Mass Spectrometry Identity	5135	Da	[± 1]	

	<b>Method Specification</b>	
<b>Determination of identity, content and purity of Tesamorelin</b>		
<i>Document number</i> TESA_006_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Superseded document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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

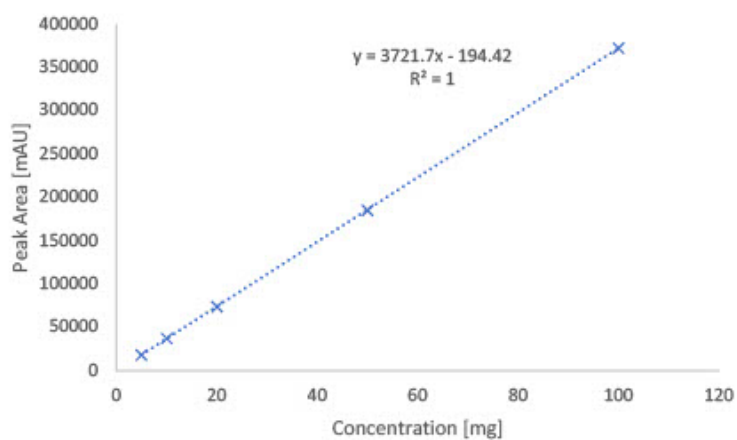
Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	end	

### 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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	225nm

Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	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 214 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
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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Mass spectrometry	Scan: positive 280-2000 Da

Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	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

	<b>Method Specification</b>	
<b>Determination of identity, content and purity of Ipamorelin</b>		
<i>Document number</i> IPA_006_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	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

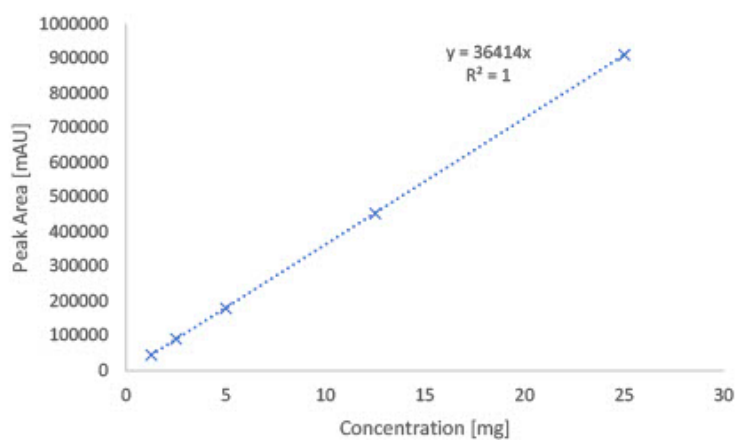
Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
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13.5	1	99
14.5	1	99
14.51	95	5
16	end	

### 1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (LCMS Grade). 100  $\mu$ L of sample was transferred to HPLC vial and diluted by 900  $\mu$ L 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
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Injection volume	2 µL
Colum Temperature	55°C
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Detection wavelength	225nm

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1.5	95	5
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14.51	95	5
16	end	

### 2.3 Purity assesment

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### 3. Identity Assessment

#### 3.1 Instrumentation

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Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Mass spectrometry	Scan: positive 280-2000 Da

Gradient Program		
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13	45	55
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#### 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:

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Where:

$mz_i$  - Measured mass of charged particle

$z_i$  - charge

H - proton mass (1.0076 Da)

ME - mass error

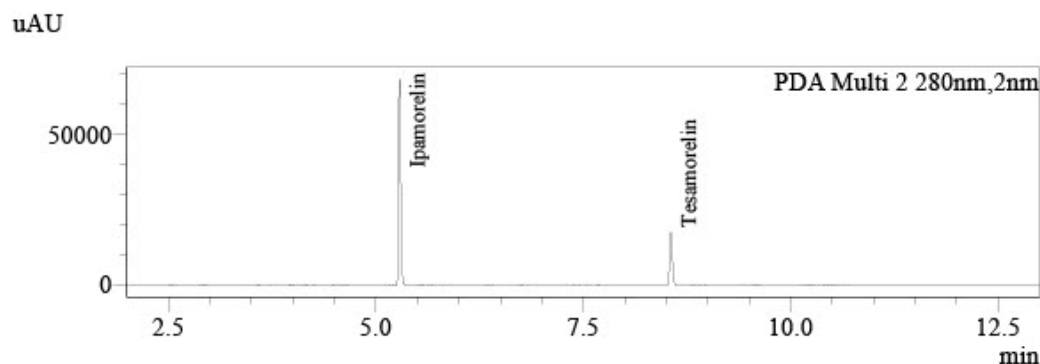
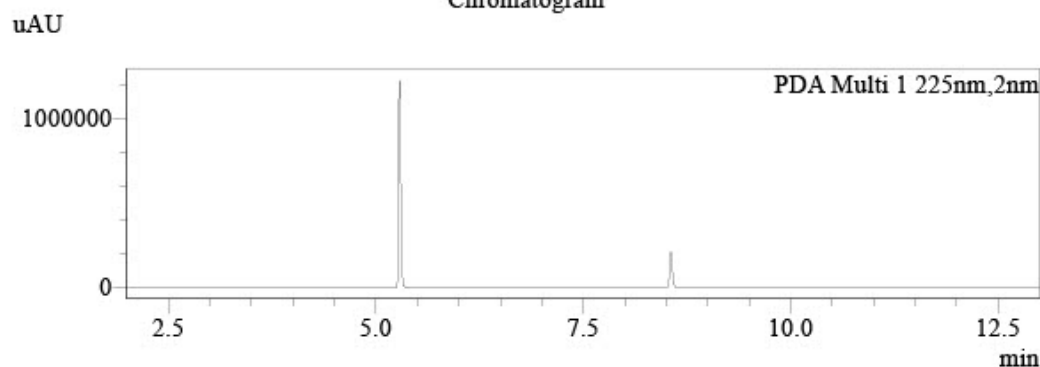
# Analysis Report



## Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information  
 Injection Volume : 2  
 Data File : LYO-0241\_013.lcd  
 Method File : Peptide screening\_V7\_Group B.lcm  
 Date Acquired : 6/16/2026 5:24:03 PM

### Chromatogram



### Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
	5.022	752	0.000		0.026
	5.284	2352802	0.000		82.700
	5.545	232	0.000		0.008
	5.740	855	0.000		0.030
	5.887	658	0.000		0.023
	6.260	953	0.000		0.034
	6.778	447	0.000		0.016
	8.275	709	0.000		0.025
	8.406	343	0.000		0.012
	8.554	486955	0.000		17.116
	9.183	279	0.000		0.010
		2844984			100.000

### Peak Table

PDA Ch2 280nm

Name	Ret. Time	Area	Conc.	Unit
Ipamorelin	5.284	129758	3.573	mg
Tesamorelin	8.554	40381	10.902	mg

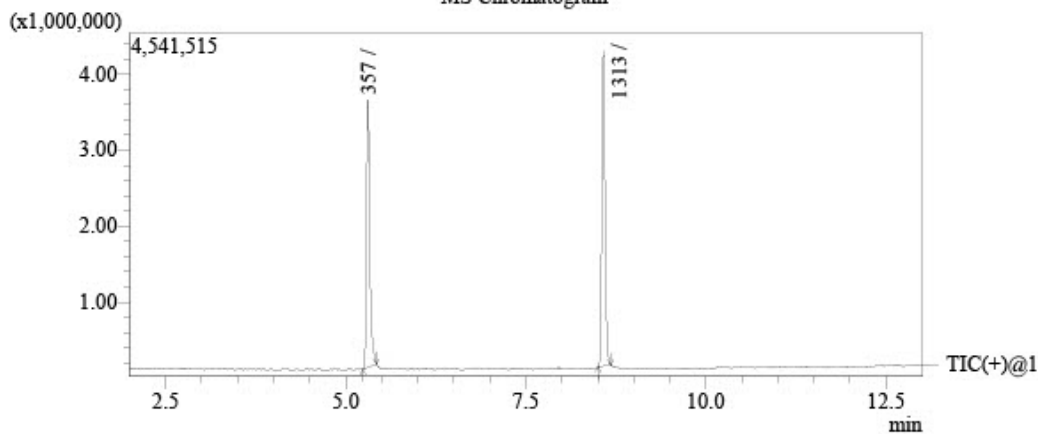
Name	Ret. Time	Area	Conc.	Unit
		170139		

# Analysis Report



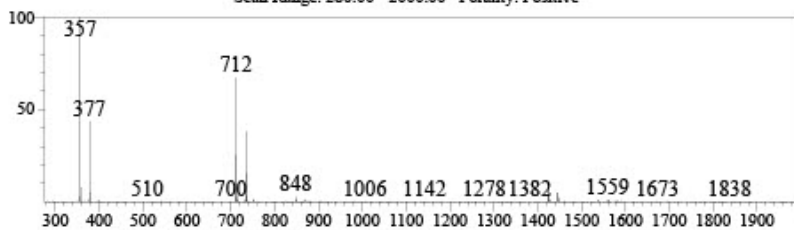
## Analysis of identity of active ingredient by UHPLC with mass spectrometric detection

MS Chromatogram



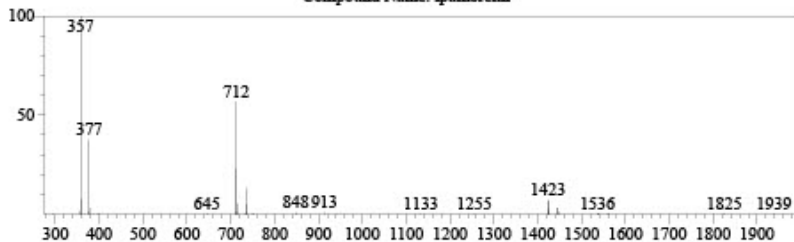
Library Search

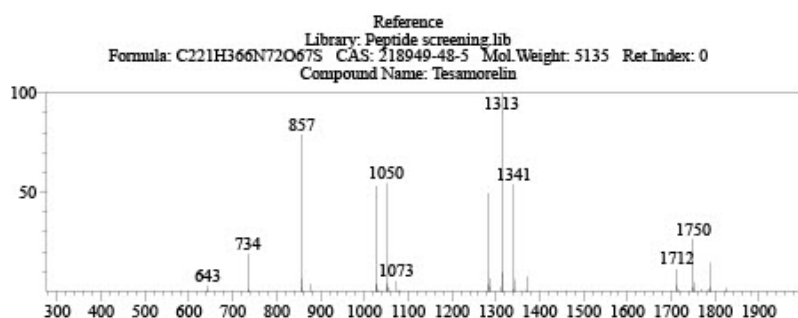
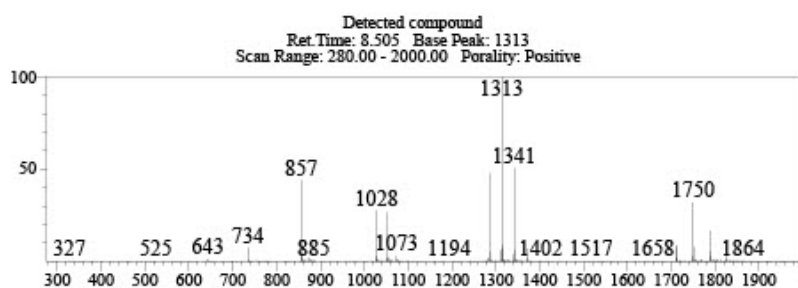
Detected compound  
Ret. Time: 5.244 Base Peak: 357  
Scan Range: 280.00 - 2000.00 Polarity: Positive




Reference

Library: Peptide screening lib  
Formula: C<sub>38</sub>H<sub>49</sub>N<sub>9</sub>O<sub>5</sub> CAS: 170851-70-4 Mol. Weight: 711 Ret. Index: 0  
Compound Name: Ipamorelin





	<b>Method Specification</b>	
<b>Determination of bacterial endotoxin content of lyophilized samples</b>		
<i>Document number</i> ENDOTOX_0616_2026	<i>Superseded document</i> -	<i>Number of pages</i> 2

## 1. Chromgenic LAL Assay Determination of Bacterial Endotoxin content of sample

### 1.1. Instrumentation

- Pipette set 1-1000 µL
- Thermostatically controlled water bath
- UV VIS spectrometer ( Shimadzu UV-1601)
- GenScript ToxinSensor Chromgenic LAL Endotoxin Assay kit

### 1.2. Chemicals

- LAL Reagent water (endotoxin free)
- Limulus Amoebocyte Lysate
- LAL Substrate
- Color Stabilizer #1
- Color Stabilizer #2
- Color Stabilizer #3
- 35% HCl (p.a.)

### 1.3. Sample preparation

1. Sample container was weighed prior to dissolution and measured weight was marked.
2. Sample was completely dissolved in its container by 2 mL of LAL Reagent water.
3. 100 µL of the sample was aliquoted for analysis.
4. After analysis container was emptied and dried.
5. Dry mass of container was measured and exact weight of dissolved content was determined as:

$$m_{dc} = m_{sample} - m_{container}$$

### 1.4. Toxin sensor Chromgenic LAL Endotoxin Assay kit preparation

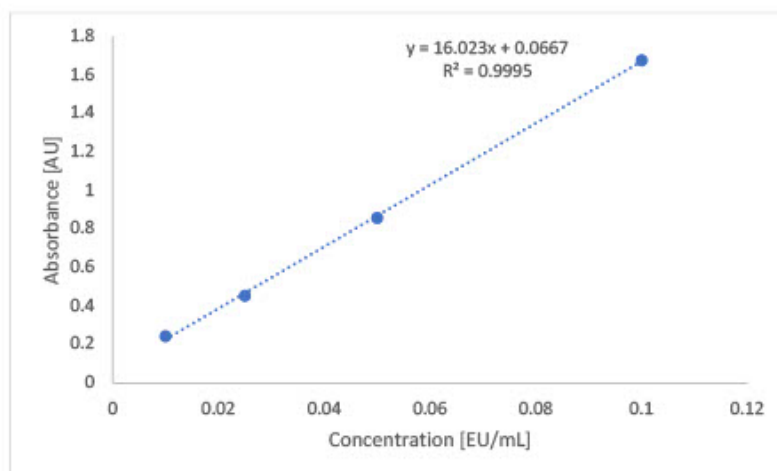
Procedures regarding preparation of reaction solutions possible to find in:

[https://www.genscript.com/site2/document/5292\\_20080806231827.PDF](https://www.genscript.com/site2/document/5292_20080806231827.PDF)

### 1.5. Measurement procedure

	Standards	Samples	Blank
Standards (mL)	0.1	-	-
Samples (mL)	-	0.1	-
LAL Reagent Water (mL)	-	-	0.1
LAL Solution (mL)	0.1	0.1	0.1
Mix well and incubate at 37°C for 27 min			
Substrate solution (mL)	0.1	0.1	0.1
Mix well and incubate at 37°C for 6 min			
Color Stabilizer #1 solution	0.5	0.5	0.5
Color Stabilizer #2 solution	0.5	0.5	0.5
Color Stabilizer #3 solution	0.5	0.5	0.5
Mix well and read the absorbance at 545nm			

### 1.6. Calibration curve



### 1.7. Calculation of endotoxin content

Endotoxin content of the sample was calculated from the calibration curve as:


$$\text{Endotox}[EU/mg] = \frac{\left(\frac{ABS_{sample}}{S_{calib}}\right) * 20}{m_{sample}}$$

$ABS_{sample}$  = Measured absorbance of sample

$S_{calib}$  = Slope of calibration curve

$m_{sample}$  = real measured mass of sample

20 = dilution factor of measured sample

	<b>Method Specification</b>		
<b>Determination of bioburden of lyophilized samples</b>			
<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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