

Certificate Of Analysis



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Sample Identification

Sample Name	MOTS-C 10 mg	Batch Number	2025259	Date Published	2025-07-25 18:22
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Results for Lyo-0055

Analysis of Peptide Identity, Content and Purity	Result	Unit	Uncertainty	Reporting Limit
MOTS-C Assay Peptide Screening	9.94	mg	[± 0.05]	
MOTS-C Identification by RT Peptide Screening	0.999		[± 0.005]	
MOTS-C Identification by spectrum Peptide Screening	1.00		[± 0.01]	
MOTS-C Purity Peptide Screening	> 99.8	%		

Bioburden	Result	Unit	Uncertainty	Reporting Limit
Total Aerobic Microbial Count USP <61> Plate Count Method	25	CFU/g	[± 2]	>= 1000
Total Yeast and Mold Count USP <61> Plate Count Method	Not detected	CFU/g		>= 100

Endotoxin Analysis	Result	Unit	Uncertainty	Reporting Limit
Bacterial Endotoxin USP<85> Bacterial Endotoxin Chromogenic Test	0.0100	EU/mg	[± 0.0002]	> 0.5

Heavy Metals	Result	Unit	Uncertainty	Reporting Limit
Arsenic Elemental Impurities Screening	Not detected	ppm		>= 1.5
Cadmium Elemental Impurities Screening	Not detected	ppm		>= 0.5
Cobalt Elemental Impurities Screening	Not detected	ppm		>= 25
Lead Elemental Impurities Screening	Not detected	ppm		>= 1.5

Heavy Metals	Result	Unit	Uncertainty	Reporting Limit	
Nickel Elemental Impurities Screening	Not detected	<i>ppm</i>		>= 25	△
Quicksilver Elemental Impurities Screening	Not detected	<i>ppm</i>		>= 1.5	△
Vanadium Elemental Impurities Screening	Not detected	<i>ppm</i>		>= 25	△

Attachments for Lyo-0055

 LIQUILABS analyze to improve	Method Specification		
Determination of identity, content and purity of MOTS-C			
Document number MOTS_001_2021	Specified document -	Number of pages 2	

1. Content and Purity Assessment

1.1. Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu SCL-10A Dup	C210141121233
Degassing Unit	Shimadzu DDU-10A	NA
UPSI flow	Shimadzu FCB-10Pa	NA
Pump	Shimadzu LC-10ADup	C208841290214
Autosampler	Shimadzu SIL-10ADup	C210541091114
Column thermostat	Shimadzu CTO-10ADup	C210323720143
Detector	Shimadzu SPD-10ADup	C208942335310

1.2. Chromatographic conditions

Chromatographic conditions	
Eluent A	1% TFA in Water (HPLC, Gradient Grade)
Eluent B	1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	2ml/min
Program	Gradient elution
Injection volume	2 µL
Column Temperature	35 °C
Column	Acclaim ACE UltraCore C18, 150x3,0 mm, 5,5µm
Detection wavelength	214nm

Gradient Program		
Time [min]	A [%]	B [%]
5	99	1
25	95	5
20	5	95
25.01	99	1
32	end	

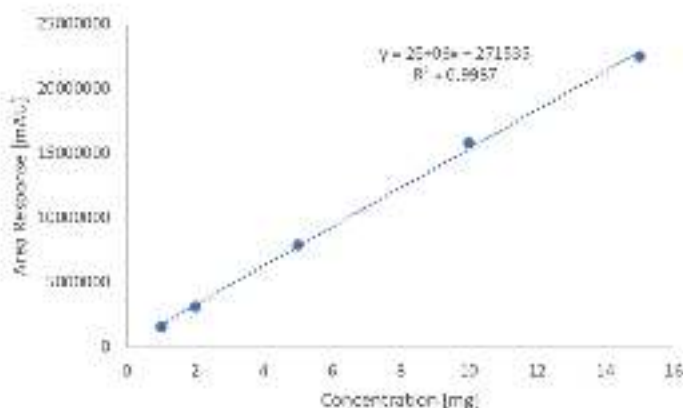
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1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquot part of 1 mL was dispensed into HPLC vial for analysis.

1.4. Calibration curve

Calibration curve detail	
Quantitative method	External Standard
Calibration Type	Linear
Number of calibration points	5
Force through Zero	Disabled
Weighting Method	None



2. Purity assessment

1.5. Calculation of purity of peptide

Purity of MOTS-C in sample was determined by area normalization method as ratio of MOTS-C peak and sum of all peaks detected at wavelength 214 nm.

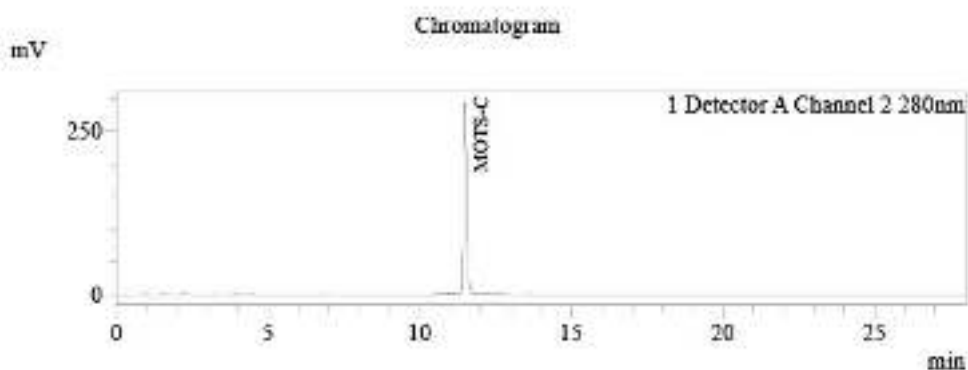
$$Purity(\%) = \frac{Peak\ Area_{MOTS-C}}{\sum Peak\ Area}$$

Analysis Report



Injection Volume : 2
Data File : LYO-0055-P01_002_004.lcd
Method File : Peptide screening_new.lcm
Date Acquired : 30.06.2025 17:05:03

Sample Information



Peak Table

Detector A Channel 2 280nm					
Peak#	Name	Ret. Time	Conc	Unit	Area%
1	MOTS-C	11.483	9.941	mg	100.000
Total			9.941		100.000

Attachment for Lyo-0055
Filename: MOTS-C.jpg

 LIQUILABS simple to secure	Method Specification		
Determination of bacterial endotoxin content of lyophilized samples			
Document number <i>LAB001001_001_2025</i>	Typical document -	Number of pages 2	

1. Chromogenic 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 Chromogenic LAL Endotoxin Assay kit

1.2. Chemicals

- LAL Reagent water (endotoxin free)
- Limulus Amebocyte 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 Chromogenic LAL Endotoxin Assay kit preparation

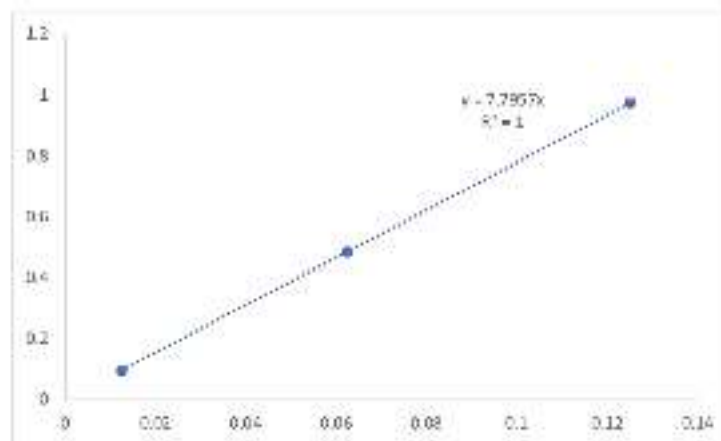
Procedures regarding preparation of reaction solutions possible to find in:

<https://www.genscript.com/sites/default/files/2020-06/0606231827.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 8 min			
Color Stabilizer #1 solution	0.0	0.0	0.0
Color Stabilizer #2 solution	0.0	0.0	0.0
Color Stabilizer #3 solution	0.0	0.0	0.0
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:

$$\text{Endotoxin [EU/mg]} = \frac{\left(\frac{ABS_{\text{sample}}}{S_{\text{slope}}} \right) \cdot 20}{m_{\text{sample}}}$$

ABS_{sample} = Measured absorbance of sample

S_{slope} = Slope of calibration curve

m_{sample} = real measured mass of sample

20 = dilution factor of measured sample

 LIQUILABS laboratory services	Method Specification	
Determination of bioburden of lyophilized samples		
<i>Method identifier</i> LYO_005_26.25	<i>Specimen description</i> -	<i>Number of pages</i> 3

1. Instrumentation and chemicals

1.1. Instruments used

- Sterile Syringe 2ml Luer
- Sterile needles
- Ready-made PCA Plate Count Agar
- Ready-made 360 Plate Count Agar

1.2. Chemicals

Sterile physiological solution (0.9% NaCl)

2. Sample preparation and inoculation

2.1. Sample preparation

1. Pre-heated sterile needle/syringe was used for measuring exactly 2 ml of sterile physiological solution.
2. Needle was changed and by new sterile rubber tip of petri dish container was removed 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. Process 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 into another 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: inoculation and cultivation

1. By sterile needle 1 ml of solution was filled into the sterile syringe.
2. Needle was placed about 1 cm from the flame for 10 seconds in sterilize.
3. Consequently 1 ml of solution was poured into the ready to use sterile petri dish filled with Sabi agar and petri dish was closed.
4. This was repeated for two petri dishes.
5. By sterile needle 1 ml of sterile physiological saline was filled into the sterile needle and was inoculated onto one sterile petri dish filled with Sabi 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:

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

CFU_{avg} = average CFU counted from n inoculations

CFU_k = CFU counted per inoculation

n = number of inoculations

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

CFU_{avg} = Average CFU counted from n inoculations

m_s = mass of sample (mg)

DF = Dilution factor

*Negative control sample is evaluated as positive, process have to be repeated due to possible contamination in the process of inoculation or cultivation.



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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