

Certificate Of Analysis



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Sample Identification

Sample Name	Sodium Chloride (0.9%) 10ml	Batch Number	2024214	Date Published	2025-09-13 10:12
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Results for LIQ-0010

Analysis of Peptide Identity, Content and Purity	Result	Unit	Uncertainty	Reporting Limit
pH determination	7.00		[± 0.1]	5.5 - 7

Bioburden	Result	Unit	Uncertainty	Reporting Limit
Total Aerobic Microbial Count USP <61> Plate Count Method	Not detected	CFU/g		<= 100
Total Yeast and Mold Count USP <61> Plate Count Method	Not detected	CFU/g		<= 10

Endotoxin Analysis	Result	Unit	Uncertainty	Reporting Limit
Bacterial Endotoxin USP<85> Bacterial Endotoxin Chromogenic Test	Not detected	EU/mg		<= 0.25

Attachments for LIQ-0010

 LIQUILABS laboratory services	Method Specification		
Determination of bioburden of lyophilized samples			
Method number LIQ_001_2022	Applicable documents -	Number of pages 2	

1. Instrumentation and chemicals

1.1. Instruments used

- Sterile Syringe 2ml Luer
- Sterile needles
- Ready-made PCA Plate ROTI Aquares
- Ready-made Seb Plate ROTI Aquares

1.2. Chemicals

Sterile physiological solution (0.9% NaCl)

2. Sample preparation and inoculation

2.1. Sample preparation

1. Pre-sterilized needle and syringe was used for measuring exactly 2 ml of sterile physiological solution.
2. Needle was changed and by new sterile rubber tip of peptid. 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 flocs.
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 needles, 1 ml of sterile physiological solution was filled into the sterile needle and was inoculated into another sterile petri dish filled with PCA agar (negative control sample).
6. Samples and negative control sample were placed in incubator at temperature 22°C for 24h.

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Attachment for LIQ-0010
 Filename: Bioburden-images-0.jpg

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 concentrations

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

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

 LIQUILABS simple to secure	Method Specification		
Determination of bacterial endotoxin content of lyophilized samples			
Document number ENDOTOX_001_2025	Typical document ENDOTOX_001_2025	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)
- GlauScript 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

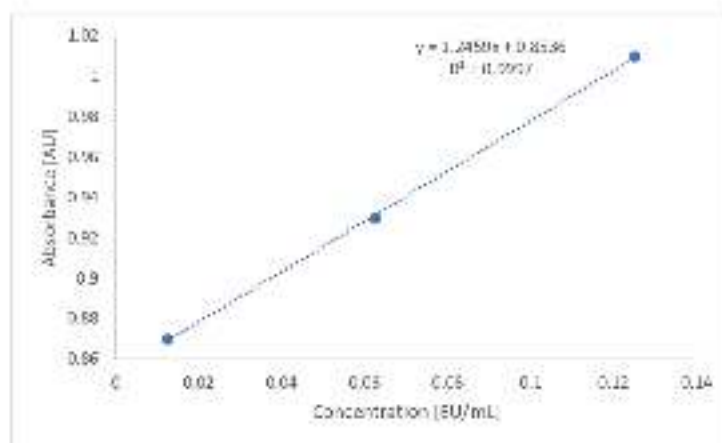
Procedures regarding preparation of reaction solutions possible to find in:

https://www.genscript.com/site/document/5293_20080606231827.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

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Attachment for LIQ-0010

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Responsibles



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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