Certificate Of Analysis

LIQUILABS
Analytical services

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Sample Identification

Sample Name	Bacteriostatic Water 10 ml	**Batch Number**	2024214	**Date Published**	2025-09-13 10:10

Results for LIQ-0008

Active substances	Result	Unit	Uncertainty	Reporting Limit
Benzyl alcohol content Stabilizers	0.9180	*%*	[± 9e-04]	0.9 - 1.1

Analysis of Peptide Identity, Content and Purity	Result	Unit	Uncertainty	Reporting Limit
pH determination	6.84		[± 0.1]	4.5 - 7

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

Attachments for LIQ-0008

LIQUILABS Analytical services	Method Specification	
Determination of content of Benzyl alcohol in bacteriostatic water		
Document number BENZOH_001_2025	*Superseded document* -	*Number of pages*

1. Content Assesment

1.1. Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu SCL-10ADvp	C21014112659
Degassing Unit	Shimadzu DGU-14A	NA
LPGE valve	Shimadzu FCV-10Avp	NA
Pump	Shimadzu LC-10ADvp	C20964130094
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Colum Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

1.2. Chromatographic conditions

Chromatographic conditions	
Eluent A	Water (HPLC, Gradient Grade)
Eluent B	Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Colum Temperature	40°C
Column	Avantor ACE UltraCore 150x3mm 3.5µm
Detection wavelenght	260nm

Gradient Program		
Time [min]	A [%]	B [%]
2	95	5
10	5	95
12	5	95
12.01	95	5
15	end	

1

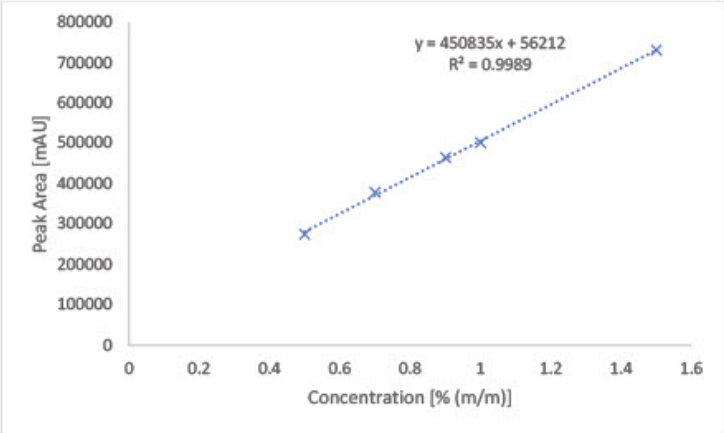
Attachment for LIQ-0008
Filename: 1757757680316-327cc467-1ed2-4e67-bebd-b239505c30f6_1.jpg

1.3. Sample preparation

1 mL of sample was pipetted into HPLC vial. 0.5µL of sample was injected.

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



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Analysis Report

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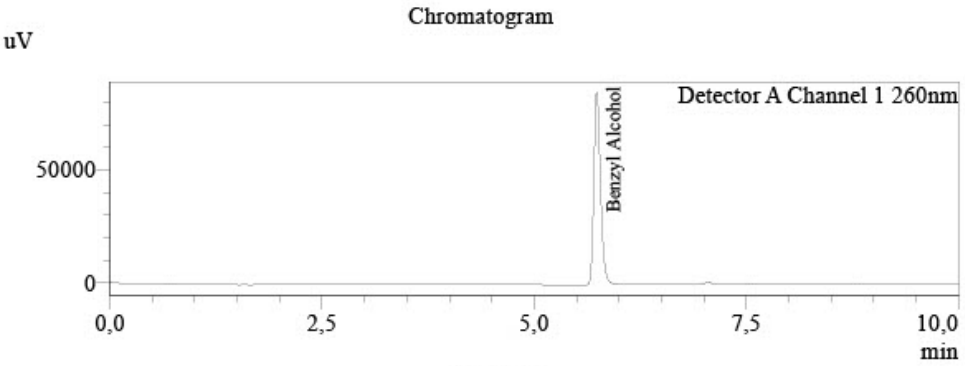
Sample Information

Injection Volume	: 0,5
Data File	: LIQ-0008__005.lcd
Method File	: Benzylalcohol.lcm
Date Acquired	: 12.09.2025 18:43:24

Chromatogram



Peak Table

Detector A Channel 1 260nm

Peak#	Name	Ret. Time	Conc.	Unit	Area%
1	Benzyl Alcohol	5,738	0,918	% (m/m)	100,000
Total					100,000

Peak Table

Detector A Channel 2 280nm

Peak#	Name	Ret. Time	Conc.	Unit
1		5,742	0,000	
2		14,553	0,000	
Total				

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

1.1. Instrumentation

- Pipette set 1-1000 µL
- Termostatically 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:

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

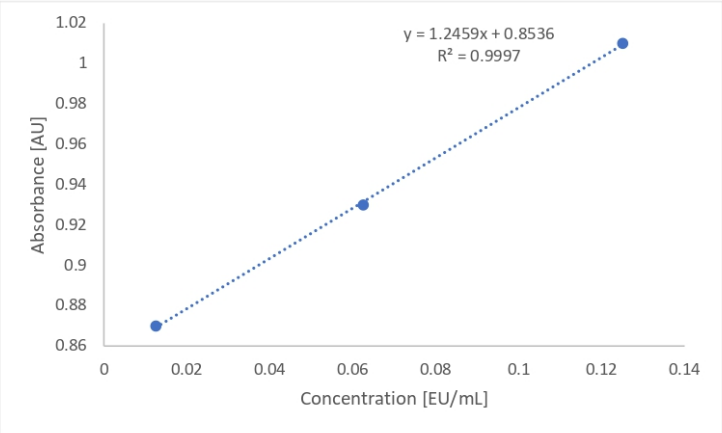
1.4. Toxin sensor Chromgenic LAL Endotoxin Assay kit preparation

Procedures regarding preparation of reaction solutions possible to find in:
https://www.genscript.com/site2/document/5292_20080806231827.PDF

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:

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

$$ABS_{sample} = Measured\ absorbance\ of\ sample$$
$$S_{calib} = Slope\ of\ calibration\ curve$$
$$m_{sample} = real\ measured\ mass\ of\ sample$$
$$20 = dilution\ factor\ of\ measured\ sample$$

Attachment for LIQ-0008
Filename: Endotoxin_072025_1_page-0002.jpg

Responsibles

Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.
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