

Certificate Of Analysis



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Sample Identification

Sample Name	BAC Water Dark Blue Top	Batch Number	GF082025018	Date Published	2026-01-28 11:44
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Results for LIQ-0014

Active substances	Result	Unit	Uncertainty	Reporting Limit
Benzyl alcohol content Stabilizers	0.9090	%	[± 9e-04]	0.9 - 1.1

Analysis of Peptide Identity, Content and Purity	Result	Unit	Uncertainty	Reporting Limit
pH determination	6.83		[± 0.1]	4.5 - 7

Endotoxin Analysis	Result	Unit	Uncertainty	Reporting Limit
Bacterial Endotoxin USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	Not detected	EU/mg		<= 0.25

Attachments for LIQ-0014

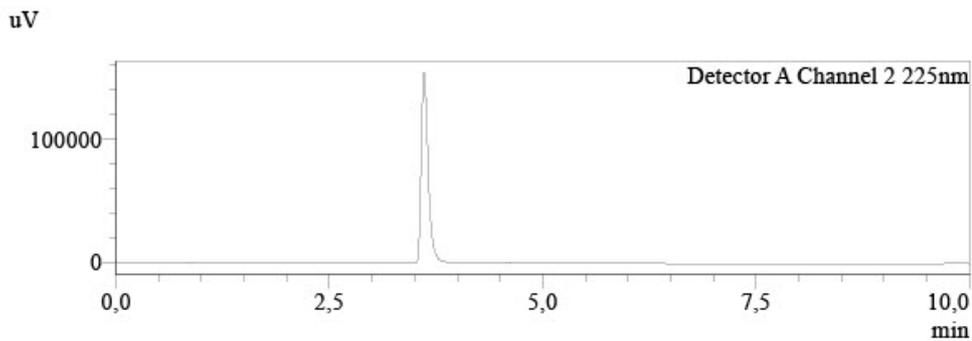
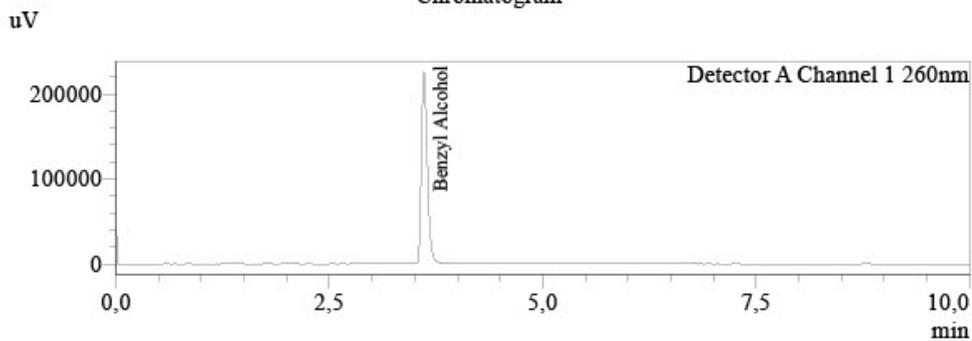
Analysis Report



Sample Information

Injection Volume : 1
Data File : LIQ-0014_004.lcd
Method File : Benzylalcohol v2.0.lcm
Date Acquired : 23.01.2026 14:27:53

Chromatogram



Peak Table

Detector A Channel 1 260nm					
Peak#	Name	Ret. Time	Conc.	Unit	Area%
1	Benzyl Alcohol	3,608	0,909	% (m/m)	100,000
Total					100,000

Peak Table

Detector A Channel 2 225nm				
Peak#	Name	Ret. Time	Conc.	Unit
1		3,609	0,000	
Total				

Attachment for LIQ-0014
Filename: LIQ-0014.jpg

	Method Specification	
	Determination of bacterial endotoxin content of lyophilized samples	
<i>Document number</i>	<i>Superseded document</i>	<i>Number of pages</i>
ENDOTOX_012_2025_1		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

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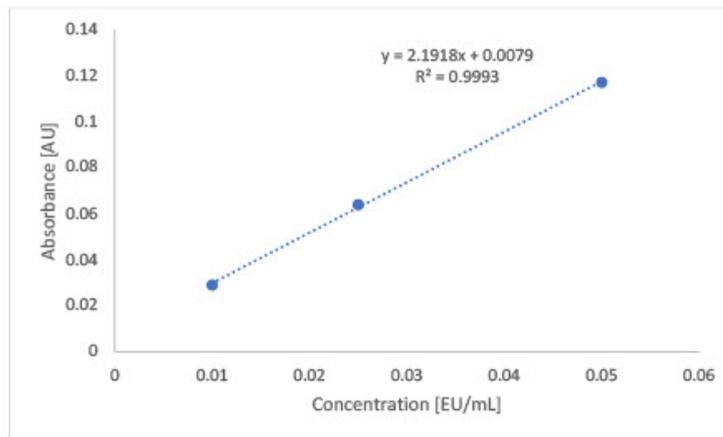
Attachment for LIQ-0014

Filename: 1765955932191-d9b89217-3e5d-4339-87cf-eaea14717e0a_1.jpg

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:

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

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



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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