

Certificate of Analysis

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Sample Identification

Sample Name Bacteriostatic Water 10ml
Batch Number 2025293
Date Published 2026-04-17 09:26

Results for LIQ-0027

Stabilizers	Result	Unit	Uncertainty	Acceptable Range
Benzyl Alcohol Content Benzyl alcohol	0.91	%	[± 0.02]	0.9 - 1.1
Peptides	Result	Unit	Uncertainty	Acceptable Range
pH Determination pH determination	6.9		[± 0.1]	4.45 - 7
Microbiology	Result	Unit	Uncertainty	Acceptable Range
Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	< 0.001	EU/mg		<= 0.25

Analysis Report

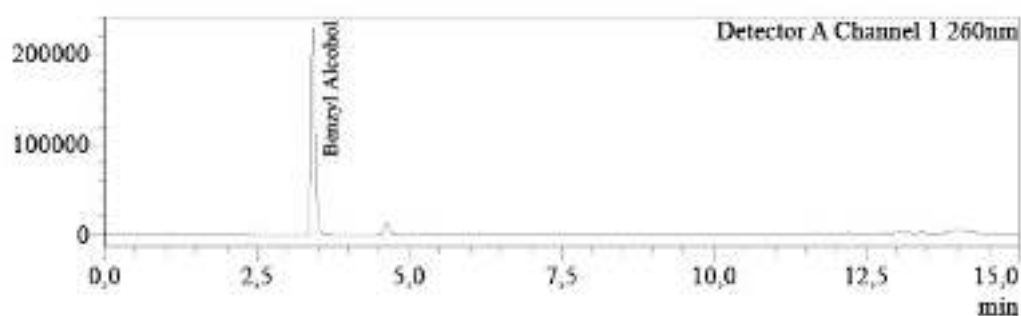


Sample Information

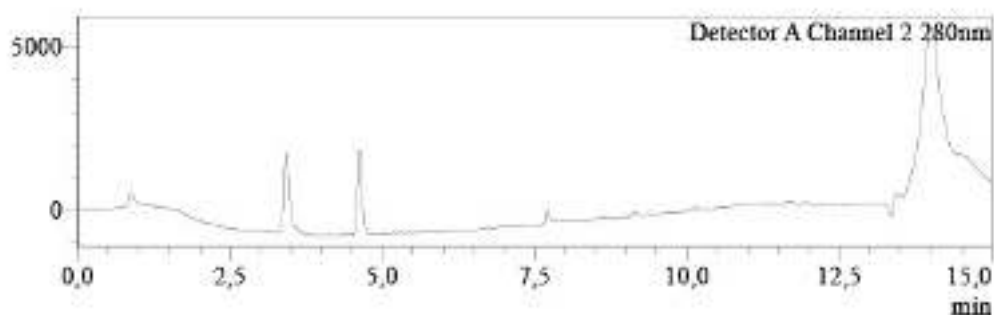
Injection Volume : 1
Data File : LIQ-0027_003.lcd
Method File : Benzylalcohol v2.0.lcm
Date Acquired : 17.04.2026 9:23:50

Chromatogram

uV



uV



Peak Table

Detector A Channel 1 260nm

Peak#	Name	Ret. Time	Conc.	Unit	Area%
1	Benzyl Alcohol	3.415	0.908	% (m/m)	100.000
Total					100.000

Peak Table

Detector A Channel 2 280nm

Peak#	Name	Ret. Time	Conc.	Unit
Total				

 LIQUILABS <i>Analytical services</i>	Method Specification	
Determination of bacterial endotoxin content of lyophilized samples		
<i>Document number</i> ENDOTOX_0402_2016	<i>Superseded document</i> -	<i>Number of pages</i> 2

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

1.1. Instrumentation

- Pipette set 1-1000 µL
- Temperature 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 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 Chromogenic LAL Endotoxin Assay kit preparation

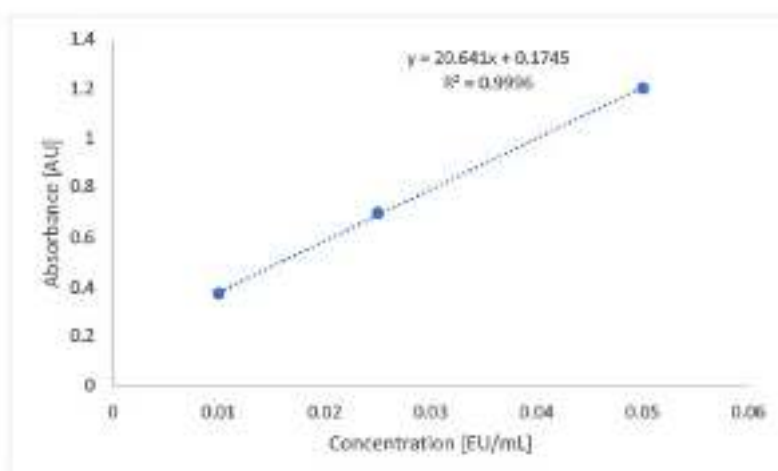
Procedures regarding preparation of reaction solutions possible to find in:

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:

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

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

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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