

Certificate of Analysis

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Sample Identification

Sample Name Cerebrolysin 30 mg
Batch Number GF-CERE30-B241
Date Published 2026-08-15 12:59

Results for LYO-0546

Microbiology	Result	Unit	Uncertainty	Acceptable Range
Total Aerobic Microbial Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	0	CFU/g	[±]	0 - 1000
Total Yeast and Mold Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	0	CFU/g	[±]	0 - 100
Bacterial Endotoxin Chromogenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromogenic Test	< 0.001	EU/mg		0 - 0.5
Elemental Impurities	Result	Unit	Uncertainty	Acceptable Range
Arsenic Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 1.5
Cadmium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 0.5
Quicksilver Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 1.5
Lead Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 1.5
Nickel Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 25
Vanadium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 25
Cobalt Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		0 - 25
Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (MS Deconvolution) Mass Spectrometry Identity	< 1	Da		
Supplements	Result	Unit	Uncertainty	Acceptable Range
Total Protein Content (Modified Biuret Method) Polar Compound Screening 10mM ammonium formate buffer	98.33	%	[± 1.97]	

Total Protein Count Standard Biuret Method

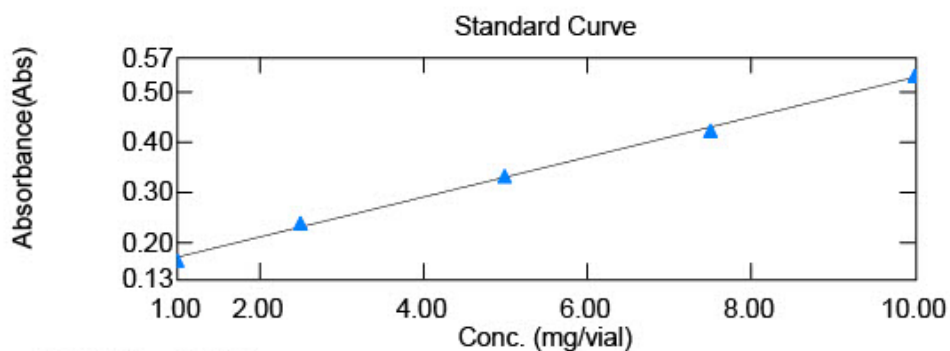


File Information

Filename: C:\UVVis-Data\Data\File_260812_103532.vqud
Date/Time: 08/12/2026 10:54:45 AM

Instrument Information

Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12536253123)



$$y = 0.0399561x + 0.129859$$
$$r^2 = 0.99858$$

	Sample Name	Conc	Raw_WL546.0	Dilution Rate
1	LYO-0542	0.264	0.1325	4.00
2	LYO-0546	29.500	0.3263	6.00

Endotoxin Determination Report

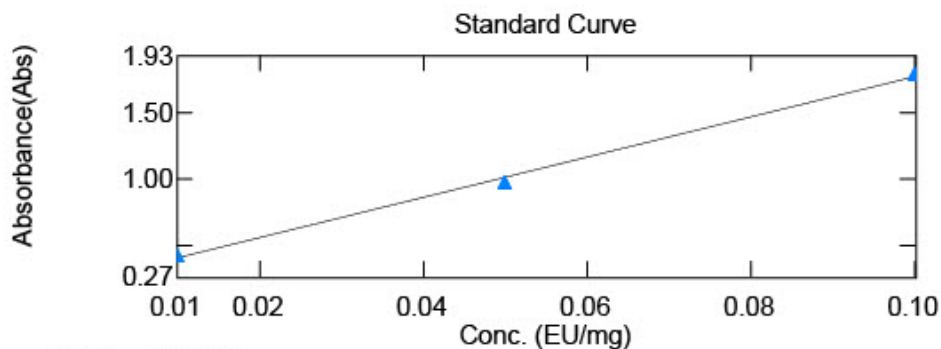


File Information

Filename: C:\UVVis-Data\Data\File_260813_140812.vqud
Date/Time: 08/13/2026 03:25:51 PM

Instrument Information

Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12536253123)



$$y = 15.1410x + 0.259749$$
$$r^2 = 0.99749$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-0573	0.816	0.8775	20.00
2	LYO-0560	0.765	0.8388	20.00
3	LYO-0559	1.047	1.0521	20.00
4	LYO-0583	3.016	1.4015	40.00
5	LYO-0584	1.016	1.0292	20.00
6	LYO-0586	0.678	0.7727	20.00
7	LYO-0588	-0.017	0.2472	20.00
8	LYO-0590	5.611	2.3837	40.00
9	LYO-0592	0.381	0.5482	20.00
10	LYO-0594	0.777	0.8479	20.00
11	LYO0595	1.338	1.2730	20.00
12	LYO-0596	1.397	0.7887	40.00
13	LYO-0597	0.634	0.4998	40.00
14	LYO-0598	1.159	1.1370	20.00
15	LYO-0599	0.486	0.6277	20.00
16	LYO-0546	-0.002	0.2587	30.00
17	LIQ-0051	-0.003	0.2210	1.00

 LIQUILABS Analytical services	Method Specification	
Determination of bioburden of lyophilized samples		
<i>Document number</i> MIC_001_2025	<i>Superseded document</i> -	<i>Number of pages</i> 2

1. Instrumentation and chemicals

1.1. Instruments used

- Sterile Syringe 2mL Luer
- Sterile needles
- Ready made PCA Plate ROTI Aquatest
- Ready made Sab4 Plate ROTI Aquatest

1.2. Chemicals

Sterile physiological solution (0.9% NaCl)

2. Sample preparation and inoculation

2.1 Sample preparation

1. Fresh sterile needle and syringe was used for measuring exactly 2 mL of sterile physiological solution.
2. Needle was changed and by new needle rubber top of peptide container was penetrated 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. Proces 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 onto one sterile 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.

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 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 Sab4 agar and petri dish was closed.
4. Proces 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 onto one sterile petri dish filled with Sab4 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:

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

CFU_{avg} = average CFU counted from n inoculations

CFU_n = CFU counted per inoculation

n = number of inoculations

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

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 incubation.

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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