

Certificate of Analysis

Nexus Research Laboratories EOOD

Nexus Research Laboratories EOOD
Str. Vrabcha No. 17A, Floor 1, Apt. 3,
Oborishte District
1000 Sofia
Bulgaria
partnerships@peptrolabs.com

Liquilabs s.r.o.

Inovační 122
252 41 Zlatníky-Hodkovice
Czechia
www.liquilabs.cz



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Sample Identification

Sample Name Tirzepatide 10 mg
Batch Number XD-TR10-PO06
Date Published 2026-10-01 10:10

Results for LYO-1028

Peptides	Result	Unit	Uncertainty	Acceptable Range
Tirzepatide Assay Peptide Screening 0.1% TFA	9.61	mg	[± 0.05]	
Tirzepatide Purity Peptide Screening 0.1% TFA	99.7	%	[± 0.5]	
Tirzepatide Identification by Spectrum (FTIR) Peptide Screening 0.1% TFA	959		[± 5]	
Tirzepatide Identification by RT Peptide Screening 0.1% TFA	0.997		[± 0.005]	
Microbiology	Result	Unit	Uncertainty	Acceptable Range
Bacterial Endotoxin Chromogenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromogenic Test	0.009	EU/mg	[± 0]	
Elemental Impurities	Result	Unit	Uncertainty	Acceptable Range
Arsenic Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Cadmium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Quicksilver Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Lead Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Nickel Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Vanadium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Cobalt Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (MS Deconvolution) Mass Spectrometry Identity	4813	g/mol	[± 1]	

	Method Specification	
Determination of identity, content and purity of Tirzepatide		
<i>Document number</i> TIRZ_008_2026	<i>Superseded document</i> -	<i>Number of pages</i> 4

1. Content Assessment

1.1. Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu CBM-40 Lite	L221226351398
Degassing Unit	Shimadzu DGU-403	NA
Pump	Shimadzu LC-40B XR	L22146350580
Autosampler	Shimadzu SIL-40C XR	L22216351622
Colum Thermostat	Shimadzu CTO-40S	L22236351602
PDA Detector	Shimadzu SPD-M40	L22276352808
SQ MS Detector	Shimadzu LCMS-2050	O12476200760

1.2. Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

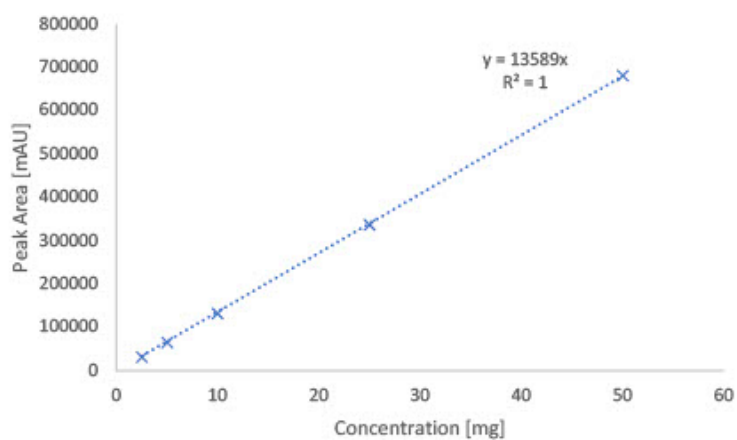
Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (LCMS Grade). 100 µL of sample was transferred to HPLC vial and diluted by 900 µL water (LCMS Grade) and submitted for analysis.

1.4. Calibration curve

Calibration curve detail	
Quantitative method	External Standard
Calibration Type	Linear
Number of calibration points	5
Force through Zero	Enabled
Weighting Method	None



2. Purity assessment

2.1 Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu CBM-40 Lite	L221226351398
Degassing Unit	Shimadzu DGU-403	NA
Pump	Shimadzu LC-40B XR	L22146350580
Autosampler	Shimadzu SIL-40C XR	L22216351622
Colum Thermostat	Shimadzu CTO-40S	L22236351602
PDA Detector	Shimadzu SPD-M40	L22276352808
SQ MS Detector	Shimadzu LCMS-2050	O12476200760

2.2 Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	225nm

Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

2.3 Purity assesment

Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelenght of 225 nm.

3. Identity Assessment

3.1 Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu CBM-40 Lite	L221226351398
Degassing Unit	Shimadzu DGU-403	NA
Pump	Shimadzu LC-40B XR	L22146350580
Autosampler	Shimadzu SIL-40C XR	L22216351622
Column Thermostat	Shimadzu CTO-40S	L22236351602
PDA Detector	Shimadzu SPD-M40	L22276352808
SQ MS Detector	Shimadzu LCMS-2050	O12476200760

3.2 Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% DFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% DFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.8 mL/min
Program	Gradient elution
Injection volume	2 µL
Column Temperature	60°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

Gradient Program		
Time [min]	A [%]	B [%]
1	98	2
13.99	35	65
14	5	95
15	5	95
15.01	98	2
19	end	

3.3 Molecular Ion Mass evaluation

Molecular ion mass was determined by deconvolution of multiply charged ESI-MS spectra to calculate the average neutral (zero-charge) molecular mass by equation:

$$M(\text{neutral}) = (z_i((mz_i) - H)) - ME$$

Where:

mz_i - Measured mass of charged particle

z_i - charge

H - proton mass (1.0076 Da)

ME - mass error

Analysis Report

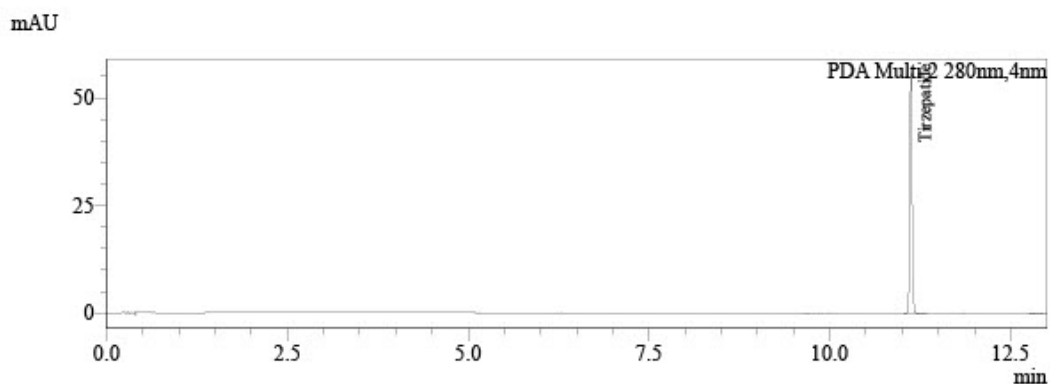
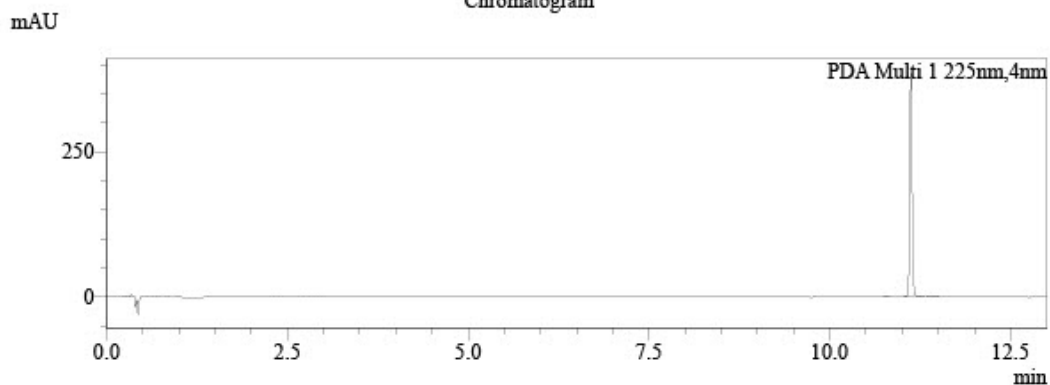


Analysis of quantity of active ingredient by UHPLC with MS detection

Sample Information

Injection Volume : 2
Data File : LYO-1028_008.lcd
Method File : Peptide Screening_DFA_Group A.lcm
Date Acquired : 9/30/2026 1:25:43 PM

Chromatogram



Peak Table

PDA Ch1 225nm

Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
1		10.770	714	0.079	0.000	
2		11.121	902215	99.712	0.000	
3		11.374	1893	0.209	0.000	
Total			904822	100.000		

Peak Table

PDA Ch2 280nm

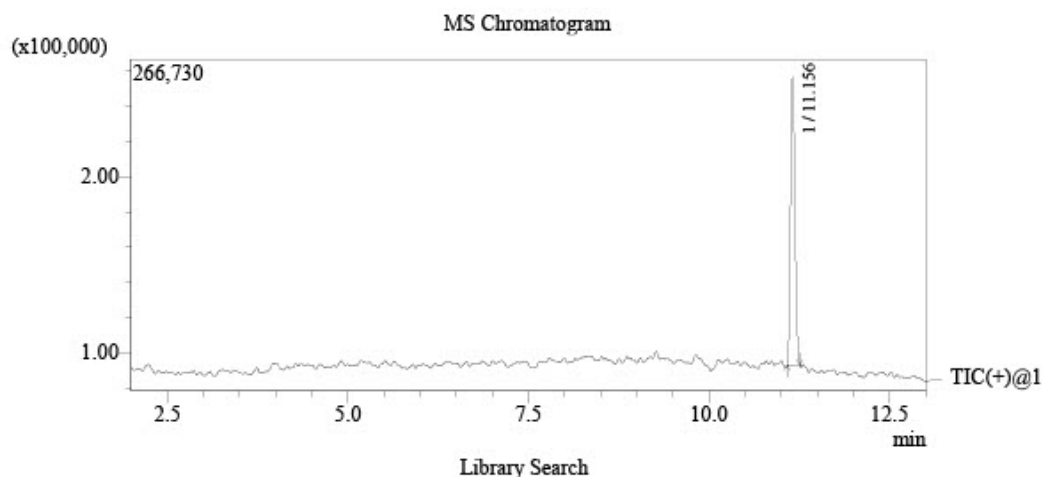
Peak#	Name	Ret. Time	Area	Area%	Conc.	Unit
1	Tirzepatide	11.121	128442	96.098	9.611	mg
2		12.800	1003	0.751	0.000	
3		14.262	4213	3.152	0.000	
Total			133658	100.000		

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Analysis Report

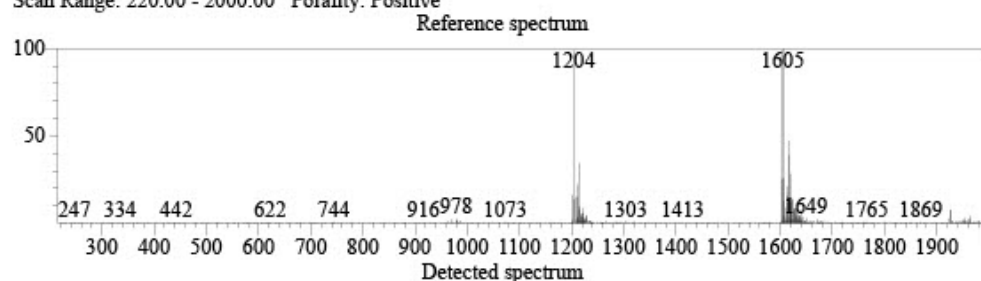


Identification of active ingredient by UHPLC Mass Spectrometry



Base Peak: 1605(16080)

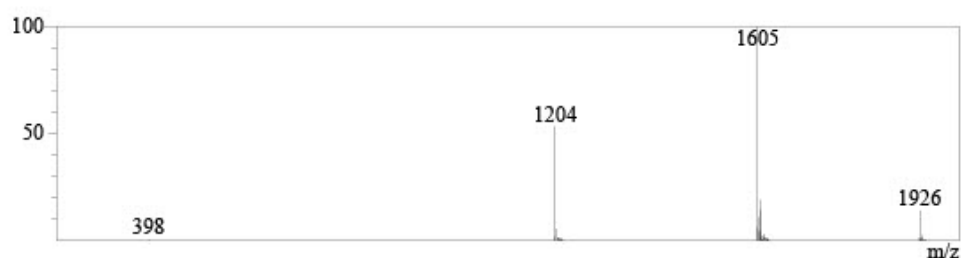
Scan Range: 220.00 - 2000.00 Polarity: Positive



Library: Peptide Screening DFA.lib

Formula: C₂₂₅H₃₄₈N₄₈O₆₈ CAS: 223788-19-2 Mol.Weight: 4813(0!=)

Compound Name: Tirzepatide



Endotoxin Determination Report

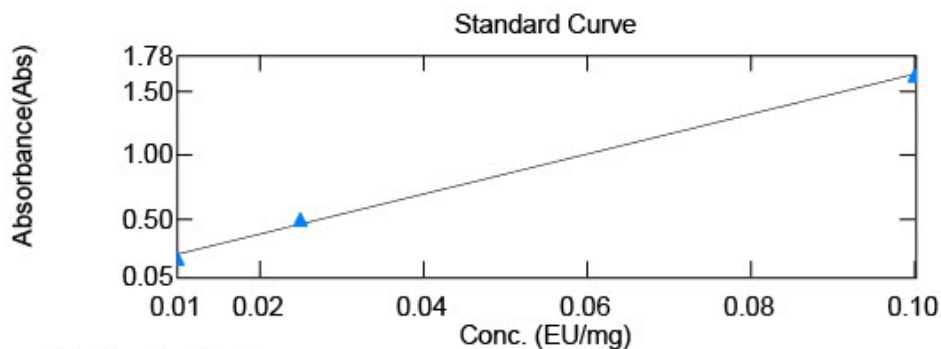


File Information

Filename: C:\UVVis-Data\Data\File_260930_145842.vqud
Date/Time: 09/30/2026 03:59:11 PM

Instrument Information

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



$$y = 15.7052x + 0.0656609$$
$$r^2 = 0.99825$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-1014	0.055	0.1088	20.00
2	LYO-1015	0.019	0.0804	20.00
3	LYO-1016	0.113	0.1547	20.00
4	LYO-1017	2.333	0.9816	40.00
5	LYO-1018	1.396	1.1619	20.00
6	LYO-1022	0.077	0.1259	20.00
7	LYO-1023	0.073	0.1231	20.00
8	LYO-1028	0.025	0.0851	20.00
9	LYO-1032	0.070	0.1206	20.00
10	LYO-1033	0.023	0.0839	20.00
11	LYO-1034	0.023	0.0838	20.00
12	LYO-1019	4.611	0.9709	80.00
13	LYO-1020	0.043	0.0995	20.00
14	LYO-1021	0.020	0.0816	20.00
15	LYO-1000	0.021	0.0818	20.00
16	LYO-1001	0.023	0.0841	20.00
17	LYO-1002	0.036	0.0943	20.00
18	LYO-1003	0.029	0.0884	20.00
19	LYO-1004	0.022	0.0832	20.00
20	LYO-1005	0.018	0.0797	20.00

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
21	LYO-1006	1.201	1.0090	20.00
22	LYO-1007	0.690	0.6079	20.00
23	LYO-1008	0.040	0.0968	20.00
24	LYO-1009	1.688	0.7283	40.00
25	LYO-1010	0.024	0.0846	20.00
26	LYO-1011	35.865	0.7697	800.00
27	LYO-1036	1.937	0.8261	40.00
28	LIQ-0077	0.002	0.0989	1.00
29	LIQ-0078	0.002	0.0965	1.00
30	LIQ-0079	0.002	0.0938	1.00
31	LIQ-0080	0.003	0.1202	1.00
32	LIQ-0081	0.002	0.1005	1.00
33	LIQ-0082	0.003	0.1160	1.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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