

Certificate of Analysis

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Sample Identification

Sample Name Tirzepatide 30 mg
Batch Number 20265522
Date Published 2026-05-28 13:52

Results for LYO-0172

Peptides	Result	Unit	Uncertainty	Acceptable Range
Tirzepatide Assay Peptide Screening 0.1% TFA	28.7	mg	[± 0.1]	
Tirzepatide Purity Peptide Screening 0.1% TFA	> 99.8	%		
Tirzepatide Identification by Spectrum (FTIR) Peptide Screening 0.1% TFA	1000		[± 5]	
Tirzepatide Identification by RT Peptide Screening 0.1% TFA	0.993		[± 0.005]	

	Method Specification	
Determination of identity, content and purity of Tirzepatide		
<i>Document number</i> TIRZ_003_2026	<i>Superseded document</i> -	<i>Number of pages</i> 3

1. Content Assesment

1.1. Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu CBM-20A	L20235355693
Degassing Unit	Shimadzu DGU-14A	NA
Pump A	Shimadzu LC-20AD	L20104350216
Pump B	Shimadzu LC-20AD	L20104451348
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Colum Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

1.2. Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.4 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Colum Temperature	60°C
Column	Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm
Detection wavelength	280nm

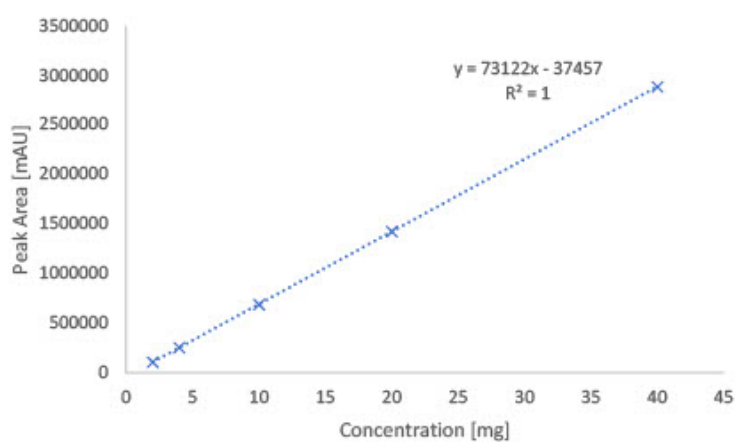
Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
20.50	5	95
21.00	5	95
21.05	95	5
26	end	

1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquote part of 1 mL was dispensed into HPLC vial for analysis.

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



2. Purity assessment

2.1 Instrumentation

Module	Name	Serial Number
System Controller	Shimadzu CBM-20A	L20235355693
Degassing Unit	Shimadzu DGU-14A	NA
Pump A	Shimadzu LC-20AD	L20104350216
Pump B	Shimadzu LC-20AD	L20104451348
Autosampler	Shimadzu SIL-10ADvp	C21054109114
Colum Thermostat	Shimadzu CTO-10ACvp	C21033770144
Detector	Shimadzu SPD-10ADvp	C20994233588

2.2 Chromatographic conditions

Chromatographic conditions	
Eluent A	0.1% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.4 mL/min
Program	Gradient elution
Injection volume	0.5 µL
Colum Temperature	60°C
Column	Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm
Detection wavelength	214nm

Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
20.50	5	95
21.00	5	95
21.05	95	5
26	end	

1.5. Sample preparation

Whole amount of container was dissolved in 2mL of water (HPLC, Gradient Grade). Aliquote part of 1 mL was dispensed into HPLC vial for analysis.

1.6. 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 214 nm.

Analysis Report

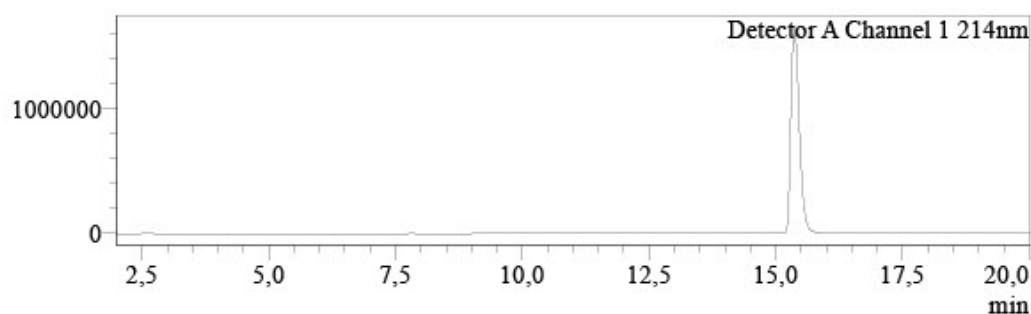


Sample Information

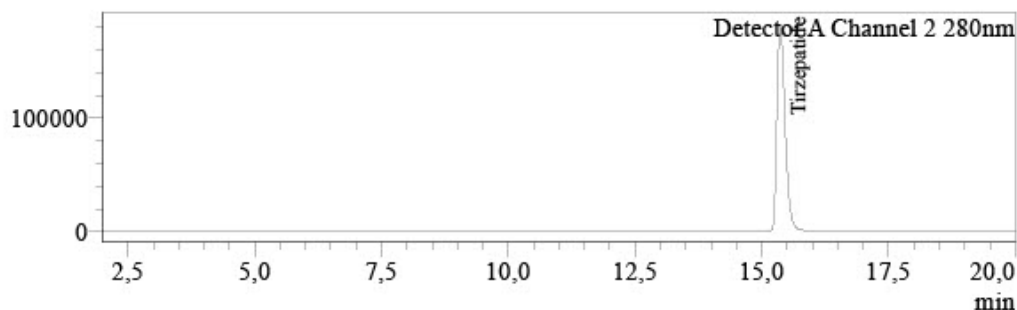
Injection Volume : 0,5
Data File : LYO-0172_008.lcd
Method File : Peptide screening_202602_GLPs_A.lcm
Date Acquired : 27.05.2026 20:02:08

Chromatogram

uAU



uAU



Peak Table

Detector A Channel 1 214nm

Peak#	Name	Ret. Time	Conc.	Unit	Area%
1		14.792	0,000		0,038
2		15.370	0,000		99,954
3		16,079	0,000		0,008
Total					100,000

Peak Table

Detector A Channel 2 280nm

Peak#	Name	Ret. Time	Conc.	Unit
1	Tirzepatide	15.367	28.670	mg
Total				

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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