

Certificate of Analysis

Compound Tirzepatide

Label Claim 30 mg

Batch/Lot hmup5hx



Analyte

Peptide Analysis

Chromatographic purity

Tirzepatide

Mass Spectral Match

<u>Result</u>	<u>Units</u>	<u>LOQ</u>	<u>% of Label</u>	<u>Method</u>	<u>Date</u>	<u>CAS</u>
>99.9	%	0.5		HPLC-UV/MS	5/29/2026	
34.4	mg	0.5	114.6	HPLC-UV-MS	5/29/2026	2023788-19-2
ID Confirmed				HPLC-UV-MS	5/29/2026	

Safer.

The data presented are from the analysis of the sample shown and meet Krause Analytical internal quality assurance criteria unless otherwise flagged.

Methods shown reference current Krause Analytical SOPs

ND - Not detected LOQ - limit of quantification

All values reported on a per vial basis unless otherwise noted

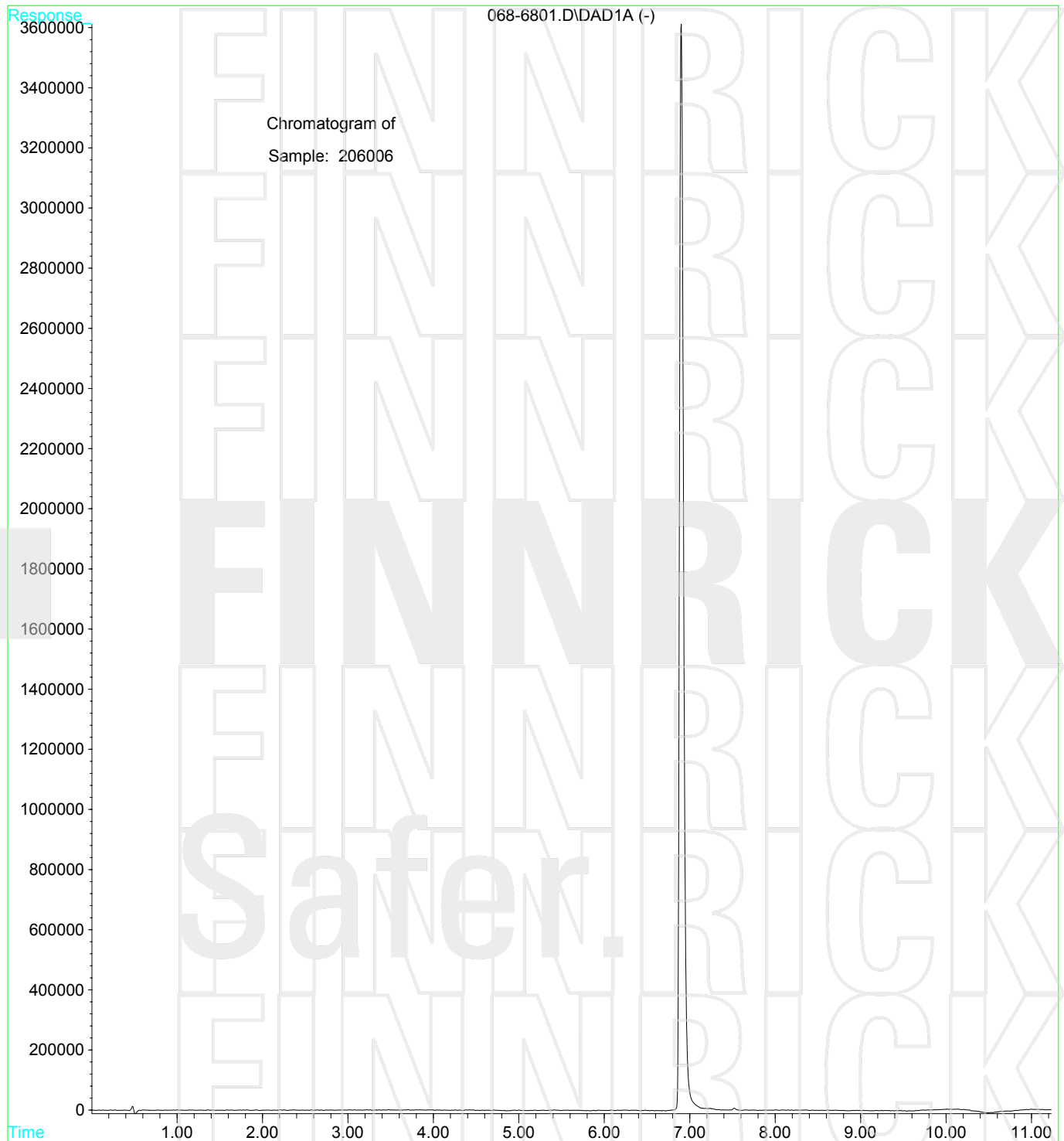
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Respectfully submitted,

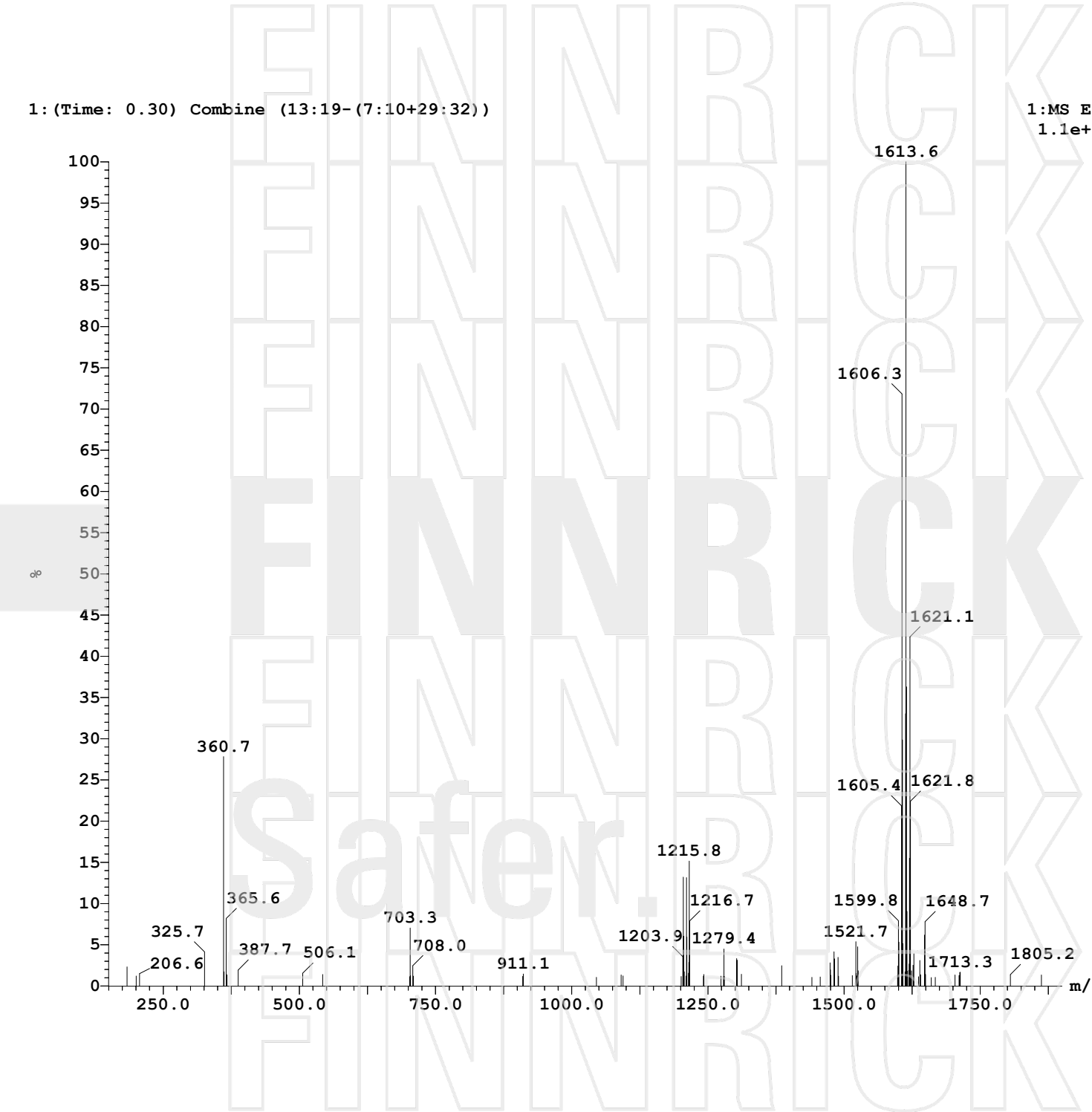


Mark C. Krause
Laboratory Director

CHROMATOGRAM

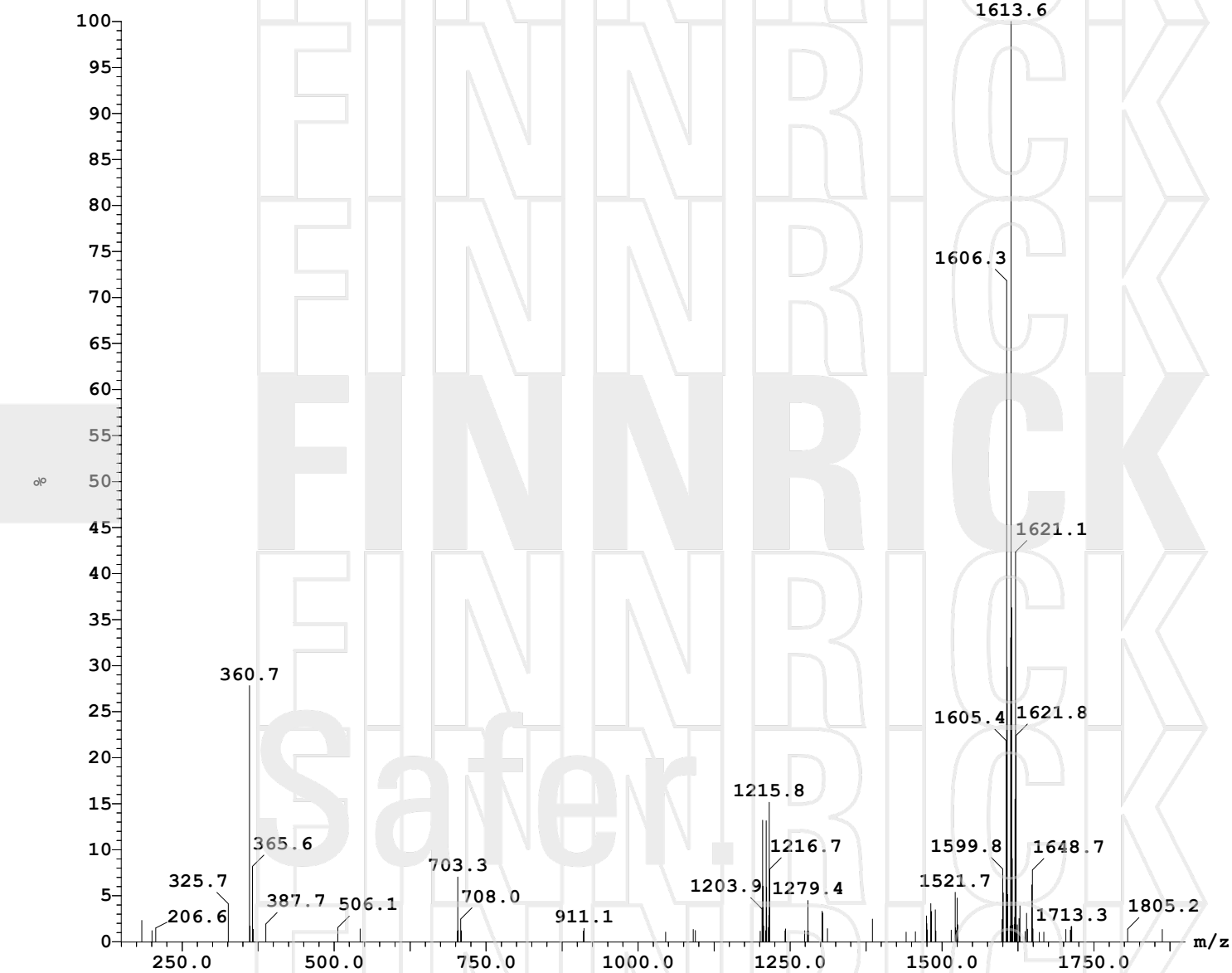


Sample Report:



1: (Time: 0.30) Combine (13:19-(7:10+29:32))

1:MS ES+
1.1e+005





Methods Summary

Purity/Potency/Identification

USP/NF 621

- 2 mL of purified water is added to the lyophilized powder in the vial, and the contents mixed to dissolve the lyophilized powder.
- An aliquot is taken from the vial and diluted to contain approximately 500 mg/L of the peptide.
- The diluted sample is analyzed by HPLC-UV-MS.
- The mass spectrum obtained is compared to an authentic standard of the peptide for identification.
- The total area of all of the peaks in the chromatogram is calculated, and the area of the peak of the peptide is divided by the total area to obtain the chromatographic purity value, reported in percent.
- The area of the peptide is compared to the area of the peptide peak in the known standard to obtain a concentration in the solution. This concentration is used to calculate the total mass of peptide in the vial, which is compared to the stated mass (label claim) and reported as both total mass in the vial and as a percent of the label claim.

Endotoxins

USP/NF 86

- 2 mL of purified water is added to the lyophilized powder in the vial, and the contents mixed to dissolve the lyophilized powder.
- An aliquot is taken from the vial and diluted in endotoxin-free water.
- The diluted sample is analyzed for endotoxins using the LAL method.

Metals

USP/NF 233

- 2 mL of purified water is added to the lyophilized powder in the vial, and the contents mixed to dissolve the lyophilized powder.
- An aliquot is taken from the vial and diluted in deionized water.
- The diluted aliquot is analyzed against known standards by ICP-MS