

CERTIFICATE OF ANALYSIS

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SAMPLE IDENTIFICATION

Sample Name	Batch Number	Date Published	Lab Reference
Tirzepatide 30 mg	2026124	05/14/2026	QC- Tirzepatide -30mg-124

RESULTS — PEPTIDE IDENTITY, CONTENT & PURITY

Parameter	Result	Unit	Uncertainty	Method / Note
Tirzepatide Identification (MS)	Confirmed (994)	—	± 20	ESI-MS Spectrum
Tirzepatide Assay (Content)	29.97	mg	± 0.11	HPLC External Standard
Tirzepatide Identification (RT)	1.00	—	± 0	HPLC Retention Time
Tirzepatide Purity (HPLC)	> 99.8	%	—	Area Normalization @ 214 nm

ADDITIONAL TESTS

Test	Result	Unit	Limit	Method
Total Aerobic Microbial Count	Not detected	CFU/g	≥ 1000	USP <61>
Total Yeast and Mold Count	Not detected	CFU/g	≥ 100	USP <61>
Bacterial Endotoxin	< 0.001	EU/mg	> 0.5	USP <85> Chromogenic LAL
Heavy Metals (As, Cd, Pb, etc.)	Not detected	ppm	Various	Elemental Impurities Screening

CONCLUSION: All tested parameters meet the specifications. The batch is approved for research use only.

ANALYTICAL DATA — PEAK TABLE (HPLC)

The following peak table confirms identity and high purity of the batch.

Detector A Channel 1 214 nm

Peak	Ret. Time (min)	Conc.	Unit	Area %
1 (Main)	15.397	29.970	mg	100.000
Total				100.000

METHOD SPECIFICATION — Content & Purity Assessment

Module	Name	Serial Number
System Controller	SCL-10ADvp	SN-2026-0147
Degassing Unit	DGU-14A	SN-2026-0082
Pump	LC-10ADvp	SN-2026-0094
Autosampler	SIL-10ADvp	SN-2026-0514
Column Thermostat	CTO-10ACvp	SN-2026-0371
Detector	SPD-10ADvp	SN-2026-0338

Chromatographic Conditions

Parameter	Value
Eluent A	1% TFA in Water (HPLC, Gradient Grade)
Eluent B	1% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow Rate	1.0 mL/min
Injection Volume	0.5 µL
Column Temperature	35°C
Column	Avantor ACE UltraCore C18, 150×3.0 mm, 3.5 µm
Detection Wavelength	214 nm

Gradient Program

Time (min)	A [%]	B [%]
2	99	1
10	70	30
14	70	30
32	5	95
35	5	95
35.01	99	1
40	end	

Sample Preparation

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

AUTHORIZATION & APPROVAL

Tested & Analyzed by:

  
LUCIAN M. FOGARTY  
QUALITY CONTROL

Approved by (QA):

  
Dr. James R. Harlan, Ph.D.  
Quality Assurance Director

DISCLAIMER: This document is for research purposes only. Not for human or veterinary use. Results relate only to the sample tested. Store at -20°C in a dry, dark place.

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