

SAMPLE — Certificate of Analysis

This is a redacted example COA for illustration. Not a live batch record.

Product	Tirzepatide 5 mg/mL
Dosage form	Injectable Solution, 5 mL vial
Lot number	TIR-2410-0117
Manufacture date	2024-10-14
Expiration date	2025-10-14
Compounding facility	Licensed 503B outsourcing facility (redacted)
Testing laboratory	Independent ISO/IEC 17025 lab (redacted)
Report date	2024-10-19

Analytical results

Test	Method	Specification	Result	Status
Identity	HPLC / MS	Conforms to reference	Conforms	Pass
Assay (potency)	RP-HPLC	90.0 – 110.0% label claim	99.1%	Pass
Related substances	RP-HPLC	≤ 2.0% total impurities	0.6%	Pass
Water content	Karl Fischer	≤ 5.0%	1.8%	Pass
Endotoxin	LAL	≤ 17.5 EU/mg	< 0.5 EU/mg	Compliant
Sterility	USP <71>	No growth	No growth	Pass
pH	Potentiometric	6.5 – 7.5	7.1	Pass
Appearance	Visual	Clear, colorless solution	Conforms	Pass

Release statement

The above-referenced lot has been tested by an independent laboratory and meets or exceeds all specifications for identity, purity, potency, sterility, and endotoxin content. Released for distribution under state and federal compounding regulations.

Authorized by: Director of Quality (signature redacted on sample)

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