# **Certificate of Analysis (COA)**

Product: Tirzepatide Brand: TrimFast Batch No.: TRZ-2025-001 Manufacture Date: 2025-03-15 Expiry Date: 2027-03-15 Test Date: 2025-03-20 Sampled By: Quality Control Department Tested By: FRANZLAB GmbH, Germany Lab Accreditation: ISO/IEC 17025:2017

### **Product Description:**

Name: Tirzepatide Form: Lyophilized (freeze-dried) white powder Strength: 5mg per vial Appearance: White to off-white sterile powder, free from visible contaminants Status: This product is supplied as a raw, unmixed powder. It has not been reconstituted or diluted. Solubility (for information only): Soluble in sterile water for injection

#### **Analytical Testing Results:**

Test	Specification	Result	Method	
Identification (HPLC/MS)	Positive for Tirzepatide	Pass	HPLC, Mass Spectrometr	
Purity by HPLC	>= 98.0%	99.76%	HPLC	
Related Substances	<= 1.0% total impurities	0.21%	HPLC	
Water Content (Karl Fischer)	<= 5.0%	1.2%	USP <921>	
Endotoxins (LAL)	<= 0.25 EU/mg	< 0.05 EU/mg	USP <85>	
Bacterial Endotoxin Test	Must comply	Complies	LAL Test	
Sterility	No growth	No growth	USP <71>	
pH (if reconstituted)	6.5 - 7.5	7.1 (N/A for raw	7.1 (N/A for raw pow/ser)<791>	
Residual Solvents	Below ICH Q3C limits	Pass	GC-MS	
Heavy Metals	<= 10 ppm	< 1 ppm	ICP-MS	

## Packaging & Storage:

Container: Sterile 5ml Type I glass vial with rubber stopper and flip-off seal Storage Conditions: 2°C - 8°C. Protect from light. Do not freeze.

Handling Note: Product must be reconstituted with sterile water prior to use under aseptic conditions.

## Conclusion:

Batch TRZ-2025-001 of Tirzepatide 5mg complies with all tested specifications. The product is certified as pharmaceutically pure and sterile. It is supplied as a raw, lyophilized white powder only - not mixed or pre-diluted.