

12393 Belcher Road S, Suite 450
 Largo, FL 33773
 Phone No.: (727) 471 0850
 Fax No.: (727) 544 3595



CERTIFICATE OF ANALYSIS AND COMPLIANCE

Product Name: Tirzepatide and Vitamin B6 Injection, 10 mg/mL and 10 mg/mL

Page 1 of 2

Batch No: I841H001A1

Pack Size: 25 Vials / Carton

Compounding Date: 2025/08/01

Specification No: I841

Standard Test Method No: B42

Beyond Use Date: 2026/04/27

Storage Conditions: Store between 2°C to 8°C (36°F to 46°F). Do not freeze. Protect from light.

BPI Labs, LLC., certifies that the methods used in, and the facilities and controls used for the manufacture, processing, packaging, storage, labeling, and testing of this product at our manufacturing site conform to the current Good Manufacturing Practices in accordance with 21 CFR Parts 210 and 211 Regulations.

Serial No.	Test	Specification	Result
1.	Description	A clear colorless to slightly yellow solution	A clear colorless solution
2.	Color of Solution by UV	NMT 0.2 Abs at 460 nm	0.0 Abs at 460 nm
3.	Identification of Tirzepatide by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the test Assay	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the test Assay
4.	Identification of Pyridoxine Hydrochloride by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the test Assay	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the test Assay
5.	pH USP <791>	Between 6.5 – 7.5	7.2
6.	Container Content USP <697>	NLT 1.0 mL	1.1 mL
7.	Particulate Matter USP <1>	Foreign Matter (Visible Particulates): Free from Visible Particulate matter.	Free from Visible Particulate matter
		Subvisible Particles USP <788> Method-1 Light Obscuration Particles ≥ 10 µm: NMT 6000 per container Particles ≥ 25 µm: NMT 600 per container	Particles ≥ 10 µm: 12 per container Particles ≥ 25 µm: 0 per container
8.	Tirzepatide Assay by HPLC	The Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of Tirzepatide (C ₂₂₅ H ₃₄₈ N ₄₈ O ₈₈)	102.1 %
9.	Pyridoxine Hydrochloride Assay by HPLC	The Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of Pyridoxine Hydrochloride (C ₈ H ₁₁ NO ₃ · HCl)	100.4 %

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Serial No.	Test	Specification	Result
10.	Benzyl Alcohol Content by HPLC	NLT 70.0% and NMT 110.0%	100.1 %
11.	Bacterial Endotoxins Test USP <85>	NMT 23.8 EU / mg of Tirzepatide	Less than 5.0 EU / mg of Tirzepatide
12.	Sterility Tests USP <71>	No evidence of microbial growth	No microbial growth observed

NMT: Not more than.
 NLT: Not less than.

Note: Batch was packaged from the Filled Product I841H001A.

The batch records and analytical records were reviewed and the batch was manufactured, packaged and tested in compliance with current Good Manufacturing Practices

The batch confirms with the specifications and is certified for release based on above requirements for distribution.

Quality Assurance Person Preparing Certificate <small>(Print Name / Signature / Date)</small>	Quality Assurance Person Authorizing Batch Release <small>(Print Name / Signature / Date)</small>
Marco Otolara  08/20/25	Mauricio Salazar M. Salazar 08/20/25
Title: Quality Assurance Disposition Auditor	Title: Chief Quality & Compliance Officer (CQCO)