
CERTIFICATE OF ANALYSIS AND COMPLIANCE

Product Name: Semaglutide Injection, 12.5 mg/2.5 ml (5 mg/ml)		**Page 1 of 2**
Batch No: l831H001A1	**Pack Size: 25 Vials / Carton**	**Compounding Date: 2025/01/13**
Specification No: 1831	Standard Test Method No: 832	**Beyond Use Date: 2026/01/07**
Storage Conditions:	Store between 2°C to 8°C (36° to 46°F). Do not freeze. Protect from light.	

The Lab 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 solution	A clear colorless solution
2.	Color of Solution By UV	NMT 0.1 Abs at 460 nm	0.0 Abs at 460 nm
3.	Identification A (by HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay
4.	pH USP <791>	Between 7.0 - 7.8	**7.7**
5.	Container Content USP <697>	**NLT 2.5** ml	2.7 ml
6.	Particulate Matter USP <1>	Foreign Matter (Visible Particulates): Free from Visible Particulates	Free from Visible Particulates
		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: 186 per container Particles 25 µm: 8 per container
7.	Assay by HPLC	Semaglutide Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of Semaglutide (C1B?H2e1N4sOse)	102.6 %
8.	Benzyl Alcohol content by HPLC	NLT 70.0% and NMT 110.0%	103.4 %
9.	Bacterial Endotoxins Test USP <85>	NMT 167 EU / mg of Semaglutide	Less than 20 EU/ mg of Semaglutide

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Serial No.	Test	Specification	Result
10.	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 1831H001A.

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 (Print Name/ Sicmature / Date)	**Quality Assurance Person Authorizing Batch Release** (Print Name/ Siqnature / Date)
Heba Shenouda Hebe. 02/03/zS	Mauricio Salazar M. Salazar OZ/03/25
Title: Quality Assurance Supervisor	**Title: Chief Quality & Compliance Officer (CQCO)**