ProRx
A PHARMACEUTICAL OUTSOURCING FACILITY

CERTIFICATION OF ANALYSIS

Product: Semaglutide ٢.٥mg/ml (٤ mL vial)	NDC: ٨٤١٣٩-٢٢٥-٠٤
Test Date: ١٢ December ٢٠٢٤	Batch No.: ProRx١٢١١٢٤-١
Date of Mfg: ١١ December ٢٠٢٤	Date of Exp: ١٠ June ٢٠٢٥

Test	Specification	Result
Appearance	Clear solution	Conforms
Semaglutide content by Eagle	٢.٢٥ to ٢.٧٥ mg/mL	٢.٥٩ mg/mL
Phenol content by Eagle	٤.٠ to ٥.٥ mg/mL	٤.٩٤ mg/mL
Sterility by ScanRDI	Conforms to sterility test as per USP <٧١<	Pass
Endotoxin	Conforms to specifications as per USP <٨٥<	Pass
Particulate	Conforms to specifications as per USP <٧٨٨<	Pass

Results excluding osmolality, appearance, and pH transcribed from third-party testing from Eagle Analytical.

Conclusion: Test results comply with product specifications

Pharmacist In Charge: Initials/Date	Rohemt Bilal	١٢/١٩/٢٠٢٤
Reviewed by: Initials/Date	Ais n Smi	١٩Dec٢٠٢٤

619 Jeffers Circle, Exton, PA 19341
prorxpharma.com

ProRx
A PHARMACEUTICAL OUTSOURCING FACILITY

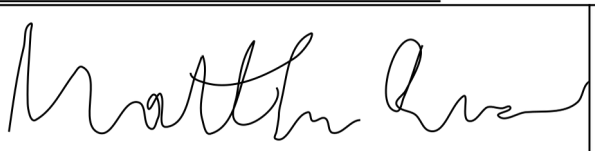
CERTIFICATION OF ANALYSIS

Product: Tirzepatide ٢٠ mg/mL (٣ mL vial)	NDC: ٨٤١٣٩-٢١٠-٠٢
Test Date: ١٢ March ٢٠٢٥	Batch No.: ProRx٠٣١١٢٥-٢
Date of Mfg: ١١ March ٢٠٢٥	Date of Exp: ٠٧ September ٢٠٢٥

Test	Specification	Result
Appearance	Clear solution	Conforms
Tirzeptaide content by Eagle	١٨.٠٠ to ٢٢.٠٠ mg/mL	٢٠.٠ mg/mL
Phenol content by Eagle	٤.٠ to ٥.٥ mg/mL	٥.٢٩ mg/mL
Sterility by ScanRDI	Conforms to sterility test as per USP <٧١>	Pass
Endotoxin	Conforms to specifications as per USP <٨٥>	Pass
Particulate	Conforms to specifications as per USP <٧٨٨>	Pass

Results excluding appearance transcribed from third-party testing from Eagle Analytical.

Conclusion: Test results comply with product specifications

Approved by: Initials/Date		١٨ March ٢٠٢٥
Reviewed by: Initials/Date	Aislynn Smith	١٨Mar٢٠٢٥

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LABORATORY REPORT

ProRx
619 Jeffers Cirle
Exton, PA 19341

Phone: 850-554-7809

Account #: E71770
Sample Name: Tirzepatide 60mg/3ml
Lot #: Prorx031125-2
Storage Conditions: Refrigerated

Date Received: 3/12/2025

Submission #: ETX-250311-0119

Chemistry Tests:

Potency (Peptides) (Tirzepatide : 2.00000 %) Date Started: 3/13/2025 Date Completed: 3/17/2025

Measured Concentration:	2.00 %
Potency:	100.0 %
Method:	USP<621>
Disclaimer:	This testing was performed in accordance with the CGMP regulations, using a formulation-specific validated analytical method.

Potency (Solution) (Phenol : 0.50000 %) Date Started: 3/13/2025 Date Completed: 3/17/2025

Measured Concentration:	0.529 % 105.8 % USP<621>
Potency:	This testing was performed in accordance with the cGMP regulations, using a formulation-specific validated analytical method.
Method:	
Disclaimer:	

Microbiology Tests:

ScanRDI Sterility Test Date Started: 3/12/2025 Date Completed: 3/14/2025

Method Suitability: ETX-241029-0220	
Result:	Pass

USP <788> Particulate Matter in Injections Date Started: 3/13/2025 Date Completed: 3/14/2025

Test Method:	USP<788> - Method 1 Light Obscuration Particulate Count Test
Small Volume Injection - 10um (Numerical):	129.2000 Particles/Container
Small Volume Injection - 10um (Pass/Fail):	Pass
Small Volume Injection - 25um (Numerical):	0.2000 Particles/Container
Small Volume Injection - 25um (Pass/Fail):	Pass

USP <85> Bacterial Endotoxin Test Date Started: 3/13/2025 Date Completed: 3/14/2025

Numerical Value :	<10 EU/mL
Endotoxin Limit:	350 EU/mL
Result:	Pass

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CERTIFICATION OF ANALYSIS

Product: Nicotinamide Adenine Dinucleotide (NAD) ١٠٠ mg /ml ١٠ ml MDV	NDC: ٨٤١٣٩-٣١٠-١٠
Test Date: ٠٢ May ٢٠٢٥	Batch No.: ProRx٠٤٢٥٢٥-٣
Date of Mfg: ٢٥ Apr ٢٠٢٥	Date of Exp: ٢٤ Jul ٢٠٢٥

Test	Specification	Result
Appearance	Clear to yellow solution	Conforms
NAD content	٩٠ to ١١٠ mg /mL	٩٧.٤ mg /mL
Benzyl Alcohol content	٠.٩ to ١.١ mg /mL	١.٠١ mg /mL
Sterility by ScanRDI	Conforms to sterility test as per USP <٧١<	Pass
Endotoxin	Conforms to specifications as per USP <٨٥<	Pass
Particulate	Conforms to specifications as per USP <٧٨٨<	Pass

Results excluding appearance transcribed from third-party testing from Eagle Analytical Services Inc.

Conclusion: Test results comply with product specifications

Pharmacist In Charge: Initials /Date	Matthew Bross	2025-05-05
Reviewed by: Initials /Date	Aislynn Smith	2025-05-05

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浙江湃肽生物股份有限公司
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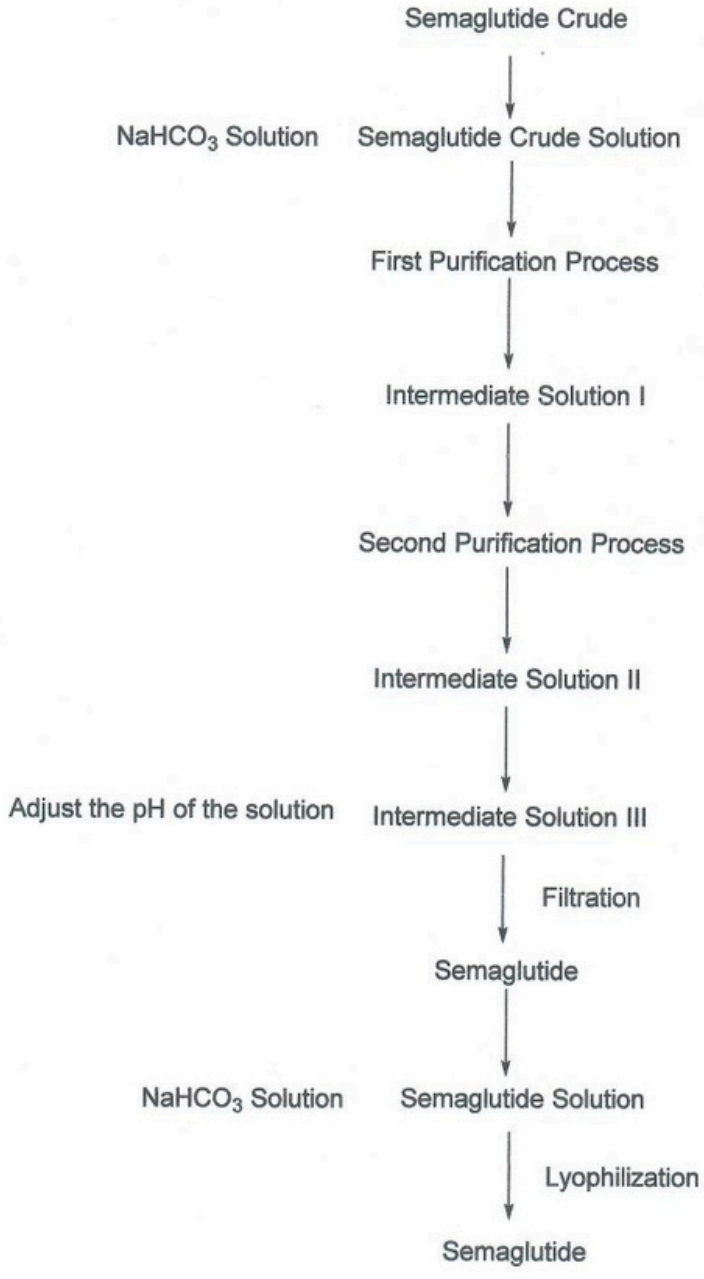
Tel: ++86-575-83130006-8023
Email:zpc@peptide-china.com
https://www.peptide-china.com

Declaration of Semaglutide API Salt Free Form

The Semaglutide API manufactured by Zhejiang Peptites Biotech Co., Ltd. is obtained through solid phase peptide synthesis, cleavage of resin-bound peptide, reverse phase HPLC purification and lyophilization. The flow chart from the purification to the end of the process is displayed as follows:



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1）Starting from AM resin Fmoc protected amino acids (for some residues, Fmoc protected dipeptide fragments as building blocks) were assembled stepwisely from the C-terminal to the N-terminal according to the sequence of Semaglutide. When it came to the branch site, the side chain was preferentially constructed and then the assembling of the main chain continued. After solid phase peptide synthesis, resin-bound peptide was obtained.

2）After cleavage of resin-bound peptide and precipitation of cleavage cocktail, the crude product of Semaglutide was obtained.

3）Through dissolving of the crude product, and then primary purification and secondary purification, Semaglutide solution with qualified purity was obtained.

4）With pH adjustment and precipitation, the solid state of Semaglutide API was obtained. In order to adjust the dispersity and homogeneity, sodium bicarbonate solution was charged. The obtained solution was filtered, then lyophilized to afford the final product.

In conclusion, the API of Semaglutide obtained by our process is salt free. The charge of sodium bicarbonate solution in the process is used for cosolvation. The resulting sodium cations exist as residue in the final API. Therefore, it is hereby declared that the Semaglutide API manufactured by Zhejiang Peptites Biotech Co., Ltd. is a salt-free form.

Signature: 杨志刚 Yang Zhigang (QP)

Date: 2023.06.29

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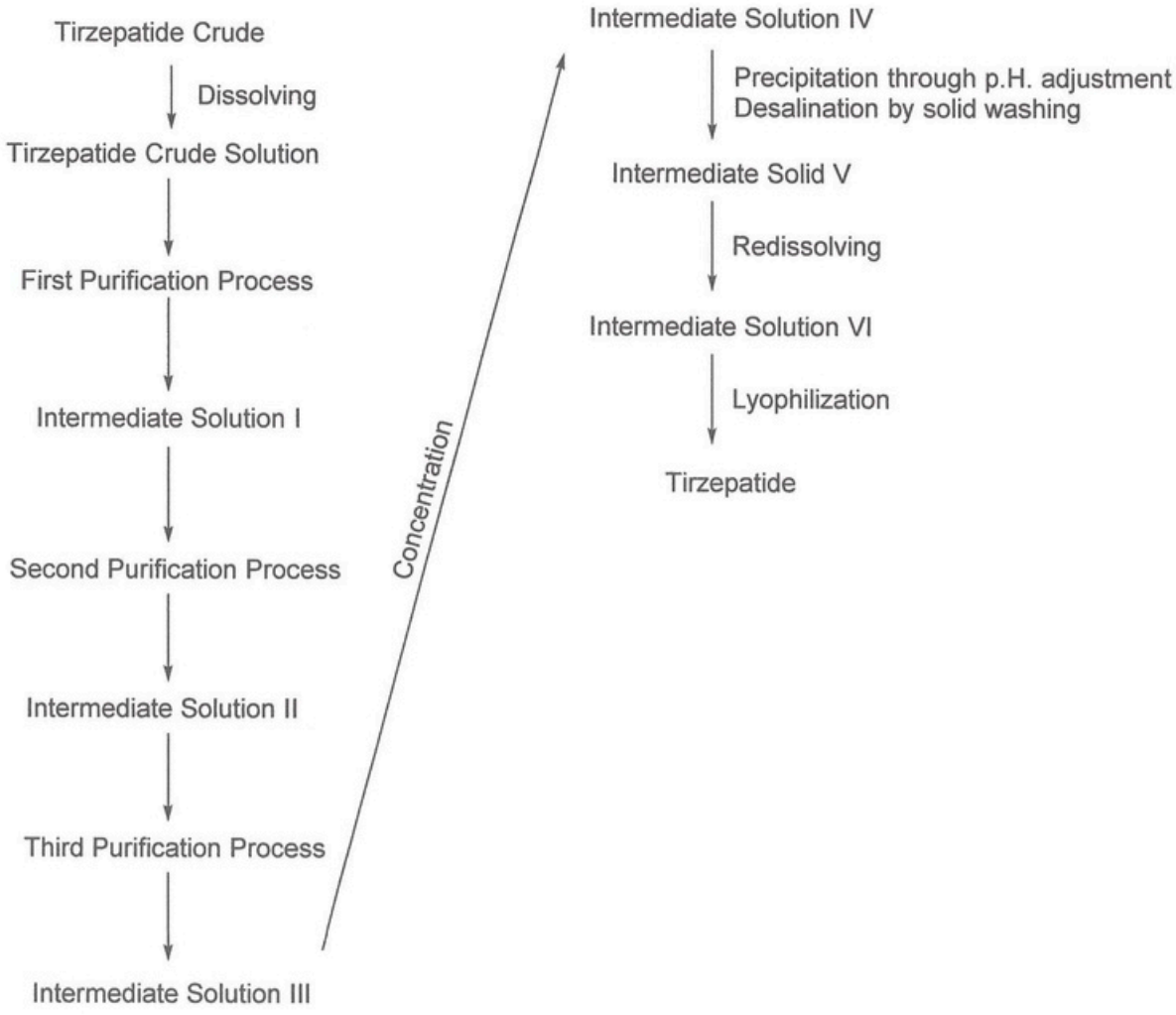
Email:zpc@peptide-china.com
https://www.peptide-china.com

Declaration of Tirzepatide API Salt Free Form

The Tirzepatide API manufactured by Zhejiang Peptites Biotech Co., Ltd. is obtained through solid phase peptide synthesis, cleavage of resin-bound peptide, reverse phase HPLC purification and lyophilization. The flow chart from Tirzepatide crude to Tirzepatide process is displayed as follows:



1）Starting from Rink-Amide AM resin Fmoc protected amino acids (for some residues, Fmoc protected dipeptide, Boc protected tetrapeptide, Fmoc protected pentapeptide fragments acted as building blocks) were assembled stepwisely from the C-terminal to the N-terminal according to the sequence of Tirzepatide.

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2）The resin-bound peptide obtained from step 1 was then cleaved and the cleavage cocktain solution was precipitated to yield Tirzepatide Crude.

3）Through dissolving of the crude product, primary purification, secondary purification, and tertiary purificaion, Tirzepatide solution with qualified purity was obtained (Intermediate Solution III in the flow chart). It was then concentrated to afford Intermediate Solution IV.

4）With pH adjustment and precipitation, the solid state of Tirzepatide API was obtained. It was then rinsed with solvent to remove the salt. In order to adjust the dispersity and homogeneity, sodium hydroxide solution was charged. The obtained solution was filtered for sterilization, then lyophilized to afford the final product.

In conclusion, the API of Tirzepatide obtained by our process is salt free. The charge of sodium hydroxide solution in the process is used for cosolvation. The resulting sodium cations exist as residue in the final API. Therefore, it is hereby declared that the Tirzepatide API manufactured by Zhejiang Peptites Biotech Co., Ltd. is a salt-free form.

Signature:

Date: 2024.05.23