

## DALIAN HANDOM CHEMICALS CO.,LTD.

Add.: RM702, Unit 1, Building 21, Liuhe Road, Ganjingzi Dist, Dalian, Liaoning, China E-mail: info@handom-chem.com Web.: www.handom-chem.com

## **Certificate of Analysis**

**Invoice Number: 23HDC/INV140** 

Date: Dec. 4th, 2023

Product Name		Semaglutide		CAS No.		910463-68-2			
Molecular Formula			C <sub>187</sub> H <sub>291</sub> N <sub>45</sub> O <sub>59</sub>		Molecular Weight	4113.58			
Sequence		Ala-A amino	His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-N6-[N-(17-carboxy-1-oxoheptadecyl-L-γ-glutamyl[2-(2-aminoethoxy)ethoxy]acetyl[2-2-aminoethoxy)ethoxy]acetyl]-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly-OH						
Batch No.		HDC20231121 Batch Quantity			35.00g				
Mfg. Date		Nov 21st, 2023 Retest Date		Nov 20th, 2026					
Test Items		Specifications			Test Results				
Appearance		White or off-white powder			White powder				
Solubility			Freely soluble in water; Firstly, to add freshly boiled and cooled water to make a clear solution containing 0.15mg of semaglutide in 1ml. Then, to adjust the pH of the solution to 5.5 with 0.05M hydrochloric acid and keep for 30 seconds. Finally, to adjust the pH of the solution to 3.0 and keep 30 seconds. The solution should be turbid in the range of pH 3.0 to 5.5.			Conforms			
Identification	HPLC		As obtained in the Assay, the difference between the retention time of the major peak of the sample solution and the reference solution should be less than 1 minute.			Conforms			
	Peptide Mapping		Peptide mapping of sample solution is similar to that of reference solution.			Conforms			
	N-terminal amino acid sequence					Conforms			
pH Value		$7.0 \sim 8.0$			7.5				
Water Content (K. F)		Not more than 8.0%			5.5%				
Related Substances			Hydrophilic Impurities		NMT 1.5%	0.6%			
			Hydrophobic Impurities 1		NMT 1.0%	0.5%			
			Hydrophobic Impurities 2		NMT 0.2%	Not detected			
		Total Impurities		NMT 2.0%	1.1%				
High Molecular Weight Proteins		Not more than 0.2%			0.1%				
			Ethanol		NMT 0.5%	0.1%			
Residual Solvents		Acetonitrile		NMT 0.041%	0.026%				
		Dichloromethane NMT 0.06%		Not detected					
Biological Activity		Should be 0.7U ~ 1.3U per 1mg			0.8U/mg				
Residual Host Cell Protein		Not more than 100ng/mg	-	大连汉德姆精细化	学的有限公司				

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Batch No.		HDC20231121	Batch Quantity		35.00g		
Mfg. Date		Nov 21st, 2023		Retest Date	Nov 20th, 2026		
Test Items		Specif	Test Results				
Residual Host Cell DNA		Not more than 10ng/mg	<1.25ng/mg				
Bacterial Endotoxins		Not more than 10EU/mg	Conforms				
Microbial Limits		Total Aerobic Microbial Count		NMT 100CFU/g	Conforms		
		Total Yeasts and Moulds Cou	unt	NMT 100CFU/g	Conforms		
Assay(C <sub>187</sub> H <sub>291</sub> N <sub>45</sub> O <sub>59</sub> )		Containing Semaglutide 0.76	0.88mg/mg				
Conclusion		The testing results of this batch are complied with the Enterprise Standard.					

**Storage Conditions:** Preserved in unopened original containers at a temperature of -20±5°C for long-term storage; kept away from direct sunlight, heat and moisture.

**Remark:** This product was prepared by chemical synthesis. For research and development use only, not for human use.

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