



# Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.  
TEL: 0086-571-86758373 FAX: 0086-571-81131109

## CERTIFICATE OF ANALYSIS

<b>Product Name</b>	Semaglutide		
<b>Batch No.</b>	P20240304	<b>CAS No.</b>	910463-68-2
<b>Molecular Formula</b>	C <sub>187</sub> H <sub>291</sub> N <sub>45</sub> O <sub>59</sub>	<b>Molecular Weight</b>	4113.58
<b>Mfg. Date</b>	2024.03.04	<b>Expiry Date</b>	2027.03.04
<b>Quantity</b>	200G	<b>Shipping Qty</b>	200G
<b>Sequence</b>	His- Aib- Glu- Thr- Phe- Thr- Ser- Asp- Val- Ser- Ser- Tyr- Leu- Glu- Gly - Gln- Ala- Ala- N6 - [ N- ( 1 7 - carboxy- l- oxoheptadecyl- L- γ - glutamyl[ 2 - ( 2 - aminoethoxy] acetyl[ 2 - 2 - aminoethoxy) ethoxy] acetyl] - Lys- Glu- Phe- Ile- Ala- Trp- Leu- Val- Arg- Gly- Arg- Gly-OH		
<b>Items</b>	<b>Specification</b>		<b>Results</b>
<b>Appearance/ Colors</b>	White or almost white powder		White loose powder
<b>Solubility</b>	Freely soluble in water; Firstly, to add freshly boiled and cooled water to make a clear solution containing 0.15 mg of semaglutide in 1 ml. Then, to adjust the pH of the solution to 5.5 with 0.05 M 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 rang of pH 3.0 to 5.5		Conforms
<b>Specific Optical Rotation[α]<sub>D</sub><sup>20</sup></b>	-15.0° to -10.0°(anhydrous and odium ion-free substance, C= 10 mg/ml, H <sub>2</sub> O)		-12.0°
<b>Identification by HPLC</b>	The retention time of the principal peak of the test solution corresponds to that of the reference solution, as obtained in the assay		Conforms
<b>Molecular Ion Mass by MS</b>	4113.58 ± 1.0		4113.67
<b>Amino Acid Content</b>	Asp:0.9-1.1 Ser:2.7-3.3 Glu:4.5-5.5 Gly:3.6-4.4 His:0.9-1.1 Arg:1.8-2.2 Thr:1.8-2.2 Ala:2.7-3.3 Aib:0.9-1.1 Tyr:0.9-1.1 Val:1.8-2.2 Lys:0.9-1.1 Ile:0.9-1.1 Leu:1.8-2.2 Phe:1.8-2.2 AEEA: Should be detected		1.0 2.9 5.0 4.0 1.0 2.0 2.0 3.1 1.1 1.0 2.0 1.0 1.0 2.0 2.0 2.0 Conforms





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<b>Peptide Map</b>	The peptide map of the test solution corresponds to that of the reference solution, as obtained in the assay	Conforms
<b>Specific Activity</b>	70%~150%	115%
<b>PH</b>	7.0-9.0	8.1
<b>Water Content(K.F)</b>	≤ 8.0%	4.6%
<b>Solution Clarity and Color</b>	Clear and colorless	Conforms
<b>Purity(HPLC)</b>	≥ 95.0%	97.0%
<b>Related Substance (HPLC)</b>	Total impurity ≤ 5.0%	3.0%
<b>High Molecular Protein</b>	≤ 0.50%	ND
<b>Residual Solvent</b>	Acetonitrile ≤ 410 ppm	ND
	Isopropyl ether ≤ 5000 ppm	ND
<b>Host Cell Protein</b>	≤ 0.01%	Conforms
<b>Host Cell DNA</b>	≤ 10.0ng/mg	Conforms
<b>Microbial Limits</b>	TAMC ≤ 10 <sup>3</sup> cfu/g	Conforms
	TYMC ≤ 10 <sup>2</sup> cfu/g	Conforms
<b>Trifluoroacetate Ion</b>	≤ 0.10%	ND
<b>Acetate Ion</b>	≤ 0.10%	ND
<b>Phosphate Ion</b>	≤ 0.10%	ND
<b>Peptide Content</b>	≥ 85.0%	91.1%
<b>Particle Size Distribution</b>	90% particles (d <sub>90</sub> ): < 30 μm	Conforms
<b>Storage</b>	Preserve in tight containers. Store at a temperature -15°C to -25°C	
<b>Conclusion</b>	The product tested Conform with In-house standard	

QC: Lin Jia Xin

Reviewer: Sheng Jia hao

Checker: Tan Ying ying

