

# Certificate of Analysis

ANALYTICAL TESTING

COA No.: C005A23002-01

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		
Batch No.	C005A-D230301	Batch Quantity	1840.859g		
Manufacturing Date	Mar. 29 <sup>th</sup> , 2023	Retest Date	Mar. 28 <sup>th</sup> , 2026		
Sampling Date	Apr. 1 <sup>st</sup> , 2023	Report Date	Apr. 18 <sup>th</sup> , 2023		
【ITEMS】		【SPECIFICATIONS】		【RESULTS】	
Appearance		White or almost white loose powder or lumps		White loose 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 for 30 seconds. The solution should be turbid in the range of pH 3.0 to 5.5		Conforms	
Specific rotation[α] <sup>20</sup> <sub>D</sub>		-15.0° to -10.0° on the anhydrous and sodium-free basis(C=10mg/ml in water)		-14.2°	
Identification	Identification by HPLC	The retention time of the principal peak of the test solution corresponds to that of the reference solution, as obtained in the Assay		Conforms	
	Identification by MS	4113.58 ± 1.0		4113.00	
	Amino acid content	Asp: 0.9 to 1.1 Ser: 2.7 to 3.3 Glu: 4.5 to 5.5 Gly: 3.6 to 4.4 His: 0.9 to 1.1 Arg: 1.8 to 2.2 Thr: 1.8 to 2.2 Ala: 2.7 to 3.3 Aib: 0.9 to 1.1 Tyr: 0.9 to 1.1 Val: 1.8 to 2.2 Lys: 0.9 to 1.1 Ile: 0.9 to 1.1 Leu: 1.8 to 2.2 Phe: 1.8 to 2.2 AEEA: Should be detected		Asp: 1.0 Ser: 3.0 Glu: 5.1 Gly: 4.0 His: 1.0 Arg: 2.0 Thr: 2.0 Ala: 3.0 Aib: 1.1 Tyr: 1.0 Val: 2.0 Lys: 1.0 Ile: 1.0 Leu: 2.0 Phe: 1.9 AEEA: Be detected	
Water (Karl Fischer)		NMT 8.0%		4.2%	
Clarity and color of solution		Clear and colorless		Conforms	
pH		Should be 7.0 to 9.0		8.1	
Sodium ion		Should be 1.5 to 4.0%		2.3%	

Prepared by: Yinyang Xiao Apr. 18<sup>th</sup>, 2023 QC reviewed by: Hao. Zeng Apr. 18<sup>th</sup>, 2023  
 QA reviewed by: Li Tang Apr. 18<sup>th</sup>, 2023 Released by: Hongfeng He Apr. 18<sup>th</sup>, 2023

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Related substances 1	Impurity A NMT 0.3% Impurity D NMT 0.3% Impurity E NMT 0.1% Other impurity (Except for RRT≈0.95) NMT 0.1% Total impurities NMT 1.5%	N.D. 0.07% N.D. 0.04% 0.3%
Related substances 2	Impurity B NMT 0.1% Impurity C NMT 0.1%	N.D. N.D.
High molecular protein	NMT 0.5%	0.02%
Residual solvents	Methanol NMT 3000ppm Isopropanol NMT 5000ppm Acetonitrile NMT 410ppm DCM NMT 600ppm Isopropyl ether NMT 5000ppm DMF NMT 880ppm	N.D. N.D. 24ppm N.D. 2ppm N.D.
Acid group ions	Trifluoroacetate ion NMT 0.1 % Phosphate ion NMT 0.1% Chloride ion NMT 0.1% Acetate ion NMT 0.1%	N.D. N.D. 0.002% 0.021%
Bacterial endotoxin	Less than 10EU/mg	Conforms
Microbial enumeration tests	TAMC NMT 200 cfu/g; TYMC NMT 100 cfu/g	<10cfu/g <10cfu/g
Assay	Containing Semaglutide (C <sub>187</sub> H <sub>291</sub> N <sub>45</sub> O <sub>59</sub> ) 95.0%~105.0%, on the anhydrous and sodium-free basis.	100.3%
<b>Conclusion:</b> This batch of product complies with <i>Enterprise Specification</i> (STP-QC-5010-02(01))		

Storage: Keep in tight container, protect from light, store at a temperature of  $-20 \pm 5^{\circ}\text{C}$ .

Prepared by: Yinyang Xiao Apr. 16th 2023    QC reviewed by: Hao Zeng, Apr. 18th, 2023  
 QA reviewed by: Li Tang Apr. 18th, 2023    Released by: Hongfen He, Apr. 18th, 2023