



河北能纤化工进出口有限公司

Hebei Nengqi an Chemical Import and Export Co., LTD.

Certificate of Analysis

Product	Semaglutide	CAS No.:	910463-68-2
Molecular Formula	C ₁₈₇ H ₂₉₁ N ₄₅ O ₅₉	Molecular Weight	4113.58
Sequence	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.	NQ-240507	Quantity	1200g
Mfgr. Date	May.07 th , 2024	Retest Date	May.06 th , 2026

【ITEMS】	【SPECIFICATIONS】	【RESULTS】
Appearance	White or almost white loose powder	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 30 seconds. The solution should be turbid in the range of pH 3.0 to 5.5.	Conforms
Specific optical rotation [α] _D ²⁰	-15.0 ° to -10.0 ° (anhydrous and sodium-free basis, C=10mg/ml, H ₂ O)	-13.8 °
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
Molecular Ion Mass	4113.58±1.0	Conforms
Amino acid content	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	0.9 2.8 4.8 3.8 1.0 2.1 1.9 2.8 1.0 0.9 1.9



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	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 0.9 1.9 1.9 Conforms
pH	6.0~9.0	7.3
Water content(KF)	NMT 8.0%	2.8%
Solution clarity and color	Clear and colorless	Conforms
Related substances (HPLC)	Any individual impurity: NMT 0.5% Total impurities: NMT 1.5%	0.2% 0.3%
Purity(HPLC)	NLT 98.0%	99.7%
Sodium ion	1.0%-2.0%	1.6%
High molecular protein	NMT 0.5%	0.02%
Residual solvent	Methylene chloride NMT 600ppm Acetonitrile NMT 410ppm Methyl tert-butyl ether NMT 5000 ppm DMF NMT 880ppm	N.D 84ppm N.D N.D
Peptide Content	Reported value	95.3%
Bacterial Endotoxins	NMT 10EU/mg	Conforms
Microbial Limits	TAMC NMT 200cfu/g TYMC NMT 100cfu/g	10cfu/g <10cfu/g
Acid group ions	Trifluoroacetate ion NMT 0.1% Acetate ion NMT 0.1%	N.D N.D
Assay(C₁₈₇H₂₉₁N₄₅O₅₉)	95.0%-105.0%(Calculated with reference to the anhydrous and sodium-free basis.)	98.5%
Storage	Keep in tight container, protect from light, store at a temperature of -20±5 °C.	
Conclusion: This batch of product complies with Enterprise Standard.		

Reported By: Yuwen Kang

Reviewed By: Yuanke Dai

