

Certificate of analysis

Semaglutide Expressed Injection Grade

CAS No	910463-68-2	Code	BIOJSEGEX-1G
Lot No	CMT-2404004F	Manufacture Date	Apr.25, 2024
Expiry Date	Apr.24, 2026	Quantity	30G

Testing Items	Specifications	Results
Appearance	White or almost white powder	White loose powder
Sequence	His-Aib-Glu-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)acetyl[2-2-aminoethoxy)ethoxy]acetyl]-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly-OH	Conforms
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 $[\alpha]^{20}_D$	-15.0° to -10.0° (anhydrous and odium ion-free substance, C=10mg/ml, H ₂ O)	-12.0°
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 by MS	4113.58 ± 1.0	4113.67
Amino Acid Content	Asp: 0.9~1.1	1.0
	Ser: 2.7~3.3	2.9
	Glu: 4.5~5.5	5.0
	Gly: 3.6~4.4	4.0
	His: 0.9~1.1	1.0
	Arg: 1.8~2.2	2.0
	Thr: 1.8~2.2	2.0
	Ala: 2.7~3.3	3.1
	Aib: 0.9~1.1	1.1
	Tyr: 0.9~1.1	1.0
	Val: 1.8~2.2	2.0
	Lys: 0.9~1.1	1.0
	Ile: 0.9~1.1	1.0
	Leu: 1.8~2.2	2.0
	Phe: 1.8~2.2	2.0
AEEA: Should be detected	Conforms	

Peptide Map	The peptide map of the test solution corresponds to that of the reference solution, as obtained in the assay	Conforms
Specific Activity	70%~150%	105%
pH	7.0~9.0	7.3
Water content(K.F)	≤8.0%	3.8%
Solution Clarity and Color	Clear and colorless	Conforms
Purity(HPLC)	≥99.0%	99.3%
Related Substance (HPLC)	Total impurities ≤1.0% Maximum single impurity ≤0.5%	0.7% 0.3%
High Molecular Protein	≤0.30%	0.15%
Residual Solvent	Acetonitrile ≤410ppm Isopropyl ether ≤5000ppm	0.7ppm ND
Bacterial Endotoxins	<10EU/mg	Conforms
Host Cell Protein	≤0.01%	Conforms
Host Cell DNA	≤10.0ng/mg	Conforms
Microbial Limits	TAMC ≤100cfu/g TYMC ≤100cfu/g	Conforms
Trifluoroacetate Ion	≤0.10%	ND
Acetate Ion	≤0.10%	ND
Phosphate Ion	≤0.10%	ND
Sodium Ion	≤3.0%	1.5%
Assay	≥85.0%	92.8%
Conclusion	This product conforms to In-house standard	

***Storage: Store at -15°C ~ -25°C, Protect from moisture and light.**