

Certification of Analysis

Product Name	Semaglutide	CAS No.	910463-68-2
Molecular Formula	C ₁₈₇ H ₂₉₁ N ₄₅ O ₈₉	Batch No.	P230525-YS840388
Molecular Weight	4113.58	Manufacturing Date	25.03.2025
Storage	Cool dry place	Retest Date	25.03.2025
Sequence	His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-N ⁶ -[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		
TEST		SPECIFICATION	RESULT
1	Appearance	White powder	White powder
2	Solubility	Freely soluble in water; Firstly, add 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 rang of pH 3.0 to 5.5.	Conforms
3	Specific optical rotation [α] _D ²⁰ -	-15.0°to-10.0(anhydrous and odium ion-free substance,C=10mg/ml,H ₂ O)	-12
4	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
5	Molecular Ion Mass	4113.58±1.0	Conforms
6	PH	7.0-9.0	7.9
7	Water Content (K.F)	NMT 8.0%	0.039
8	Solution clarity and color	Clear and colorless	Conforms

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9	<i>Amino acid content</i>	Asp: 0.9-1.1	1
		Ser:2.7-3.3	2.9
		Glu: 4.5-5.5	5
		Gly:3.6-4.4	4
		His: 0.9-1.1	1
		Arg:1.8-2.2	2
		Thr:1.8-2.2	2
		Ala:2.7-3.3	3.1
		Aib:0.9-1.1	1.1
		Tyr:0.9-1.1	1
		Val:1.8-2.2	2
		Lys:0.9-1.1	1
		Ile: 0.9-1.1	1
		Leu:1.8-2.2	2
		Phe:1.8-2.2	2
		AAEA: Should be detected	Conforms
10	<i>Related substances I</i>	Impurity A:NMT 0.3%	N.D
		Impurity D: NMT 0.3%	N.D
		Impurity E: NMT 0.1%	N.D
		Any individual impurity: NMT0.1%	N.D
		Total impurities: NMT1.5%	0.03%
11	<i>Related substances II (HPLC)</i>	Impurity B: NMT 0.1%	N.D
		Impurity C: NMT 0.1%	N.D
12	<i>Sodium ion</i>	1.5%-4.0%	2.20%
13	<i>High molecular protein</i>	NMT 0.5%	N.D
14	<i>Residual solvent</i>	Methylene chloride NMT 600ppm	N.D
		Acetonitrile NMT 410ppm	11ppm
		Methanol NMT 3000ppm	N.D
		DMF NMT 880ppm	N.D
		Isopropyl ether NMT 5000ppm	2ppm
		Isopropanol NMT 5000ppm	N.D
15	<i>Bacterial Endotoxins</i>	NMT 50EU/mg	Conforms
16	<i>Microbial Limits</i>	TAMC NMT 200cfu/g	<10cfu/g
		TYMC NMT 100cfu/g	<10cfu/g
17	<i>Acid group ions</i>	Trifluoroacetate ion NMT 0.1%	N.D
		Phosphate ion NMT 0.1%	N.D
		Chloride ion NMT 0.1%	0.01%
		Acetate ion NMT 0.1%	N.D
18	<i>Assay (C187H291N45O₈)</i>	95.0%-105.0%(Calculated with	96.90%