



瑾 岗 医 药 技 术 开 发 有 限 公 司

Hangzhou Jinlan Pharm-Drugs Technology CO., Ltd.

Certificate of Analysis

Product name	Semaglutide	CAS	910463-68-2
Batch no.	20230620	QTY	1200g
Manufacture date	2023-06-20	Test Date	2023-06-20
Report Date	2023-06-20	Retest date	2024-06-20
Package	50g/drum	Test method	G06 STP-QS-D006(Version No.09)
Storage condition	In an airtight container, protected from light, at a temperature of -15°C to -25°C		

Item	Specification	Results	
Appearance	White or almost white powder or loose lump	Conforms	
Solubility	Freely soluble in in water	Conforms	
MW	4112.6-4114.6 Da	4113.8 Da	
HPLC identification	Examine the chromatograms obtained in the assay.The retention time of main peak obtained in sample solution should be in accordance with retention time of main peak obtained in standard solution.	Conforms	
PH	7.0~9.0(C=5mg/ml)	7.8	
Appearance of solution	Colorless and clear liquid (C=10mg/ml)	Conforms	
Water	≤10%	3.7%	
Amino acid analysis	Asp	0.9-1.1	0.9
	Ser	2.1-3.9	2.6
	Glu	4.5-5.5	5.1
	Gly	3.6-4.4	4.0
	His	0.9-1.1	1.0
	Arg	1.8-2.2	2.1
	Thr	1.8-2.2	2.0
	Ala	2.7-3.3	3.0
	Aib	0.7-1.3	1.1
	Tyr	0.9-1.1	1.0
	Val	1.8-2.2	2.2
	Lys	0.9-1.1	1.0
	Ile	0.9-1.1	1.0
	Leu	1.8-2.2	2.1
Phe	1.8-2.2	2.1	
Trp	Present	Present	
Sodium ion	1.0%~3.0%	2.1%	
Carbonate	≤0.50%	0.09%	
Acetic acid	≤0.50%	N.D	
Trifluoroacetic acid	≤0.25%	N.D.	

Related Substance	G06-IM60	≤0.2%	0.08%
	G06-IM01	≤0.2%	0.07%
	G06-1M59	≤0.2%	0.06%
	G06-IM28	≤0.2%	0.08%
	G06-IM03	≤0.2%	0.07%
	Any other Unknown individual impurity	≤0.1%	N.D.
	Total Impurities	≤2.0%	0.29%
Residue solvents	Acetonitrile	≤410ppm	N.D.
	Triethylamine	≤5000ppm	17 ppm
	NN'-Diisopropylcarbodiimide	≤100ppm	N.D.
Polymer	≤0.5%		0.03%
Bacterial endotoxins	<10EU/mg		<10EU/mg
Microbial limit	Total aerobic microbial count	≤10 ² cfu/g	<10 cfu/g
	Total yeast and mold count	≤10 ² cfu/g	<10 cfu/g
	Escherichia coli	Absent	N.D.
Peptide content	≥80.0%		93.5%
Assay(on anhydrous and salt free substance basis)	95.0%-105.0%		99.3%
Conclusion	The test results conform to the enterprise standards.		

Tested by: Meng Xiao

Checked by: Shen Junli

Approved by: He Youguang

