



Hybio Pharmaceutical (Wuhan) Co.,Ltd.

Certificate of Analysis

S202411-001

QC2-P12-01

Product Name	Semaglutide	Batch Number	0372401A
Manufacture Date	Jul.09, 2024	Batch size	5kg
Test Date	Jul.13, 2024	Report Date	Nov.09, 2024
Retest Date	Jul.08, 2029	Storage	Store under -20±5℃ without direct sunlight after sealing
Test Standard	Semaglutide (SGL) quality specification (USA)		
Test Item	Specification	Result	
[Character]			
Appearance	The substance is white or off-white powder or loose mass	White powder	
Hygroscopicity	Hygroscopic	Conform (11%)	
Solubility	Freely soluble in water, insoluble in acetonitrile	Conform	
Specific optical rotation	$[\alpha]_D^{20} = -6.0^{\circ} \sim -16.0^{\circ}$ (calculated on the anhydrous and Sodium ion-free basis)	-7.0°	
[Identification]			
HPLC	Under the assay test, the difference between the retention time of the main peak of the test solution and that of the control solution shall not exceed 1minute	Conform(0.04min)	
MS	The monoisotopic molecular weight of the sample should be $4111.1 \pm 1.0\text{Da}$	4111.0Da	
Peptide mapping	The spectrum of the test solution should be consistent with the spectrum of the reference solution	Consist with the spectrum of the reference	
[Check]			
pH	6.0~9.0	6.4	
Water content	≤10.0%	3.5%	
Clarity and color of solution	The solution should be clear and colorless. Turbidity, if any, should not be more intense than the Reference Suspension No.1 stipulated in EP <2.2.1>.	Clear and colorless	

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Test Item	Specification	Result	
Amino acid analysis	Asp: 0.8~1.2	1.0	
	Ser: 2.4~3.6	2.7	
	Glu: 4.0~6.0	5.3	
	Gly: 3.2~4.8	3.9	
	His: 0.8~1.2	1.0	
	Aib: 0.8~1.2	1.2	
	Arg: 1.6~2.4	1.9	
	Thr: 1.6~2.4	1.9	
	Ala: 2.4~3.6	3.0	
	Tyr: 0.8~1.2	0.9	
	Val: 1.6~2.4	1.9	
	Lys: 0.8~1.2	1.0	
	Ile: 0.8~1.2	1.0	
	Leu: 1.6~2.4	2.0	
	Phe: 1.6~2.4	1.9	
	AEAA:1.6~2.4	2.0	
	Trp: Detected	Detected	
Related substance	IM-A $\leq$ 0.10%	N.D	
	IM-B $\leq$ 0.15%	0.03%	
	IM-C $\leq$ 0.3%	N.D	
	IM-D $\leq$ 0.15%	N.D	
	IM-F $\leq$ 0.10%	N.D	
	IM-G $\leq$ 0.10%	0.03%	
	IM-H $\leq$ 0.15%	0.02%	
	Unknown largest single impurity $<$ 0.10%	0.04%	
Purity	Total impurities $\leq$ 1.5%	0.24%	
	The purity should be $\geq$ 98.5%	99.8%	
Macromolecular impurities	$\leq$ 0.3%	0.02%	
Sulfate	$\leq$ 0.15%	0.01%	
Sodium ion	$\leq$ 3.0%	1.1%	
Residual solvent	Acetonitrile $\leq$ 0.041%	N.D	



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Test Item	Specification	Result	
Bacterial endotoxins	<2EU/mg	<2EU/mg	
Microbial limits	TAMC: ≤10 ² cfu/g TYMC: ≤5×10 ¹ cfu/g	TAMC: 1cfu/g TYMC: <1cfu/g	
[Assay]			
Peptide content	≥80.0%	97.6%	
Assay	95.0%~105.0% (anhydrous and sodium ion-free substance)	102.3%	
No content below			
武汉三药制药有限公司 4201161601876			
Conclusion	Tests were performed according to Semaglutide (SGL) quality specification (USA) ,the results conform with specification.		
Remark	R&D only.		
Reporter	Ming Yang	Date	Nov. 09, 2024
Reviewer	Zhaoyin Li	Date	Nov. 09, 2024

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