



Hybio Pharmaceutical (Wuhan) Co.,Ltd.

Certificate of Analysis

DE202508-010

QC2-P12-01

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Product Name	Semaglutide	Batch Number	0402401A
Manufacture Date	Jan.17, 2025	Delivery Quantity	370g
Test Date	Jan.20, 2025	Report Date	Aug.07, 2025
Retest Date	Jan.16, 2030	Storage	Store under -20±5℃ without direct sunlight after sealing
Test Standard	2-TSF-0055 Semaglutide (MGL) quality specification (version 1.0)		
Test Item	Specification	Result	
[Character]			
Appearance	The substance is white or off-white powder or loose mass	White powder	
Hygroscopicity	Hygroscopic	Conform (14%)	
Solubility	Freely soluble in water, very slightly soluble in ethanol	Conform	
[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 1 minute	Conform(0.07min)	
MS	The monoisotopic molecular weight of the sample should be 4111.1±0.5Da	4111.0Da	
Peptide mapping	The spectrum of the sample solution should be consistent with the spectrum of the reference solution	Consist with the spectrum of the reference	
[Check]			
pH	7.0~9.0	8.1	
Water content	≤8.0%	2.3%	
Clarity of solution	≤2NTU	0.3NTU	
Color of solution	Colorless	Colorless	
Residual solvents	Acetonitrile≤0.041%	0.0016%	
Sulfate	≤0.10%	0.003%	
Sodium ion	≤3.0%	2.4%	
Ammonium ion	≤0.10%	0.01%	
Macromolecular impurities	≤0.3%	0.02%	



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Test Standard		2-TSF-0055 Semaglutide (MGL) quality specification (version 1.0)		
Test Item		Specification		Result
Amino acid analysis	Asp: 0.9~1.1		1.0	
	Ser: 2.4~3.0		2.7	
	Glu: 4.5~5.5		5.0	
	Gly: 3.6~4.4		4.0	
	His: 0.9~1.1		1.0	
	Aib: 0.7~1.3		1.2	
	Arg: 1.8~2.2		1.9	
	Thr: 1.8~2.2		1.9	
	Ala: 2.7~3.3		3.0	
	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	
	Trp: Detected		Detected	
	Related substances	SEMA-IM-A≤0.10%		0.01%
SEMA-IM-B≤0.10%		0.01%		
SEMA-IM-C≤0.3%		0.01%		
SEMA-IM-D≤0.10%		N.D.		
SEMA-IM-F≤0.10%		0.06%		
SEMA-IM-G≤0.05%		0.05%		
SEMA-IM-H≤0.15%		0.01%		
RRT0.96≤0.10%		0.01%		
Unknown impurity<0.10%		0.07%		
Total impurities≤1.5%		0.38%		
Bacterial endotoxin	<10EU/mg		<5EU/mg	
Microbial limit	TAMC: ≤10 ² cfu/g		TAMC: 1cfu/g	
	TYMC: ≤5×10 ¹ cfu/g		TYMC: <1cfu/g	
[Assay]	Assay test			Each 1mg containing Semaglutide (C ₁₈₇ H ₂₉₁ N ₄₅ O ₅₉) should be 0.76~1.00mg. 0.97mg(96.9%)
Conclusion		Tests were performed according to 2-TSF-0055 Semaglutide (MGL) quality specification (version 1.0), the results conform with specification.		
Remark		/		
Reporter		Heng Xu	Date	Aug. 07, 2025
Reviewer		Qi Fang	Date	Aug. 07, 2025

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