



Hybio Pharmaceutical (Wuhan) Co., Ltd

Certificate of Analysis

METAPHARMACEUTICAL

N DE LOTE:

0129125

S202210-001

2021/225

QC2-P3-01

Product Name	Semaglutide		
Batch number	0302201A	Batch size	/
Manufacture Date	Oct.12, 2023	Test Date	Oct.15, 2023
Retest Date	Oct.11, 2028	Report Date	Oct.28, 2023
Test Standard	2-TSF-0039 Semaglutide 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 (13%)	
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 (0.001min)	
MS	The monoisotopic molecular weight of the sample should be 4111.1±1.0Da	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	6.0~8.0	6.4	
Water content	≤8.0%	2.1%	
Solution clarity	≤2NTU	0.3NTU	
Solution color	The solution is colorless	Colorless	
Residual solvent	Acetonitrile≤0.041%	0.0008%	
Sulfate	≤0.15%	0.009%	
Sodium ion	≤3.0%	1.3%	
Macromolecular impurities	≤0.3%	N.D	

Add: No.9, Linkong West Street, Hengdian Street, Huangpi District, Wuhan City, China

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Test Item	Specification	Result	
Amino acid analysis	Asp: 0.9~1.1	1.1	
	Ser: 2.4~3.3	2.7	
	Glu: 4.5~5.5	5.4	
	Gly: 3.6~4.4	3.9	
	His: 0.9~1.1	1.0	
	Aib: 0.7~1.3	1.3	
	Arg: 1.8~2.2	1.9	
	Thr: 1.8~2.2	2.0	
	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	1.1	
	Ile: 0.9~1.1	1.0	
	Leu: 1.8~2.2	2.0	
	Phe: 1.8~2.2	1.8	
	Trp: Detected	Detected	
Related Substance	IM-A≤0.10%	N.D	
	IM-B≤0.15%	0.02%	
	IM-C≤0.3%	N.D	
	IM-D≤0.15%	N.D	
	IM-F≤0.10%	N.D	
	IM-G≤0.10%	0.06%	
	IM-H≤0.15%	0.05%	
	Unknown largest single impurity<0.10%	0.05%	
Bacterial endotoxins	Total impurities≤1.5%	0.35%	
	<10EU/mg	<5EU/mg	
Microbial limits	TAMC: ≤10 ² cfu/g	TAMC: <1cfu/g	
	TYMC: ≤5×10 ¹ cfu/g	TYMC: 1cfu/g	

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Test Item	Specification	Result	
[Assay]			
Assay	Each 1mg API shall contain 0.76~1.00mg of Semaglutide (C ₁₈₇ H ₂₉₁ N ₄₅ O ₅₉).	0.99mg	
No content below			

