



Hybio Pharmaceutical (Wuhan) Co.,Ltd.

Certificate of Analysis

CPY202209-006

QC2-P3-01

Product Name	Semaglutide		
Batch Number	0302203A	Batch	1524.39g
Manufacture Date	Sept.02, 2022	Test Date	Sept.05, 2022
Retest Date	Sept.01, 2027	Report Date	Sept.13, 2022
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 (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 1minute	Conform(0.2min)	
MS	The monoisotopic molecular weight of the sample should be $4111.1 \pm 1.0\text{Da}$	4111.7Da	
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	$\leq 8.0\%$	3.3%	
Solution clarity	$\leq 2\text{NTU}$	0.6NTU	
Solution color	The solution is colorless	Colorless	
Residual solvent	Acetonitrile $\leq 0.041\%$	N.D	
Sulfate	$\leq 0.15\%$	0.004%	
Sodium ion	$\leq 3.0\%$	1.2%	
Macromolecular impurities	$\leq 0.3\%$	0.01%	



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Test Item	Specification	Result	
Amino acid analysis	Asp: 0.9~1.1	1.0	
	Ser: 2.4~3.3	2.5	
	Glu: 4.5~5.5	5.2	
	Gly: 3.6~4.4	3.9	
	His: 0.9~1.1	1.0	
	Aib: 0.7~1.3	1.2	
	Arg: 1.8~2.2	2.0	
	Thr: 1.8~2.2	1.9	
	Ala: 2.7~3.3	2.9	
	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	2.0	
	Phe: 1.8~2.2	2.1	
	Trp: Detected	Detected	
Related substance	IM-A $\leq$ 0.10%	N.D	
	IM-B $\leq$ 0.15%	0.04%	
	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%	0.02%	
	IM-H $\leq$ 0.15%	N.D	
	Unknown largest single impurity $\leq$ 0.10%	0.04%	
Bacterial endotoxins	$\leq$ 10EU/mg		$\leq$ 5EU/mg
Microbial limits	TAMC: $\leq 10^2$ cfu/g		TAMC: ≤ 1 cfu/g
	TYMC: $\leq 5 \times 10^1$ cfu/g		TYMC: ≤ 1 cfu/g



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

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