Hybio Pharmaceutical（Wuhan）Co.,Ltd.

Certificate of Analysis

DE202412-033 QC2-P12-01

Product Name	Tirzepatide	Batch Number	0422401A
Manufacture Date	Sept.26,2024	Delivery Quantity	5g
Test Date	Oct.08, 2024	Report Date	Dec.17, 2024
Retest Date	Sept.25,2026	Storage	Store under -20±5℃ without direct sunlight after sealing
Test Standard	2-TSF-0052 Tirzepatide quality specification (Version 2.0)		

Test Item	Specification	Result
[Character]		
Appearance	White or off-white powder or loose lump	White powder
Hygroscopicity	Has hygroscopic properties,with a hygroscopic weight gain of less than 15% but not less than 2%	Conform(11%)
Solubility	Freely soluble in water.almost insoluble or insoluble in acetonitrile	Conform
Specific optical rotation	-25°~ -35°(calculated with reference to the anhydrous and sodium ion-free)	-29°
[Identification]		
HPLC	The RT of the main peak of sample in the assay test should be consistent with that of the reference.	Conform
MS	The monoisotopic molecular weight of the sample should be 4810.5±0.5Da	4810.5Da
Peptide mapping	The retention time of characteristic peaks P1 to P5 in the chromatogram of the sample solution is consistent with the retention time of the reference solution	Conform
[Check]		
pH	6.0~8.5	6.2
Water content	≤10.0%	2.0%
Clarity and color of solution	The solution is colorless and clear	conform
Sodium ion	≤3.0%	0.9%

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Test Item	Specification	Result
Amino acid analysis	Asp: 1.8～2.2	2.1
	Ser: 4.0～5.0	4.2
	Glu: 3.6～4.4	4.1
	Gly: 3.6～4.4	3.9
	Thr: 1.5～2.2	1.8
	Ala: 3.6～4.4	4.0
	Pro: 3.6～4.4	4.1
	Tyr: 1.8～2.2	1.9
	Aib: 1.8～2.2	1.9
	Lys: 1.8～2.2	2.2
	Val: 0.9～1.1	1.0
	Ile: 2.7～3.3	3.0
	Leu: 1.8～2.2	2.0
	Phe: 1.8～2.2	1.9
Related substance	Method I	
	Impurity A≤0.15%	0.10%
	Method II	
	Impurity B≤0.12%	0.04%
	Impurities at position C and D(Deduction Method III impurity C and Impurity D)＜0.10%	0.03%
	Impurities at position E(Deduction Method III impurity E)＜0.10%	0.05%
	Impurity G＜0.15%	0.04%
	Impurities at position H(Deduction Method III impurity H)＜0.20%	0.02%
	Impurity I≤0.20%	0.11%
	Impurity J≤0.20%	N.D
	Other single impurity＜0.20%	0.07%
	Total impurities(Impurity A in method I) ≤2.0%	0.87%
	Method III	
	Impurity C＜0.10%	0.02%
	Impurity D＜0.10%	0.01%
	Impurity E＜0.10%	0.03%
	Impurity H＜0.13%	0.09%

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Test Item	Specification	Result
Polymer impurities	≤0.20%	0.04%
Residual solvent	Methanol: ≤3000ppm Acetonitrile: ≤410ppm	25ppm 336ppm
Bacterial endotoxins	<5EU/mg	<2.5EU/mg
Microbial limits	TAMC: ≤2×10^2cfu/g TYMC: ≤5×10^1cfu/g	TAMC: <1×10cfu/g TYMC: <1×10cfu/g
[Assay]		
Assay	95.0%~105.0% (calculated with reference to the anhydrous and sodium)	101.9%

No content below

Conclusion	Tests were performed according to2-TSF-0052 Tirzepatide quality specification (Version 2.0), the results conform with specification.		
Remark	R&D only.		
Reporter	Ming Yang	Date	Dec. 17, 2024
Reviewer	Qi Fang	Date	Dec. 17. 2024.

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