



Hybio Pharmaceutical (Wuhan) Co.,Ltd.

Certificate of Analysis

R&D-TR-01

Product name	Tirzepatide	Batch Number	HY222-YZP-20260719
Batch Quantity	30kg	Storage Condition	-20℃
Manufacturing Date	Jul. 19, 2026	Test Date	Aug. 03, 2026
Report Date	Aug.05, 2026	Exp Date	Jul. 18, 2028

Item	Specification	Result
Characters		
Appearance	White to off-white Powder.	White Powder
Solubility	Soluble in water.	Conform
Identification		
Identification-HPLC	The RT of the main peak in the Assay should be consistent with that of the reference.	Consist with the RT of reference
Identification-MS	Monoisotopic molecular weight: $4810.5 \pm 0.5\text{Da}$	4810.6 Da
Test		
Water content	$\leq 10.0\%$	3.7%
pH	6.0~9.0	6.9
Polymer impurities	$\leq 1.0\%$	0.05%
Sodium ion	Report the result	1.4%
Amino acid analysis	Glu:3.2~4.8	4.2
	Ser:4.0-6.0	4.7
	Gly:3.2~4.8	4.3
	Ala:3.2~4.8	4.2
	Thr:1.6-2.4	2.1
	Tyr:1.6 -2.4	2.2
	Ile:2.4~3.6	3.2
	Leu:1.6~2.4	2.2
	Pro:3.2~4.8	4.4
	Asp:1.6-2.4	2.2
	Phe:1.6~2.4	2.1
	Lys:1.6~2.4	2.1
	Val:0.8-1.2	1.1
	Aib:1.6~2.4	2.0
Peptide content	$\geq 92.0\%$	95.2%

Add: No.9, Linkong West Street, Hengdian Street, Huangpi District, Wuhan City, China. R&D Lab



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Item	Specification	Result
Assay	95.0%~105.0% (calculated with reference to the anhydrous and sodium)	100.3%
<i>Impurities</i>		
Related Substances	Largest single unspecified impurity:≤0.5%	0.08%
	Total impurities:≤1.0%.	0.69%
<i>Purity</i>		
Purity (HPLC)	≥99.0%	99.31%
<i>Residual solvents</i>		
Acetonitrile	≤410 ppm	120 ppm
<i>Microbial tests</i>		
Bacterial endotoxins	<10.0EU/mg	<2.5EU/mg
Microbial limits	TAMC≤10 ² cfu/g	2×10 cfu/g
	TYMC≤10 ² cfu/g	1×10 cfu/g
No content below		
Note	This product is intended for scientific research use only.	

Reporter	Heng Liu fu	Date	Aug. 05, 2020
Reviewer	Cuomgliang Li	Date	Aug. 05, 2020

