

CERTIFICATE OF ANALYSIS			
Product Name		Tirzepatide	
CAS No.		2023788-19-2	
Molecular Formula		C ₂₂₅ H ₃₄₈ N ₄₈ O ₆₈	
Lot No.		10451251002B	
Sequence		Tyr- {Aib} -Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile- {Aib} -Leu-Asp-Lys-Ile-Ala-Gln-Lys {Eicossandioic acid-gammaE-(AEEA)2} -Ala-Phe-Val-Gln-Trp-Leu-Ile-Ala-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser	
Modifications		C-Terminal Amide	
Storage Conditions		Preserve in an airtight, closed container protected from light at a temperature between -20±5°C.	
Test Items		Specifications	Results
Appearance		White or off-white powder	White powder (Conforms)
Solubility		Freely soluble in water	Conforms
		Insoluble in acetonitrile	Conforms
Identification	Mass Spectrometry Identification	4810.5±0.5 Da Monoisotopic Molecular Weight	Conforms
	Chromatographic Identification	The retention time of major peak in the chromatogram obtained from sample solution should correspond to that obtained from reference solution, as obtained in the Assay	Conforms
	Bioassay Identification	The relative potency (GIPR target) of Tirzepatide should be 0.7 ~ 1.3 of the reference substance	1.15
		The relative potency (GLP-IR target) of Tirzepatide should be 0.7 ~ 1.3 of the reference substance	1.09
Assay	Related Substances I	SPD104-Z82 ≤0.1%	0.02%
		SPD104-Z94 ≤0.1%	0.03%
		SPD104-Z17 ≤0.50%	0.05%
		Sum of SPD104-Z22 and SPD104-Z18 ≤0.50%	0.08%
		Sum of SPD104-Z29 and SPD104-Z95 ≤0.30%	0.06%
		Sum of SPD104-Z8 and SPD104-Z77 ≤0.30%	0.03%
		SPD104-Z76 ≤0.1%	Not Detected
		Any Other Impurity ≤0.10%	0.05%
		Total Impurities ≤2.0%	0.37%
	Related Substances II	SPD104-Z92 ≤0.20%	0.05%
		Total Impurities of Related Substances I and Related Substances II ≤ 2.1%	0.42%
	Assay	95.0% ~ 105.0% (calculated on anhydrous and ion-free basis)	99.1%
Specific Tests	Clarity and Color of Solution	The solution should be clear and colorless	Clear and Colorless
	Specific Rotation	-19.0° to -39.0° (calculated on anhydrous and ion-free basis)	-30.1°
	Water Content	≤10.0%	2.8%
	pH	6.0 ~ 7.5	6.5
	Oligomer	≤0.5%	0.03%
	Residual Solvents	Acetonitrile ≤0.041%	0.0045%
		Dichloromethane ≤0.060%	<0.0060%
		N,N-Dimethylformamide ≤0.088%	<0.0090%
		Methyl Tert-Butyl Ether ≤0.500%	<0.0500%

Certificate of Analysis				
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Modifications		C-Terminal Amide		
Storage Conditions		Preserve in an airtight, closed container protected from light at a temperature between -20±5°C.		
Test Items		Specifications	Results	
Specific Tests	Amino Acid Analysis	Glu (Gln): 3.2 ~ 4.8	4.1	
		Ser: 4.0 ~ 6.0	4.6	
		Gly: 3.2 ~ 4.8	4.1	
		Ala: 3.2 ~ 4.8	4.0	
		Thr: 1.6 ~ 2.4	1.9	
		Tyr: 1.6 ~ 2.4	2.0	
		Ile: 2.4 ~ 3.6	3.0	
		Leu: 1.6 ~ 2.4	2.0	
		Pro: 3.2 ~ 4.8	3.8	
		Asp: 1.6 ~ 2.4	1.9	
		Phe: 1.6 ~ 2.4	2.0	
		Lys: 1.6 ~ 2.4	2.0	
		Val: 0.8 ~ 1.2	1.0	
		Aib: 1.6 ~ 2.4	2.0	
		AEEA: 1.6 ~ 2.4	1.6	
		Trp: Present	Present	
		Anion	Chloride Ion ≤0.5%	0.013%
	Trifluoroacetic Acid ≤0.5%		Not Detected	
	Phosphate Ion ≤0.5%		Not Detected	
	Cation	Sodium Ion ≤2.0%	1.0%	
		Ammonium Ion ≤0.5%	Not Detected	
	Bacterial Endotoxins	<5 EU/mg	<5 EU/mg	
	Microbial Limit	The total aerobic mesophilic count should be ≤100 cfu/g	Conforms	
		The total yeasts and molds count should be ≤50 cfu/g	Conforms	
	Conclusion		This product complies with Enterprise Standard SPE-F017-1.0, SOP-QC-F016-1.0.	
	Note: Analytical results transcribed from the original COA provided by Sinocep-Allsino Biopharmaceutical Co., Ltd. Lot No.10451251002B.			
	Date of Mfg	25 Jan 2026		Date of Exp
Date of Test	12 Feb 2026		Date of Release	13 Feb 2026
Prepared By: Liang Guo		Released By: Yaqi Chen	Date: 11 Mar 2026	

Manufacturer: Sinopep-Allsino Biopharmaceutical Co., Ltd.

Manufactured and Packaged at the FDA registered facility: No.28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu 222069, China (CHN)