



Add: 9# Lvshan Road, Xian'an Economic Development District, Xanning City, Hubei Province, China
Tel: 86-0715-8310333

Certificate of Analysis

COA No.: C086A25004-01

Product Name	Tirzepatide	GAS No.	2023788-19-2
Molecular Formula	C ₂₂₅ H ₃₄₈ N ₄₈ O ₆₈	Molecular Weight	4813.5
Batch No.	C086A-B250301	Batch Quantity	6187.625g
Manufacturing Date	Mar.7 th , 2025	Retest Date	Mar.6 th , 2027
Sampling Date	Mar.9 th , 2025	Report Date	Mar.26 th , 2025
【ITEMS】		【SPECIFICATIONS】	【RESULTS】
Appearance	White or almost white loose powder or lumps		white powder
Solubility	Freely soluble in water, 50% Acetonitrile and DMSO		Conforms
Specific rotation[α] _D ²⁰	-20.0° to -35.0°(anhydrous and sodium ion-free basis)		-29.8°
Identification	Identification by HPLC	The retention time of the principal peak of the test solution corresponds to that of the reference solution, as obtained in the Assay	Conforms
	Identification by MS	4813.5±1.0	4813.4 (Entrustment Inspection)
	Amino acid content	Ser: 4.5~5.5 Gly: 3.6~4.4 Asp: 1.8~2.2 Glu: 3.6~4.4 Thr: 1.8~2.2 Ala: 3.6~4.4 Pro: 3.6~4.4 Aib: 1.8~2.2 Lys: 1.8~2.2 Tyr: 1.8~2.2 Val: 0.9~1.1 Ile: 2.7~3.3 Leu: 1.8~2.2 Phe: 1.8~2.2 Trp: Should be detected AEEA: Should be detected	Ser: 4.6 Gly: 4.0 Asp: 2.0 Glu: 4.1 Thr: 2.0 Ala: 4.0 Pro: 4.2 Aib: 2.1 Lys: 2.0 Tyr: 2.0 Val: 1.0 Ile: 3.0 Leu: 2.1 Phe: 2.0 Trp: Be detected AEEA: Be detected
Water Content (K. F)	NMT 8.0%		1.2%
pH	Should be 5.5 to 8.0		6.5
Clarity and color of solution	Clear and colorless		Conforms
Related Substance	Impurity A NMT 0.2% Impurity B+C NMT 0.5% Impurity D+E NMT 0.7% Impurity F+G NMT 0.45% Other impurity NMT 0.1% Total impurities NMT 2.0% (Impurity <0.05% is negligible)		0.07% 0.21% 0.29% 0.21% 0.07% 0.82%

Prepared by: Kaixing Jia Mar 26th, 2025 QC reviewed by: Jingqi Chen Mar. 26th, 2025
QA reviewed by: Li Jang Mar. 26th, 2025 Released by: Hongfeng He Mar. 26th, 2025



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polymer	NMT 0.3%	0.02%
Sodium ion	NMT 2.0%	0.8%
Residual solvent	Methylene chloride NMT 600ppm Acetonitrile NMT 410ppm Methanol NMT 3000ppm Isopropyl ether NMT 5000ppm DMF NMT 880ppm	ND 25ppm ND ND ND
Peptide content	Not less than 85.0%	97.2%
Bacterial endotoxin	Less than 5 EU/mg	Conforms
Microbial enumeration tests	TAMC NMT 200 cfu/g; TYMC NMT 100 cfu/g	<10cfu/g <10cfu/g
Assay	Containing Tirzepatide (C ₂₂₅ H ₃₄₈ N ₄₈ O ₆₈) 95.0%~105.0% on the anhydrous and sodium ion free basis).	100.3%
Conclusion: This batch of product complies with Enterprise Specification (STP-QC-5038-02(02))		

Storage: Keep in tight container, shading from light, store at a temperature of -20±5°C.



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

06 JUN 2025

Prepared by: Kaixing Jin Mar. 26th, 2025

QC reviewed by: Jing Chen Mar. 26th, 2025

QA reviewed by: Li Tang, Mar. 26th, 2025

Released by: Hongfeng He, Mar. 26th, 2025