

Hangzhou Huarong Pharm Co., Limited

Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong, China.

TEL: 0086-571-86758373

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Certificate of Analysis

COA No.: C08623001-02

Product Name	Tirzepatide	CAS No.	2023788-19-2
Molecular Formula	C ₂₂₅ H ₃₄₈ N ₄₈ O ₆₈	Molecular Weight	4813.5
Batch No.	C086-A230901-Y	Batch Quantity	1562.589g
Manufacturing Date	Sep.26 th , 2023	Retest Date	Sep.25 th , 2024
Sampling Date	Sep.27 th , 2023	Report Date	Dec. 22 nd , 2023
【ITEMS】		【SPECIFICATIONS】	
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)		-29.5°
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	4813.5
	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: 5.0 Gly: 4.1 Asp:1.9 Glu: 3.9 Thr: 2.0 Ala:4.0 Pro:4.1 Aib:1.9 Lys:2.0 Tyr: 2.0 Val: 1.0 Ile: 3.0 Leu: 2.0 Phe: 2.0 Trp: Be detected AEEA: Be detected
Water Content (K. F)	NMT 8.0%		2.5%
pH	Should be 5.5 to 8.0		6.6
Clarity and color of solution	Clear and colorless		Conforms
Related Substance	RRT≈0.94 NMT 0.3% RRT≈0.97 NMT 0.15% RRT≈1.04 NMT 0.3% RRT1.05+1.07 NMT 0.5% Other impurity NMT 0.1% Total impurities NMT 1.5% (Impurity <0.05% is negligible)		0.1% 0.08% ND 0.3% 0.06% 0.6%

Prepared by: Wei Zang Dec. 22nd, 2023

QC reviewed by: Hao Zeng Dec. 22nd, 2023

QA reviewed by: Li Tang, Dec. 22nd, 2023

Released by: Hongfeng He Dec. 22nd, 2023

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polymer	NMT 0.3%	N.D
Sodium ion	NMT 2.0%	0.9%
Residual solvent	Methylene chloride NMT 600ppm	ND
	Acetonitrile NMT 410ppm	54 ppm
	Methanol NMT 3000ppm	15 ppm
	Isopropyl ether NMT 5000ppm	ND
	DMF NMT 880ppm	ND
Peptide content	Not less than 85.0%	96.0%
Bacterial endotoxin	Less than 5 EU/mg	Conforms
Microbial enumeration tests	TAMC NMT 200 cfu/g;	10cfu/g
	TYMC NMT 100 cfu/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).	96.8%

Conclusion: This batch of product complies with *Enterprise Specification* (STP-QC-5038-02(00))

Storage: Keep in tight container, shading from light, store at a temperature of $-20 \pm 5^{\circ}\text{C}$.



Prepared by: Wei Zang Dec. 21nd, 2023 QC reviewed by: Hao Zeng Dec. 22nd, 2023
 QA reviewed by: Li Tang, Dec. 22nd, 2023 Released by: Hanffeng He, Dec. 22nd, 2023