

Product Name		Tirzepatide	CAS 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] ²⁰ D		-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 NMT0.5% Impurity D+E NMT0.7% Impurity F+G NMT0.45% Other impurity NMT0.1% Total impurities NMT2.0% (Impurity <0.05%is negligible)		0.07% 0.21% 0.29% 0.21% 0.07% 0.82%

Certificate of Analysis

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:Conform to Enterprise Standard		

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

Tested by Jin KaiXing

Checked by Li Xiang

Approved by Cheng Wei

SINOWAY INDUSTRIAL CO.,LTD.

