

Certificate of Analysis

Product Name: Tirzepatide	
CAS No. : 2023788-19-2	Batch No.: 20260117
MFG.Date: 2026-01-17	EXP. Date: 2028-01-16

Results of Inspection:

Item	Specification	Results
Appearance	White or off-white powder	Complies
Identification	IR: The infrared absorption spectrum of the sample complies with the reference standard.	Complies
	HPLC: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
Solubility	Soluble in water	Complies
Clarity and Color of Solution	Clear and Colorless	Complies
Specific Rotation $[\alpha]^{20D}$	-23.5° ~ -33.5° (anhydrous and sodium ion-free substance, C=10mg/ml, H ₂ O)	-30.56°
Molecular Ion Mass	4813.45±1.0Da	4813.78Da
Amino Acid Analysis	Ser: 4.5-5.5 Asn: 1.8-2.2 Pro: 3.7-4.3 Ala: 3.7-4.3 Gly: 3.7-4.3 Ile: 2.7-3.3 Leu: 1.8-2.2 Gln: 3.7-4.3 Val: 0.9-1.1 Phe: 1.8-2.2 Lys: 1.8-2.2 Tyr: 1.8-2.2 Thr: 1.8-2.2	Complies
PH	6.0~9.0	6.22
Moisture (K.F)	≤ 10.0%	2.7%
Sodium Ion	≤ 4.0%	1.3%

Acid Group Ions	Trifluoroacetate ion $\leq 0.1\%$	Not detected
	Acetate ion $\leq 0.1\%$	Not detected
Related Substances(HPLC)	Single impurity $\leq 0.5\%$	0.2%
Residual Solvents(GC)	Dichloromethane $\leq 600\text{ppm}$	< LOQ
	N, N-dimethylformamide $\leq 880\text{ppm}$	Not detected
	Acetonitrile $\leq 410\text{ppm}$	Not detected
	Methanol $\leq 3000\text{ppm}$	Not detected
Bacterial Endotoxins	$\leq 5\text{EU/mg}$	Complies
High Molecular Weight Species	$\leq 0.3\%$	0.06%
Peptide Content	$\geq 85.0\%$	95.5%
Purity (HPLC)	$\geq 99.0\%$	99.5%
Assay (HPLC)	95.0%~105.0% (on anhydrous and salt-free substance basis)	99.2%
Conclusion	This product complies with the Enterprise standards.	
Storage	Stored in a dry and well-closed container. For short term storage: 2~8°C For long term storage: -25~-15°C	
Examiner: 李青	Checker: 赵泽涛	Reviewer: 毕连海