

Hebei Shengsuan Chemical Co., Ltd.

Certificate of analysis

Product Name	Tirzepatide CAS:2023788-19-2	Catalog No.	Z-peptide-C0163
Salt Type	Na ⁺	Batch No.	P23022801
Sequence	Tyr-{Aib}-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-{Aib}-Leu-Asp-Lys-Ile-Ala-Gln-{diac id-gamma-Glu-(AEEA)2-Lys}-Ala-Phe-Val-Gln-Trp-Leu-Ile-Ala-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2		
Manufacturing Date	2023.02.28	Received Date	2025.02.29
Report Date	2023.03.01	Retest Date	2027.02.28
Test Reference	In-house specification/Protocol specification		

Test Items	Specification	Resul ts
Appearance	White to off white powder or loose lump	Conforms
溶解性 Solubility	Soluble in H2O	Conforms
HPLC	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution
Mass Spectrum	4813.45±1.0	4814.40
Clarity and color of solution	Clear and colorless	Conforms
Water	≤ 10.0%	3.5%
Acetic acid	≤ 5.0%	N.D
Sodium ion	≤3.0%	1.2%
Related Substances (HPLC)	Any individual impurity: ≤1.0% Total impurity: ≤2.0%	0.74% 1.54%
Purity	≥98%	99.6%
Bacterial endotoxin	<10EU/mg	Conforms

	Methanol: $\leq 0.3\%$	Methanol: N.D
	Isopropanol: ≤ 0.5%	Isopropanol: N.D
Residual solvents	Acetonitrile: ≤ 0.041%	Acetonitrile: 0.025%
	Methylene chloride: ≤ 0.06%	Methylene chloride: N.D
	N,N-Dimethylformamide: ≤ 0.088%	N,N-Dimethylformamide: N.D
	Tert-butyl methyl ether: $\leq 0.5\%$	Tert-butyl methyl ether: N.D
Peptide Assay	≥85.0%	92.8%
Packaging and storage	Store at a temperature of 2~8°C, protected from light.	IV. TX
Conclusion	The test results comply with the requirements of in-house spe	ecification.

Prepared by/Date

Reviewed by/Date

Approved by/Date