

CERTIFICATE OF ANALYSIS

Product	Tirzepatide	CAS	2023788-19-2
Batch No	P20250312	Quantity	1390.05 g
Molecular Formula	C ₂₂₅ H ₃₄₈ N ₄₈ O ₆₈	Molecular Weight	4813.4514
Manufacturing Date	Mar.13,2025	Expiration Date	Mar.12,2027
Report Date	Mar.14,2025	Standard	In house
Store at	protected from light; Store at -20±5℃		
Sequence	Tyr- {Aib}-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile- {Aib}-Leu-Asp-Lys-Ile-Ala-Gln- {diacid-gamma-Glu-(AEEA) ₂ -Lys}-Ala-Phe-Val-Gln-Trp-Leu-Ile-Ala-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH ₂		
Items	Specifications		Results
Appearance	White to off white powder		Conforms
Solubility	Soluble in water		Conforms
Identifacation (HPLC)	The retention time of the main principal of the test Solution corresponds to that of the reference Solution , as obtained in the assay		Conforms
pH	6.0 to 9.0		8.0
Water content (K.F)	≤5.0%		2.8%
Acetic acid	≤0.5%		0.1%
Trifluoroacetate ion	≤0.25%		0.01%
Sodium ion	≤5.0%		1.5%
Residual solvent	Methanol≤3000ppm		40ppm
	Acetonitrile≤410ppm		200ppm
	N,N-Dimethylformamide≤880pm		ND
Related substances	Maximum single impurity≤0.5%		0.44%
	Total impurities ≤1.0%.		0.44%
Purity(HPLC)	≥98.0%		99.5%
Impurities with molecular masses greater than that of tirzepatide	≤0.30%		0.06%

Microbiological contamination	Total aerobic microbial count $\leq 10^3$ cfu/g	< 1cfu/g
	Total combined Moulds and Yeasts $\leq 10^2$ cfu/g	< 1cfu/g
Assay	95.0%~105.0%	100.4%
Assay of Peptide	$\geq 85.0\%$	95.1%
Bacterial Endotoxin test	< 50EU/mg	Conforms
This is the end of the inspection items.		
Conclusion	The product conforms to In house standard	