

河北能纤化工进出口有限公司

Hebei Nengqian Chemical Import and Export Co., LTD.

质量分析报告(COA)

Certificate of analysis

产品名称 Product Name	Tirzepatide CAS:2023788-19-2	目录编号 Catalog No.	Z-peptide-C0163
盐类型 Salt Type	Na ⁺	批号 Batch No.	P25022801
序列 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-Ser-NH ₂		
生产日期 Manufacturing Date	2025.2.28	接收日期 Received Date	2025.2.28
报告日期 Report Date	2025.2.28	复检日期 Retest Date	2026.10.08
检验依据 Test Reference	内控质量标准/协议质量标准 In-house specification/Protocol specification		

检测项目 Test Items	标准 Specification	结果 Results
外观 Appearance	本品为白色至类白色粉末或疏松块状物 White to off white powder or loose lump	Conforms
溶解性 Solubility	溶于水溶液 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
分子量 Mass Spectrum	4813.45±1.0	4814.40
澄清度 Clarity and color of solution	无色澄清 Clear and colorless	Conforms
水分 Water	≤ 10.0%	3.5%
醋酸含量 Acetic acid	≤ 5.0%	N.D
钠离子 Sodium ion	≤3.0%	1.2%
有关物质 Related Substances (HPLC)	Any individual impurity: ≤1.0% Total impurity: ≤2.0%	0.74% 1.54%
纯度 Purity	≥98%	99.6%
细菌内毒素 Bacterial endotoxin	<10EU/mg	Conforms



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Residual solvents 残留溶剂	Methanol: $\leq 0.3\%$	Methanol: N.D	
	Isopropanol: $\leq 0.5\%$	Isopropanol: N.D	
	Acetonitrile: $\leq 0.041\%$	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	
肽含量 Peptide Assay	≥85.0%	92.8%	
包装和储存	2~8℃,遮光保存。		
Packaging and storage	Store at a temperature of 2~8°C, protected from light.		
结论	检测结果与内控质量标准相符。		
Conclusion	The test results comply with the requirements of in-house specification.		
备注	仅作为化工产品供应。		
Remark	It is only supplied as chemical product.		

起草/日期

Prepared by/Date

复核/日期

Reviewed by/Date

