Certificate of Analysis 检验报告书

RESEARCH USE ONLY Report No. SQ261022-TR40-R1

品名	Product	替尔泊肽 Tirzepatide	**批号**	Batch No.	SQ261022-TR40
CAS 号	CAS No.	2023788-19-2	**规格**	Strength	40 mg
生产日期	Mfg. Date	2026-10-22	**复检日期**	Retest Date	2027-10-21
检验日期	Test Date	2026-10-25	**执行标准**	Standard	In house / 企业标准
包装形式	Packaging	3ML vial lyophilized powder / 3ML 西林瓶冻干粉包装			

Test Item 检测项目	Acceptance Criteria 可接受标准	Result 检验结果
Appearance 性状	White or off-white powder 白色或类白色粉末	white powder 白色粉末
Solubility 溶解度	Soluble or freely soluble in water 在水中溶解或易溶	freely soluble in water 易溶于水
Average Molecular Weight 平均分子量	4813.45±10.0 Da	4813.32Da
Chromatographic Identification 色谱鉴别	The retention time of the main peak of Sample Solution should be consistent with that of the Standard solution,as obtained in the Assay 在含量测定项下记录的色谱图中，供试品溶液主峰的保 留时间应与对照品溶液主峰的保留时间一致	Meet the requirement 符合规定
PH	7.0-9.0	8.5
Clarity and Color of Solution 溶液的澄清度与颜色	Clarity: Clear transparent solution, free from turbidity, precipitate and insoluble particles. 应澄清无色	Colour:Colorless,clear 符合要求
Chromatographic Purity 色谱纯度	NLT98.0% 不小于98.0%	99.2%
Related Substances 有关物质	Maximum unknown single impurity NMT 0.5% 最大未知单杂不得过0.5%	0.23%
High Molecular Weight Proteins 高分子蛋白质	NMT0.8%	0.23%
Water Content 水分	NMT 3.0%	0.04%
Heavy Metals 重金属	NMT 10ppm	ND 均未检出

Verify online / 在线核验: seqline.bio/coa/tirzepatide-40mg-sq261022-tr40

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Tirzepatide 40 mg • Batch SQ261022-TR40 • Report SQ261022-TR40-R1 (continued / 续)

Test Item 检测项目	Acceptance Criteria 可接受标准	Result 检验结果
Residual Solvents 残留溶剂	Methanol NMT 3000ppm 甲醇不得过3000ppm	53ppm
	Acetonitrile NMT 410ppm 乙腈不得过410ppm	84ppm
	Dichloromethane NMT 600ppm 二氯甲烷不得过600ppm	23ppm
	N,N-Dimethylformamide NMT 880ppm N,N-二甲基甲酰胺不得过880ppm	12ppm
Microbial Limit 微生物限度	Total Aerobic Microbial Count NMT100 cfu/g 需氧菌总数应不得过100cfu/g	Meet the requirement 符合要求
Total bacteria 细菌总数	<1CFU/mg	Meet the requirements 符合要求
Peptide Content 肽含量	95.0%~105.0%(On Anhydrous and Sodium Free) 95.0%~105.0%(以无水、无钠离子计)	100.6%
Assay 含量	38.0~42.0mg	40.24mg

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