



南京汉欣医药科技有限公司

Nanjing Hanxin Pharmaceutical Technology Co., Ltd

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Certificate of Analysis

品 名	Product	替尔泊肽Tirzepatide	批 号	Batch	HXTZ260212
规 格	Grade	注射级API for Injection	数 量	Quantity	10g
生产日期	Mfg Date	2026-02-11	复 验 期	Retest Date	2028-02-10
检验日期	Test Date	2026-05-27	标 准	Standard	In house
包装形式	双层聚乙烯袋, 单层铝塑袋				
Package	Double layer polyethylene bag, Single layer aluminium-plastic film bag				

Test Item 检测项目	Acceptance Criteria 可接受标准	Test 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 溶解性	freely soluble in water 易溶于水	Meet the requirements 符合要求
Chromatographic Identification 色谱鉴别	The retention time of the major peak of the Sample Solution should correspond to that of the Standard Solution, as obtained in the Assay. 含量测定项下, 供试品溶液中主峰的保留时间与对照溶液一致。	Meet the requirements 符合要求
Average Molecular Weight 平均分子量	4813.5±1.0 Da	4813.58 Da
Specific rotation 比旋度	-23.5°~-33.5°	-29.1°
Clarity and colour of solution 溶液的澄清度与颜色	Solution be clear, colourless 应澄清无色	Meet the requirements 符合要求
pH	6.0-9.0	7.01
Peptide Content 肽含量	NLT 85.0% 不小于 85.0%	95.1%
Assay 含量	95.0%~105.0% (anhydrous and sodium free 无水无钠离子)	98.4%
Chromatographic Purity 色谱纯度	NLT 99% 不小于99%	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%	0.16%

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Test Item 检测项目	Acceptance Criteria 可接受标准	Test Result 检验结果
Polymer 聚合物	Total impurities should be NMT 1% 杂质总量应不得过1%	0.78%
	Maximum single impurity NMT 0.3% 最大单杂不得过 0.3%	<LOD
	Total impurities should be NMT 1.0% 杂质总量应不得过1.0%	<LOD
Water Content 水分	NMT 10.0% 不得过10.0%	2.9%
Sodium Content 钠离子含量	NMT 5.0% 不得过5.0%	1.2%
Residual Solvents 残留溶剂	Methanol NMT 3000 ppm 甲醇不得过3000 ppm	<LOD (LOD=180ppm)
	Acetonitrile NMT 410 ppm 乙腈不得过410ppm	<LOD (LOD=25ppm)
	N,N-Dimethylformamide NMT 880 ppm N,N-二甲基甲酰胺不得过880 ppm	ND (LOD=53ppm)
Bacterial Endotoxins 细菌内毒素	Less than 5 EU per mg 应小于5EU/mg	Meet the requirements 符合要求
Microbial Limit 微生物限度	The total aerobic bacteria count should be NMT 100 cfu/g 需氧菌总数不超过 100cfu/g	Meet the requirements 符合要求
	Total Yeasts and Molds count does not exceed 100 cfu/g 霉菌和酵母菌总数不超过 100cfu/g	Meet the requirements 符合要求
Conclusion 结论	☒ Meet the requirements 符合要求	☐ Do not meet the requirements 不符合要求

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