CERTIFICATE OF ANALYSIS

产品检验报告

1. Product Identification 产品信息

Product Name 产品名称	Retatrutide	**Synonym / CAS No.** 别名/CAS 号	2381089-83-2
Catalog No. 产品编号	HXRT	**Batch / Lot No.** 批号	HXRT260502
Molecular Formula 分子式	C221H342N46O68	**Molecular Weight (Da)** 分子量 (Da)	4731.33
Sequence 氨基酸序列	N/A		
Quantity 数量	20 g	**Package** 包装形式	Double-layer polyethylene bag + double-layer aluminium-plastic film bag
Manufacturing Date 生产日期	2026-05-19	**Test Date** 检验日期	2026-05-29
Retest Date 复验期	2028-05-18	**Storage Condition** 储存条件	N/A
Reference Standard 检验依据	In-house Specification		

2. Test Results 检测结果

Test Item 检测项目	Specification 标准规定	Result 检验结果
2.1 Description / Physical Properties 性状 / 物理性质		
Appearance 性状	White or off-white powder	White powder
Solubility 溶解度	Soluble or freely soluble in water	Complies
Clarity & Color of Solution 溶液澄清度与颜色	Clear and colorless solution	Complies
pH pH 值	6.0 - 8.5	7.0
2.2 Identification 鉴别		
HPLC (Retention Time) HPLC 保留时间	Retention time of the main peak corresponds to that of the standard	Complies

	solution	
Mass Spectrum (Da) 质谱 (Da)	Average molecular weight 4731.3 ± 1.0 Da	4731.5 Da
Amino Acid Analysis 氨基酸分析	Not Tested	Not Tested
2.3 Purity & Related Substances (HPLC) 纯度与有关物质 (HPLC)		
Chromatographic Purity 色谱纯度	≥ 98.0% (in-house limit; supplier specification: ≥ 94.0%)	99.2%
Single Largest Impurity 最大单杂	≤ 0.5%	0.24%
Total Impurities 总杂质	≤ 2.0% (in-house limit; supplier specification: ≤ 6.0%)	0.79%
High Molecular Weight Proteins 高分子蛋白质	≤ 0.8%	0.02%
2.4 Content / Assay 含量 / 效价		
Peptide Content (N% method) 肽含量 (氮含量法)	≥ 85.0%	92.1%
Assay (anhydrous & salt-free basis) 含量 (以无水无盐计)	95.0% - 105.0% (anhydrous and sodium-free basis)	98.6%
Counter-ion Content (Sodium) 抗衡离子含量	≤ 3.0%	1.6%
2.5 Residual Solvents (GC, ICH Q3C) 残留溶剂 (气相色谱, 依据 ICH Q3C)		
Methanol 甲醇	≤ 3000 ppm	50 ppm
Ethanol 乙醇	Not Tested	Not Tested
Isopropanol 异丙醇	Not Tested	Not Tested
Acetonitrile 乙腈	≤ 410 ppm	38 ppm
Dichloromethane 二氯甲烷	≤ 600 ppm	ND
N,N-Dimethylformamide N,N-二甲基甲酰胺	≤ 880 ppm	ND
Triethylamine 三乙胺	Not Tested	Not Tested
Tert-butyl Methyl Ether 叔丁基甲基醚	Not Tested	Not Tested
2.6 Water Content (Karl Fischer) 水分 (卡尔费休法)		
Water	≤ 10.0%	5.2%

水分		
2.7 Microbiological Examination 微生物限度		
Total Aerobic Microbial Count (TAMC) 需氧菌总数	≤ 100 cfu/g	30 cfu/g
Total Yeasts and Molds Count (TYMC) 霉菌和酵母菌总数	≤ 100 cfu/g	20 cfu/g
Escherichia coli 大肠埃希菌	Not Tested	Not Tested
Bacterial Endotoxins (LAL) 细菌内毒素	< 5 EU/mg	Complies
2.8 Heavy Metals (ICP-MS, if applicable) 重金属 (ICP-MS，如适用)		
Heavy Metals (as Pb) 重金属 (以铅计)	Not Tested	Not Tested

3. Conclusion 结论

This batch HXRT260502 of Retatrutide has been tested according to the above specifications.
Result: ☑ COMPLIES ☐ DOES NOT COMPLY

本批次产品 HXRT260502 已按上述标准检验。检验结论：☑ 符合要求 ☐ 不符合要求

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