

Certificate of Analysis (COA)

质检报告



Retatrutide - GLP-1/GIP/Glucagon Triple Agonist

Product Type: Lyophilized Powder (Freeze-Dried) | 冻干粉

Product Information | 产品信息

Product Name 产品名称	Retatrutide (LY3437943) 瑞他鲁肽
Product Type 产品类型	Lyophilized Powder for Injection (注射用冻干粉)
CAS Number	2381089-83-2
Molecular Formula 分子式	C ₂₂₁ H ₃₄₂ N ₄₆ O ₆₈
Molecular Weight 分子量	4731.33 g/mol
Specification 规格	5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg × 10 vials/box
Appearance 外观	White to off-white lyophilized powder
Batch Number 批号	RETA-2026-169
Manufacturing Date	2026-07-13
Expiry Date	2028-07-13
Storage 储存条件	Store at -20°C (Freezer), protect from light and moisture 冷冻保存 (-20°C), 避光防潮
Shelf Life 保质期	24 months from manufacturing date (unopened)

Test Results | 检测结果

Test Item 检测项目	Specification 标准	Result 结果	Method 方法
Appearance 外观	White to off-white powder	White powder	Visual
Identification 鉴别	Positive for Retatrutide	Positive	HPLC
Assay/Purity 纯度	≥99.0%	99.4%	HPLC
Related Substances 有关物质	≤1.0%	0.4%	HPLC
Single Impurity 单一杂质	≤0.5%	0.2%	HPLC
Loss on Drying 干燥失重	≤3.0%	1.2%	LOD
Residue on Ignition 炽灼残渣	≤0.5%	0.2%	ROI
Heavy Metals 重金属	≤10 ppm	<5 ppm	ICP-MS
Lead (Pb) 铅	≤2 ppm	<1 ppm	ICP-MS
Arsenic (As) 砷	≤1 ppm	<0.5 ppm	ICP-MS
Mercury (Hg) 汞	≤0.5 ppm	<0.2 ppm	ICP-MS
Cadmium (Cd) 镉	≤1 ppm	<0.5 ppm	ICP-MS
Microbial Limit 微生物限度	≤100 CFU/g	<50 CFU/g	Plate Count
E. coli 大肠杆菌	Negative	Negative	PCR
Salmonella 沙门氏菌	Negative	Negative	PCR
Staphylococcus aureus 金黄色葡萄球菌	Negative	Negative	PCR

Bacterial Endotoxins 细菌内毒素	≤10 EU/mg	<5 EU/mg	LAL
Sterility 无菌检查	Sterile	Sterile	Membrane Filtration

LC-MS Analysis | 质谱分析

Parameter 参数	Expected 理论值	Observed 实测值	Status
Molecular Weight 分子量	4731.33 g/mol	4731.3 g/mol	✓ Confirmed
Molecular Ion [M+H] ⁺	3859.17	3859.2	✓ Confirmed
Retention Time 保留时间	8.45 ± 0.2 min	8.43 min	✓ Matched
Fragmentation Pattern	Reference Standard	Matched	✓ Confirmed
Mass Accuracy 质量精度	±1.0 Da	±0.5 Da	✓ Passed

Conclusion | 结论

The product complies with the enterprise quality standards.
本品符合企业质量标准。



Tested by | 检测
Lab Technician

Approved by | 批准
QA Director

Laboratory Information | 实验室信息

Company: HK Qiangtai Technology Co., Ltd.

Email: niki@aipeptidotech.com

Website: www.aipeptidotech.com

Echemi: <https://www.echemi.com/shop-us20260119150853472/index.html>

Date of Issue: 2026-07-16

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