

分析报告单
Certificate of Analysis

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产品名称 Product Name	司美格鲁肽(R&D) Semaglutide(R&D)	批号 Lot No.	0525010902-1
生产日期 Manufacture Date	2025.01.09	复验日期 Retest Date	2027.01.08
化学文摘编码 CAS No.	910463-68-2	重量 Quantity	182.3g
检查项目 Inspection Items	全检 Full inspection	报告日期 Report Date	2025.03.27

项目 Items	质量标准 Specification	检验结果 Results
外观 Appearance	白色或类白色粉末 White or off white powder	符合规定 Conforms
溶解度 Solubility	易溶于水 Freely Soluble in water;	符合规定 Conforms
溶液透明度和颜色 Solution Clarity And Color	无色澄清 Clera and colorless	符合规定 Conforms
红外光谱 Infrared Spectrum	本品的红外光吸收谱图应与对照的图谱一致 The infraed absorption spectrum of this sample should be consistent with the reference spectrum	符合规定 Conforms
旋光度 Specific Optical Rotation [α] ²⁰ _D	-16.0°to -6.0° (无水、无钠离子物质 C=10mg/ml,H ₂ O) -16.0°to -6.0°(anhydrous and sodium ion-free substance,C=10mg/ml,H ₂ O))	-10.5°
液相色谱鉴别 Identification By HPLC	供试品溶液主峰的保留时间与对照品溶液保留时间一致 The retention time of the principal peak of the test solutioncorresponds to that of the reference solution, as obtained in the Assty.	符合规定 Conforms
分子量 Molecular Ion Mass	4113.58±1.0Da	4114.22Da
氨基酸含量 Amino Acid Conctect	Asp:0.9~1.1; Ser:2.7~3.3; Glu:4.5~5.5; Gly:3.6~4.4; His:0.9~1.1; Arg:1.8~2.2; Thr:1.8~2.2; Ala:2.7~3.3; Aib:0.9~1.1; Tyr:0.9~1.1; Val:1.8~2.2; Lys:0.9~1.1 Ile:0.9~1.1; Leu:1.8~2.2; Phe:1.8~2.2 AEEA:Should be detected	符合规定 Conforms
酸碱度 pH	QC 6.0~9.0	7.67
水分 Water Content(KF)	2025.04.10 PASS 不得过 8.0% NMT 8.0%	2.6%

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有关物质 Related Substances (HPLC)	单个杂质: 不得过 0.5% single impurity:NMT0.5%	0.2%
	纯度不低于 99.0% Purity not less than 99.0%	99.6%
钠离子 Sodium Ion	1.5%-4.0%	1.8%
高分子量物质 High Molecular Weight species	不得过 0.5% NMT 0.5%	0.08%
残留溶剂 Residual Solvents(GC)	二氯甲烷不得过 600ppm Dichloromethane NMT600ppm	N.D
	N,N-二甲基甲酰胺不得过 880ppm N,N-dimethylformamide NMT880ppm	N.D
	乙腈不得过 410ppm Acetonitrile NMT 410ppm	<LOQ
	甲醇不得过 3000ppm Methanol NMT3000ppm	N.D
	甲基叔丁基醚不得过 5000ppm Methy tert-buty ether NMT5000ppm	N.D
细菌内毒素 Bacterial Endotoxins	不得过 2EU/mg NMT 2EU/mg	符合规定 Conforms
微生物限度 Microbial Limits	需氧菌总数不得过 200cfu/g TAMC NMT 200cfu/g	10cfu/g
	霉菌和酵母菌总数不得过 100cfu/g TYMC NMT 100cfu/g	5cfu/g
	大肠埃希杆菌总数不得检出 Escherichia coli:Absent	Absent
酸根离子 Acid group ions	三氟乙酸离子不得过 0.1% Trifluoroacetate ion NMT 0.1%	N.D
	醋酸离子不得过 0.1% Acetate ion NMT 0.1%	N.D
含量 Assay	95.0%-105.0% (按无水、无盐计算) 95.0%-105.0%(Calculated with reference to the anhydrous and salt-free substance)	99.8%
储存 Storage	密封, 避光于-20℃±5℃储存 Preserve in tight containers.Store at a temperature -20℃±5℃	
结论 Conclusion	符合规定 Conforms	

QC:

2025. 04. 10

QA:

PASS