



FIRST RAYS CO., LTD.

江苏泰源雍国际贸易有限公司

Sample Name: Semaglutide 样品名称: 司美格鲁肽	
Sample Package: Double layer polyethylene bag , single-layer aluminum-plastic film bag 样品包装形式: 双层聚乙烯袋, 单层铝塑袋	
Lot No. 样品批号: HBD1562-2302	Sampling Date 接样日期: 2023-02-20
Production Date 生产日期: 2023-02-14	Amount 数量: 6.0g
Test start date 检测开始日期: 2023-02-20	Test completion date 检测完成日期: 2023-02-26

Certificate of Analysis for Semaglutide

司美格鲁肽COA报告

Test Item 检测项目	Reference 方法参考	Acceptance Criteria 可接受标准	Test Result 检验结果	Single test conclusion 单项检测结论
Description 性状	In house 内控	White or almost white powder 白色至类白色粉末	White powder 白色粉末	Meet the requirement 符合要求
HPLC Identification 色谱鉴别	In house 内控	The retention time of the major peak of the Sample Solution should correspond to that of the Standard Solution, as obtained in the Assay 含量检测项下, 供试品溶液中主峰的保留时间与对照品溶液一致	Meet the requirement 符合要求	Meet the requirement 符合要求
Peptide mapping 肽谱图	In house 内控	The chromatographic profile of the Sample Solution corresponds to that of the Standard Solution. 供试品溶液的色谱图与对照溶液一致	Meet the requirement 符合要求	Meet the requirement 符合要求
pH	In house 内控	6.0~9.0	6.8	Meet the requirement 符合要求
Specific optical rotation 比旋光度	In house 内控	-6° ~ -16°	Meet the requirement 符合要求	Meet the requirement 符合要求



Assay 含量	In house 内控	It contains 0.76 mg to 1.00 mg of sermaglutide(C ₁₈₇ H ₂₉₁ N ₄₅ O ₅₉) per mg. 每1mg含司美格鲁肽应为0.76~1.00 mg	It contains 0.94 mg of sermaglutide per mg. 每1mg含司美格鲁肽 0.94 mg。	Meet the requirement 符合要求
Related Substances 有关物质	In house 内控	Hydrophilicity Impurities NMT 3.4% 亲水性杂质不得过3.4%	0.04%	Meet the requirement 符合要求
		Hydrophobicity Impurities 1 NMT 3.1% 疏水性杂质1不得过3.1%	0.16%	Meet the requirement 符合要求
		Hydrophobicity Impurities 2 NMT 0.3% 疏水性杂质2不得过0.3%	Not detected 未检出	Meet the requirement 符合要求
		Total Impurities NMT 5.5% 总杂不得过5.5%	0.20%	Meet the requirement 符合要求
High Molecular Weight Proteins 高分子蛋白	In house 内控	NMT 0.3%	Not detected 未检出	Meet the requirement 符合要求
Water Content 水分	In house 内控	NMT 10.0%	5.5%	Meet the requirement 符合要求
Residual Solvents 溶剂残留	In house 内控	Acetic acid NMT 5000 ppm 乙酸不得过5000 ppm	Not detected 未检出	Meet the requirement 符合要求
		Trifluoroacetic acid NMT 1000 ppm 三氟乙酸不得过1000 ppm	Not detected 未检出	Meet the requirement 符合要求
		Ethanol NMT 5000 ppm 乙醇不得过5000 ppm	Not detected 未检出	Meet the requirement 符合要求
		Isopropyl alcohol NMT 5000 ppm 异丙醇不得过5000 ppm	Not detected 未检出	Meet the requirement 符合要求



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		Toluene NMT 890 ppm 甲苯不得过890 ppm	Not detected 未检出	Meet the requirement 符合要求
		Acetonitrile NMT 410 ppm 乙腈不得过410ppm	Not detected 未检出	Meet the requirement 符合要求
		Benzene NMT 2 ppm 苯不得过2 ppm	Not detected 未检出	Meet the requirement 符合要求
Bacterial Endotoxins Test 细菌内毒素	In house 内控	NMT 10 IU/mg	Not detected 未检出	Meet the requirement 符合要求
Microbial Enumeration Tests 微生物限度	In house 内控	The total aerobic count does not exceed 100CFU/g 总需氧计数不超过100CFU/g	Not detected 未检出	Meet the requirement 符合要求
Bioassay 生物活性	In house 内控	0.7~1.3 Units/mg 每1mg司美格鲁肽的活性应为0.7~1.3	0.8 Units/mg	Meet the requirement 符合要求
Conclusion 结论	Qualified			

