



质量检验报告 CERTIFICATE OF ANALYSIS

产品名称(Product Name) : 司美格鲁肽 (Semaglutide)

英文名称(English Name) : Semaglutide

分子式(Molecular Formula) : C187H291N45O59

分子量(Molecular Wt) : 4113.58

储存条件(Storage Condition) : 避光;-20°C;干燥;避免反复冻融

CAS : 910463-68-2

货号(Item No) : V66009

批号 (Lot. Number) : LV449159

检测日期(Date of Testing) : 2026-03-23

复测日期(Date of Retesting) : 2029-03-22

分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS
Appearance	White or almost white lyophilized powder	White or almost white lyophilized powder
Assay	0.76-1 mg/mg	0.93400 mg/mg
Specific activity	0.7-1.3 U/mg	1.02000 U/mg
Water	10% max	1.7%
Hydrophilic impurities	0-3.4%	0.36%
Hydrophobic impurities 1	0-3.1%	0.46%
Hydrophobic impurities 2	0-0.3%	0.04%
Total of Related impurities	0-5.5%	0.86%
High molecular mass proteins	0-0.4%	0.07%
Sodium	0-4%	1.9%
Identification (Retention time)	Conform	Conform
Identification (Peptide mapping)	Conform	Conform
N-terminal amino acid sequence	Conform	Conform
Single-chain precursor ≤ 10 ppm	Conform	Conform
Host Cell Protein (HCP) ≤ 10 ppm	Conform	Conform
Residual host-cell DNA ≤ 10 ng/mg	Conform	Conform



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Microbial Limit ≤ 102 CFU/g	Conform	Conform
Endotoxin Level < 10 EU/mg	Conform	Conform
Acetonitrile residue $\leq 0.041\%$	Conform	Conform
Isopropanol residue $\leq 0.5\%$	Conform	Conform
Ethanol residue $\leq 0.3\%$	Conform	Conform
Dichloromethane residue $\leq 0.06\%$	Conform	Conform

Quality Assurance : Xiaoyong Tan



Quality Control : Yunfei Zhu

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