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分析证明书
CERTIFICATE OF ANALYSIS

Product name 品名: Semaglutide 索玛鲁肽 CAS NO.: 910463-68-2	
Batch no. 批号: 20250505	Quantity 数量: 10.1kgs
Manuf. date 生产日期: 2025/05/10	Expiry date 有效期: 2027/05/10

Items	Specifications		Results
Appearance	White or off-white powder		White powder
Solubility	Freely soluble in water		Conforms
Specific optical rotation[α] ²⁰ _D	15.0°to-10.0°(anhydrous and sodium ion-free substance, C=10mg/ml,H ₂ O)		10.3°
Identification by HPLC	The retention time of the principal peak of the test solution corresponds to that of the reference solution,as obtained in the Assay.		Conforms
PH	7.0-9.0		8.82
Water Content	≤8.0%		1.71%
Purity(HPLC)	≥98.0%		98.31%
Related substances(HPLC)	The largest other individual impurity ≤1.0%		0.66%
	The total impurities ≤2.0%		0.69%
Residual solvent	DCM	≤600ppm	N.D
	ACN	≤410ppm	01 ppm
	MetOH	≤3000ppm	N.D
	DMF	≤880ppm	N.D
	Isopropyl ether	≤5000ppm	N.D
	Isopropanl	≤5000ppm	N.D
Acid group ions	TFA	≤0.1%	N.D
	PO ₄ ³⁺	≤0.1%	N.D
	Cl	≤ 0.1%	N.D
	HAC	≤ 0.1%	N.D
Microbiological tests	Total microbacterial count	≤1000 CFU/g	Conforms
	Yeast and Mould	≤100 CFU/g	Conforms
	Escherichia Coil presence	Negative	Conforms
	Salmonella	Negative	Conforms
	P.Aeruginosa	Negative	Conforms
	S.Aureus	Negative	Conforms
Bacterial Endotoxins	≤10EU/mg		Conforms
Total heavy metal test	≤10.0 ppm		Conforms
Sodium ion	≤5.0%		2.6%
Peptide Content (Mass Balance)	≥80.0%		94.0%
Conclusion:conformed with the product standards.			
Storage Conditions:Keep in tight container,protectfrom light,store at a temperature of-20±5℃.			

复核人 Checker:

化验人 Analyst:



