

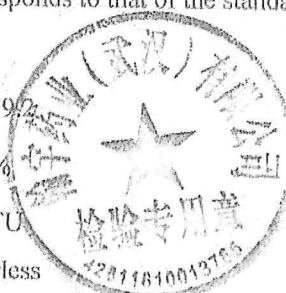


Hybio Pharmaceutical (Wuhan) Co., Ltd.
Certificate of Analysis

DE202503-019

QC2-P12-01

Product Name	Liraglutide	Batch Number	0012427A
Manufacture Date	Nov.03, 2024	Delivery Quantity	50g
Test Date	Nov.07, 2024	Report Date	Mar.07, 2025
Retest Date	Nov.02, 2027	Storage	Store under $-20 \pm 5^{\circ}\text{C}$ without direct sunlight after sealing
Test Standard	2-TSF-0006 Liraglutide quality specification (USA) (version 5.0)		
Test Item	Specification	Result	
[Character]			
Appearance	White or off-white powder or loose lump	White loose lump	
Hygroscopicity	Hygroscopic, the hygroscopicity should be not less than 2% and less than 15%.	Conform (13%)	
Solubility	Freely soluble in water, 10mmol/L phosphate buffer, and 0.1mol/L sodium hydroxide solution.	Conform	
Specific optical rotation	$[\alpha]_D^{25} = -15^{\circ} \sim -25^{\circ}$ (calculated with reference to the anhydrous, anions-free, sodium ion-free and ammonium ion-free substance)	-18°	
[Identification]			
HPLC	The RT of the main peak of sample in the assay test should be consistent with that of the reference.	Consist with the RT of reference	
Monoisotopic weight	The monoisotopic weight of the sample should be 3748.4Da ~3749.4Da	3749.2Da	
Peptide mapping	The chromatographic profile of the sample corresponds to that of the standard	Consist with the reference	
[Check]			
pH	8.2~9.2	8.7	
Water content	$\leq 8.0\%$	4.1%	
Clarity of solution	$\leq 2\text{NTU}$	1.1NTU	
Color of solution	Colorless	Colorless	



METAPHARMACEUTICAL

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02/06/2025

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Hybio Pharmaceutical (Wuhan) Co.,Ltd.

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DE202503-019

QC2-P12-01

Product Name	Liraglutide	Batch Number	0012427A
Test Standard	2-TSF-0006 Liraglutide quality specification (USA) (version 5.0)		
Test Item	Specification	Result	
Residual solvent	Methanol:≤3000ppm	N.D	
	Acetonitrile:≤410ppm	N.D	
	Pyridine:≤200ppm	N.D	
	Isopropanol:≤5000ppm	N.D	
	Dichloromethane:≤600ppm	N.D	
	N-Methyl pyrrolidone:≤530ppm	N.D	
	N, N-Dimethylformamide:≤880ppm	N.D	
Amino acid analysis	Asp:0.9~1.1	1.1	
	Ser:2.4~3.0	2.6	
	Glu:4.5~5.5	5.2	
	Gly:3.6~4.4	3.9	
	His:0.9~1.1	1.0	
	Arg:1.8~2.2	2.0	
	Thr:1.8~2.2	1.9	
	Ala:3.6~4.4	4.2	
	Tyr:0.9~1.1	1.0	
	Val:1.8~2.2	2.0	
	Lys:0.9~1.1	1.1	
	Ile:0.9~1.1	1.0	
	Leu:1.8~2.2	2.0	
	Phe:1.8~2.2	2.0	
	Trp:detected	Detected	
Anions	Acetate ion:≤0.5%	0.01%	
	Phosphate ion:≤0.1%	N.D	
	Carbonate ion:≤0.4%	0.07%	
	Trifluoroacetate ion:≤0.1%	N.D	
Ammonium ion	≤0.2%	<0.005%	
Sodium ion	≤3.0%	2.2%	
Elemental impurities	Pd≤1.0ppm	<0.1ppm	
	Ni≤10.0ppm	<1.0ppm	
Macromolecular impurities	≤0.5%	N.D	

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DE202503-019

QC2-P12-01

QC2-P12-0

Product Name	Liraglutide	Batch Number	0012427A
Test Standard	2-TSF-0006 Liraglutide quality specification (USA) (version 5.0)		
Test Item	Specification	Result	
Related substance	Specified identified impurities		
	Lira-IM-M $\leq$ 0.15%	<0.05%	
	Lira-IM-C $\leq$ 0.15%	<0.05%	
	Lira-IM-D $\leq$ 0.15%	<0.05%	
	Lira-IM-F $\leq$ 0.25%	0.11%	
	Lira-IM-G $\leq$ 0.15%	N.D	
	Lira-IM-H $\leq$ 0.25%	0.05%	
	Lira-IM-I $\leq$ 0.10%	N.D	
	Lira-IM-J $\leq$ 0.10%	N.D	
	Lira-IM-K $\leq$ 0.25%	0.11%	
	Lira-IM-L $\leq$ 0.15%	<0.05%	
	Lira-IM-N $\leq$ 0.15%	<0.05%	
	Lira-IM-O $\leq$ 0.15%	N.D	
	Any unspecified impurity $\leq$ 0.10%	<0.05%	
	Total impurities $\leq$ 2.0%	0.52%	
Bacterial endotoxins	<10EU/mg	<4.8EU/mg	
Microbial limits [Assay]	TAMC $\leq$ 10 ² cfu/g	TAMC: 1 $\times$ 10cfu/g	
	TYMC $\leq$ 50cfu/g	TYMC: <1 $\times$ 10cfu/g	
Peptide content	85.0%~100.0%	93.7%	
Assay	95.0%~103.0% (C ₁₇₂ H ₂₆₅ N ₄₃ O ₅₁), calculated with reference to the anhydrous, anions-free, sodium ion-free and ammonium ion-free substance	100.1%	
No content below			
Conclusion	Tests were performed according to 2-TSF-0006 Liraglutide quality specification (USA) (version 5.0), the results conform with specification.		
Remark	/		
Reporter	Mig Yang	Date	Mar. 07. 2025
Reviewer	Qi Fang	Date	Mar. 07. 2025

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