

Certificate of Analysis

Product Name	Liraglutide sodium salt	Batch No.	M23X04120
CAS No.	204656-20-2	MFG. Date	Apr 12, 2023
CAT No.	P100120	Retest Date	Apr 11, 2026
Items	Specification	Results	
Appearance	White or almost white powder or loose lumps	Conforms	
Solubility	Freely soluble in water, slightly soluble in methanol, very slightly soluble in ethanol	Conforms	
Amino acid content	Asp: 0.9-1.1 Glu: 4.5~ 5.5 Ser: 2.7~3.3 His: 0.9 ~1.1 Gly: 3.6~4.4 Arg: 1.8~2.2 Thr: 1.8~2.2 Ala: 3.6~4.4 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	1.0 5.0 3.0 1.0 4.0 2.1 2.0 3.9 1.0 2.1 1.1 1.0 1.9 2.0	
Purity (HPLC)	≥ 98%	99.8%	
Peptide content (N%)	≥ 80%	93.9%	
Water Content	≤ 8%	2.8%	
Sodium ion	2.0~4.0%	2.6%	
MS	3751.3±1.0	3751.0	
pH	8.7~9.5	8.9	

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Specific optical rotation	-15.0 ° ~-30.0 ° on the anhydrous and sodium-free basis (C=10mg/ml in water, at 25 C)	-17.3°
Residual solvents I	Isopropyl ether ≤ 5000ppm Methylene chloride ≤ 600ppm Methanol ≤ 3000ppm Acetonitrile ≤ 10ppm	N.D N.D N.D 155ppm
Residual solvents II	N.N-Dimethylformamide ≤ 880 ppm	17 ppm
Bacterial endotoxin	< 10EU/mg	Conforms
Microbial enumeration tests	TAMC ≤ 200cfu/g TAMC ≤ 100cfu/g	<10cfu/g <10cfu/g
Assay	Containing Liraglutide (C172H26N43O51) 95.0%~105.0%, on the anhydrous and sodium-free basis.	99.3%
Conclusion	Corresponds.	
Storage Condition	Short-term storage: 2-8 °C Long-term storage: -20 °C	

QC:

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QA:

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