



DALIAN HANDOM CHEMICALS CO.,LTD.

Add.: RM702, Unit 1, Building 21, Liuhe Road, Ganjingzi Dist, Dalian, Liaoning, China
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Certificate of Analysis

Product Name	Liraglutide	CAS No.	204656-20-2
Molecular Formula	C ₁₇₂ H ₂₆₅ N ₄₃ O ₅₁	Molecular Weight	3751.29
Batch No.	HDC20220606	Batch Quantity	15.50g
Mfg. Date	Jun 6 th , 2022	Retest Date	Jun 5 th , 2024
Test Items	Specifications	Test Results	
Appearance	White or almost white loose powder	Conforms	
Solubility	Freely soluble in water, soluble in methanol, very slightly soluble in ethanol	Conforms	
Hygroscopicity	Hygroscopic	Conforms	
Specific optical rotation	-15.0° to -30.0° (on the anhydrous and sodium ion-free substance, c=10mg/ml in water at 25°C)	-16.5°	
Identification(By HPLC)	The retention time of Liraglutide peak of the <i>Sample solution</i> corresponds to that of the <i>Standard solution</i> , as obtained in the <i>Assay</i> .	Conforms	
Molecular Ion Mass	3751.29	Conforms	
Amino acid content	Asp: 0.9 ~ 1.1	1.0	
	Glu: 4.5 ~ 5.5	5.1	
	Ser: 2.7 ~ 3.3	3.0	
	Gly: 3.6 ~ 4.4	4.0	
	His: 0.9 ~ 1.1	1.0	
	Arg: 1.8 ~ 2.2	2.0	
	Thr: 1.8 ~ 2.2	2.0	
	Ala: 3.6 ~ 4.4	4.1	
	Aib: 0.9 ~ 1.1	1.1	
	Tyr: 0.9 ~ 1.1	1.0	
	Val: 1.8 ~ 2.2	1.9	
	Lys: 0.9 ~ 1.1	1.0	
	Ile: 0.9 ~ 1.1	1.0	
	Leu: 1.8 ~ 2.2	2.0	
Phe: 1.8 ~ 2.2	1.9		
pH Value	8.7 ~ 9.5	9.0	
Water Content(K. F)	Not more than 8.0%	6.35%	
The clarity and colour of the solution	Clear and colourless	Conforms	
Related Substances(HPLC)	Maximum single impurity: ≤1.0%	0.20%	
	Total impurities: ≤2.0%	0.29%	
High molecular protein	Not more than 0.5%	0.05%	



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Residual Solvents I	Methylene Chloride: ≤ 600 ppm	Not detected
	Acetonitrile: ≤ 410 ppm	160ppm
	Methanol: ≤ 3000 ppm	Not detected
	Isopropyl ether: ≤ 5000 ppm	8ppm
Residual Solvents II	N,N-Dimethylformamide: ≤ 880 ppm	5ppm
Bacterial Endotoxins	Not more than 10EU/mg	Conforms
Microbial Limits	TAMC: ≤ 200 CFU/g	5CFU/g
	TYMC: ≤ 100 CFU/g	< 10CFU/g
Sodium ion	2.0% ~ 4.0%	2.5%
Acid Group Ions	Trifluoroacetate ion(TFA): $\leq 0.1\%$	Not detected
	Chloride ion: $\leq 0.1\%$	0.02%
Assay(C ₁₇₂ H ₂₆₅ N ₄₃ O ₅₁)	95.0% ~ 105.0% (Calculated with reference to the anhydrous and sodium ion-free substance.)	103.8%
Conclusion	The testing results of this batch are complied with the Enterprise Standard.	

Storage Conditions: Preserved in unopened original containers at a temperature of $-20\pm 5^{\circ}\text{C}$; kept away from direct sunlight, heat and moisture.

Remark: This product was prepared by chemical synthesis. For research and development use only, not for human use.