

# Certificate of Analysis

<b>Product Name</b>	Liraglutide	<b>Product Source</b>	Workshop 106
<b>Batch No.</b>	10131190501	<b>Packaging Size</b>	967.73g/bag,1252.19g/bag,1197.98 g/bag,1132.97g/bag,550g/bag
<b>Batch Size</b>	5173.97 g	<b>Manufacture Date</b>	Jun.25, 2019
<b>Number of Packages</b>	5	<b>Retest Date</b>	Jun.24, 2023
<b>Sampling Date</b>	May 20, 2021	<b>Report Date</b>	Sep.30, 2021
<b>Test Reference</b>	QC-03-10131-04, QC-02-1288-03		
<b>Test Items</b>	<b>Acceptance Criteria</b>	<b>Test Results</b>	
Appearance	White or off-white loose powder, Hygroscopicity	White loose powder, Hygroscopicity	
Identification	Mass Spectrometry: The monoisotopic mass is 3748.95±0.5 mass units	3749.00	
	The retention time of major peak in the chromatogram obtained from test solution corresponds to that in the chromatogram obtained from reference solution, as obtained in the Assay	The retention time of major peak in the chromatogram obtained from test solution corresponds to that in the chromatogram obtained from reference solution, as obtained in the Assay	
Solubility	Soluble in water, very slightly soluble in methanol	Soluble in water, very slightly soluble in methanol	
Specific optical rotation	-15.0°~-30.0°, calculated on anhydrous, acid-free, ammonium-free and sodium-free basis	-18.3°	
Clarity and color of solution	It is clear and colorless, or the solution is not more opalescent than 1# standard turbidity solution and not more intensely colored than 1# standard yellow color solution	It is clear and colorless	
pH	7.0~9.0	7.8	
Water	NMT 8.0%	7.2%	
Acetic acid	NMT 0.5%	Not Detected	
Trifluoroacetic acid	NMT 0.5%	Not Detected	
DMF	NMT 0.088%	0.0006%	
Oligomer	NMT 1.0%	0.07%	
Phosphate ion	NMT 3.0%	0.68%	
Ammonium ion	NMT 0.5%	0.018%	

<b>Product Name</b>	Liraglutide	<b>Product Source</b>	Workshop 106
<b>Batch No.</b>	10131190501	<b>Packaging Size</b>	967.73g/bag,1252.19g/bag,1197.98g/bag,1132.97g/bag,550g/bag
<b>Batch Size</b>	5173.97 g	<b>Manufacture Date</b>	Jun.25, 2019
<b>Number of Packages</b>	5	<b>Retest Date</b>	Jun.24, 2023
<b>Sampling Date</b>	May 20, 2021	<b>Report Date</b>	Sep.30, 2021
<b>Test Reference</b>	QC-03-10131-04, QC-02-1288-03		
<b>Test Items</b>	<b>Acceptance Criteria</b>	<b>Test Results</b>	
Sodium ion	NMT 4.0%	1.9%	
Chloride ion	NMT 0.5%	Not Detected	
Ratio of amino acid	Asp: 0.9 ~ 1.1	1.0	
	His: 0.9 ~ 1.1	1.0	
	Tyr: 0.9 ~ 1.1	1.0	
	Ile: 0.9 ~ 1.1	0.9	
	Lys: 0.9 ~ 1.1	1.0	
	Leu: 1.8 ~ 2.2	2.1	
	Arg: 1.8 ~ 2.2	2.1	
	Thr: 1.8 ~ 2.2	2.0	
	Val: 1.8 ~ 2.2	2.1	
	Phe: 1.8 ~ 2.2	2.0	
	Ser: 2.4 ~ 3.6	2.9	
	Gly: 3.6 ~ 4.4	3.9	
	Ala: 3.6 ~ 4.4	4.0	
	Glu: 4.5 ~ 5.5	5.1	
Trp: Detected	Detected		
Related substances I	Impurity A & H: NMT 0.50%	0.12%	
	Impurity B: NMT 0.20%	Not Detected	
	Impurity C: NMT 0.50%	Not Detected	
	Impurity D: NMT 0.20%	0.02%	
	Impurity E & F: NMT 0.20%	Not Detected	
	Impurity G: NMT 0.20%	Not Detected	
	Impurity I: NMT 0.20%	Not Detected	
	Impurity J: NMT 0.10%	Not Detected	
Any other impurity: NMT 0.10%	0.02%		

<b>Product Name</b>	Liraglutide	<b>Product Source</b>	Workshop 106
<b>Batch No.</b>	10131190501	<b>Packaging Size</b>	967.73g/bag,1252.19g/bag,1197.98g/bag,1132.97g/bag,550g/bag
<b>Batch Size</b>	5173.97 g	<b>Manufacture Date</b>	Jun.25, 2019
<b>Number of Packages</b>	5	<b>Retest Date</b>	Jun.24, 2023
<b>Sampling Date</b>	May 20, 2021	<b>Report Date</b>	Sep.30, 2021
<b>Test Reference</b>	QC-03-10131-04, QC-02-1288-03		
<b>Test Items</b>	<b>Acceptance Criteria</b>	<b>Test Results</b>	
Related substances I	Total impurity: NMT 1.0%	0.16%	
Related substances II	Impurity K: NMT 0.20%	Not Detected	
	Impurity L: NMT 0.20%	Not Detected	
	Impurity M: NMT 0.20%	Not Detected	
	Any other impurity: NMT 0.10%	0.06%	
	Total impurity: NMT 1.0%	0.13%	
	Total impurities of related substances I and II: NMT 2.0%	0.30%	
Residual solvents	Methanol: NMT 1000ppm	Not Detected	
	Ethyl ether: NMT 5000ppm	0.0001%	
	Acetonitrile: NMT 410ppm	Not Detected	
	Dichloromethane: NMT 600ppm	Not Detected	
	Ethyl acetate: NMT 5000ppm	Not Detected	
	Pyridine: NMT 200ppm	Not Detected	
	Triisopropylsilane: NMT 1000ppm	Not Detected	
Bacterial endotoxins	Less than 2EU/mg	Less than 2EU/mg	
Microbiological examination	TAMC: NMT 100cfu/g	Less than 10cfu/g	
	TYMC: NMT 50cfu/g	Less than 10cfu/g	
	Escherichia coli: absent	Absent	
Assay	95.0%~103.0%(calculated with anhydrous, acid-free, ammonium-free, sodium-free ions)	99.1%	