上海维昱曦生物科技有限公司
Shanghai Wayx Biotechnology Co,.Ltd.
Tel: 86-21-54707036
www.Wayx-Bio.com

Certificate of Analysis

Product Name	Tirzepatide	**Control No.**	WX02-2406
Manufacturing Date	05/17/2024	**Re-test Date**	05/16/2026
Specification No.	QSP-WX02-01.03	**Report Date**	06/12/2024
Storage conditions	Preserve in an airtight closed container, protected from light, at a temperature -25°C ~ -15 °C.		

Test Items	Method	Specifications	Test Results
Appearance	Visual inspection	white or off-white powder	White powder
Solubility	USP General Notices 5.30 Description and Solubility	Soluble in water	Soluble in water
Monoisotopic mass	USP <736>	4810.5 ± 1.0 Da	Meets the requirements
Identification	HPLC USP <621>	The retention time of the main peak in the first sample solution should be consistent with the peak of the first reference sample, that is, the difference in retention time should be within ± 1 minute.	Meets the requirements
pH	USP <791>	6.0 ~ 9.0 (C=5mg/mL)	6.89
Water content	K.F. USP <921>	NMT 10.0%	6.08%
Sodium ion content	IC USP<1065>	NMT 3.0%	1.0%
Purity	HPLC USP <621>	According to the area normalization method, the purity should not be less than 99.0%.	99.8%
Related substance	HPLC USP <621>	Any other impurity: NMT 0.5%	0.1%
		Total impurities: NMT 1.5%	0.2%
Assay	HPLC USP <621>	95.0%~105.0% (anhydrous and salt-free substance)	100.6%

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Test Items	**Method**	**Specifications**	**Test Results**
Oligomer	HPLC USP <621>	NMT 0.5%	Not detected
Residual solvents	GC USP <467>	Acetonitrile: NMT 410 ppm	Not detected
Peptide content	USP <1503>	Peptide content=(1-Water content%-Sodium ion content%)* Purity*100%	92.7%
Bacterial Endotoxins	USP <85> <Gel-Clot Method>	≤10EU/mg	Meets the requirements
Microbiological Examination	USP <61> <Membrane Filtration Method >	TAMC: <100 cfu/g	Meets the requirements
		TYMC: <100 cfu/g	Meets the requirements
Conclusion	☑Conforms / ☐Not Conforms		
Remarks	N/A		

QC Prepared by/ Date:	QC Reviewed by/ Date:	QC Approved by/ Date:	QA Approved by/ Date:
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