

Certificate of Analysis			
Product	Tirzepatide	CAS No.	2023788-19-2
Product No.	LJTIR	Batch No.	LJTIR2026061701
Date of Mfg	2026/06/17	Retest Date	2028/06/16
Test Method	In-house	Quantity	14.8kg
Storage Conditions	Protected from light, sealed, store at -20℃ ± 5℃		

Test	Acceptance Criteria	Results
Appearance	White or off-white Powder	White Powder
Clarity and Color of Solution	The solution shall be clear and colorless.	Conforms
Solubility	Freely soluble in water	Conforms
Specific Rotation	Calculated on the anhydrous and sodium-ion-free basis, the specific rotation should be -23.5° to -33.5°	-26.2°
Identification by HPLC	The retention time of the main peak of the test solution shall correspond to that of the main peak of the reference solution.	Conforms
Mass spectrum	Relative Molecular Mass 4813.5 ± 1.0 Da	Conforms
Amino Acid Ratio	Asp 1.6~2.4	2.0
	Glu 3.2~4.8	3.9
	Ser 4.0~6.0	4.8
	Gly 3.2~4.8	4.1
	Thr 1.6~2.4	2.0
	Ala3.2~4.8	4.1
	Aib1.6~2.4	1.9

	Tyr 1.6~2.4	2.0
	Val 0.8~1.2	0.9
	Phe 1.6~2.4	1.9
	Ile 2.4~3.6	3.0
	Leu 1.6~2.4	2.0
	Lys 1.6~2.4	2.1
	Pro 3.2~4.8	3.4
	AEEA 1.6~2.4	1.9
pH	6.0~9.0	7.6
Water Content	≤7.0%	3.5%
Acetic Acid	≤0.5%	0.1%
Trifluoroacetic acid	≤0.5%	Not Detected
Sodium Ion	≤5.0%	1.8%
Residual Solvents	Methanol≤0.3%	0.001%
	Dichloromethane≤0.06%	Not Detected
	DMF≤0.088%	Not Detected
	Acetonitrile≤0.041%	0.002%
Related Substances	impurity 1≤0.5%	Not Detected
	impurity 2≤0.5%	Not Detected
	impurity 3≤0.5%	0.11%
	impurity 4≤0.5%	0.25%
	impurity 5≤0.5%	0.12%
	impurity 6≤0.5%	0.14%

	Other single impurity $\leq$ 0.5%	0.09%
	Total Impurities $\leq$ 1.0%	0.83%
Purity	$\geq$ 98.0%	99.1%
Bacterial Endotoxin	The endotoxin in each 1mg of Tirzepatide shall be less than 5EU.	Conforms
Microbial Limit	Total Aerobic Microbial Count (TAMC) $\leq$ 100cfu/g	4.0cfu/g
	Total Yeasts and Molds Count (TYMC) $\leq$ 100cfu/g	2.0cfu/g
	Escherichia coli: Not detectable in 1g	Not Detected
Assay	It contains 95.0% to 105.0% of Tirzepatide (C ₂₂₅ H ₃₄₈ N ₄₈ O ₆₈), calculated on the anhydrous and sodium-ion-free basis.	99.0%
Peptide Content	$\geq$ 85.0%	93.7%
Conclusion	☒ Meet the requirements ☐ Do not meet the requirements	
Remarks	It is only supplied as chemical product. It is only for R&D use.	

Reporter/Date: 张洁 2026/06/25

Approver/Date: 刘辉 2026/06/25

