



CERTIFICATE OF ANALYSIS

Issued by an ISO/IEC 17025-accredited laboratory · raw data appended (page 2)

PASS

QC released for dispatch



Scan to verify

Tirzepatide — 10mg

GIP/GLP-1 Dual Agonist

1. PRODUCT IDENTIFICATION

Synonym	GIP/GLP-1 Dual Agonist	Label claim	10mg
Sequence / structure	GIP/GLP-1 dual agonist (Aib2, Aib13, C20-diacid)	Lot / Batch	ZX260512-449 / B38661
Mol. formula	C225H348N48O68	Manufacture date	25 May 2026
Mol. weight	4813.45 g/mol	Date of analysis	8 Jun 2026
CAS number	2023788-19-2	Storage	-20 °C, dark, desiccated
Salt form	Acetate salt		

2. ANALYTICAL TEST RESULTS

Test	Method	Specification	Result	Verdict
Appearance	Visual	White/off-white powder	White to off-white lyophilized powder	PASS
Identity (ESI-MS)	LC-MS	Matches 4813.45 Da	4813.45 Da (Δ 0 ppm)	PASS
Purity	RP-HPLC, UV 220 nm	$\geq 98.0\%$ area	99.20%	PASS
Related substances	RP-HPLC	Single ≤ 1.0 / Total $\leq 2.0\%$	0.39 / 0.80%	PASS
Water content	Karl Fischer (USP <921>)	$\leq 8.0\%$	1.2%	PASS
Counter-ion: acetate	Ion chromatography	Report (3.0–15.0%)	6.9%	PASS
Net peptide content	Amino-acid analysis	$\geq 80.0\%$	91.1%	PASS
Bacterial endotoxin	LAL kinetic (USP <85>)	< 5.0 EU/mg	0.16 EU/mg	PASS
Heavy metals	ICP-MS (ICH Q3D)	Conforms	Conforms	PASS

CONCLUSION

All tested parameters CONFORM to the acceptance specifications. The batch is of high chromatographic purity ($\geq 98\%$) with an impurity profile, identity and residual/contaminant results meeting pharmaceutical-grade quality requirements. Material released. Supporting RP-HPLC chromatogram and ESI-MS spectrum are appended on page 2.

DXP.

Dr. Xu Ping

Analyst · 8 Jun 2026 · Zhongxi Research Institute

DFH.

Dr. Fang Hong (QC Manager)

Approved by · 8 Jun 2026 · Zhongxi Research Institute

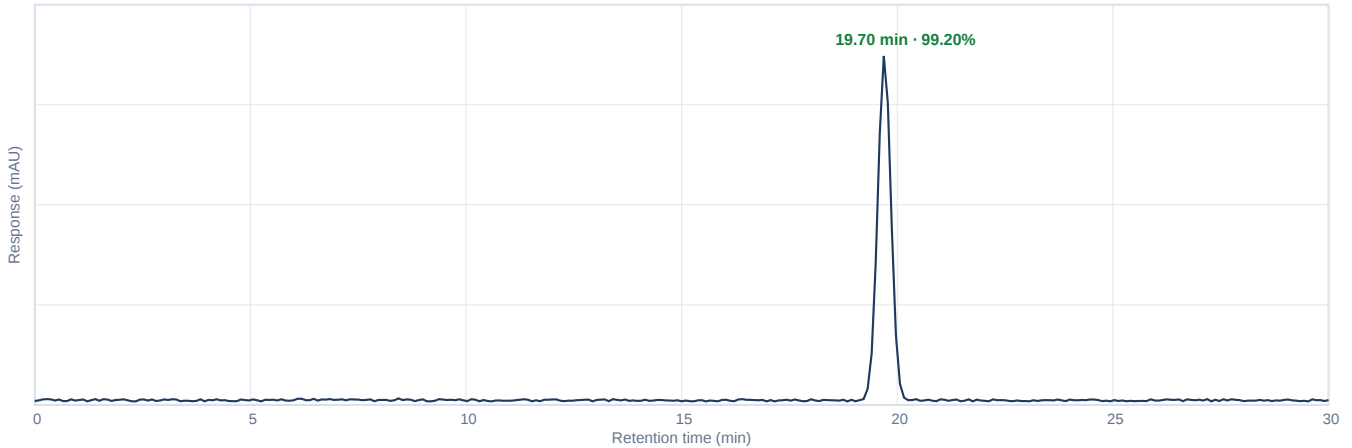


APPENDIX — ANALYTICAL RAW DATA

Tirzepatide 10mg · Lot ZX260512-449 · Cert. ZXR-COA-2026-93624

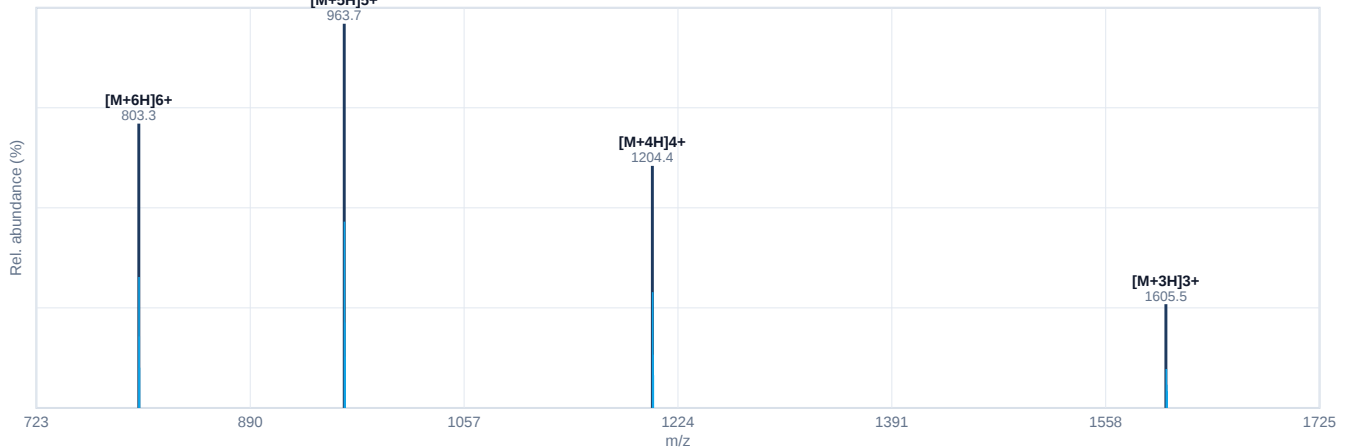


Figure 1. RP-HPLC Chromatogram (UV 220 nm)



Peak #	RT (min)	Area (μV·s)	Area %	Assignment
1	19.70	1021673	99.20	Main (target)
2	6.21	3377	0.32	Impurity / related substance
3	8.49	2808	0.26	Impurity / related substance
4	6.70	1698	0.17	Impurity / related substance
5	12.24	472	0.05	Impurity / related substance

Figure 2. ESI-MS Spectrum (positive ion mode)



Interpretation

Identity confirmed by ESI-MS. Observed ions [M+3H]³⁺ 1605.5, [M+4H]⁴⁺ 1204.4, [M+5H]⁵⁺ 963.7, [M+6H]⁶⁺ 803.3 deconvolute to a neutral monoisotopic-average mass of 4813.45 Da (theoretical 4813.45 Da; mass error 0 ppm), consistent with Tirzepatide. No co-eluting species above 0.5% indicative of misidentification.

Methods — RP-HPLC: Agilent 1260 Infinity II; Zorbax SB-C18 4.6×250 mm, 5 μm; A: 0.1% TFA in water, B: 0.1% TFA in MeCN; 10–70% B over 30 min; 1.0 mL/min; 25 °C; 20 μL injection. MS: AB Sciex TripleTOF, ESI+, capillary 4.5 kV, deconvolution by Bio Tool Kit. KF: Metrohm 901. IC: Thermo Dionex ICS-6000. ICP-MS: Agilent 7900.