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Document No.
KERUIHK-QC-IR0425

CERTIFICATE OF ANALYSIS

Tirzepatide

CAS No. 2023788-19-2

Batch No. **PB-2026-TIR-0425**
Grade **GMP**
Issue Date **Jul 28, 2026**

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ISO 9001:2015 GMP Certified

Purity (HPLC)	Molecular Weight	Test Method	Endotoxin
99.1%	4813.47 Da	RP-HPLC / MALDI-TOF	< 0.3 EU/mg

Appearance	Storage Condition	Retest Date
White lyophilized powder	-20°C, dry, dark	24 months from manufacture

Amino Acid Sequence (39 residues)

Tyr-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-Ala-Met-Asp-Lys-Ile-His-Gln-Gln-Asp-Phe-Val-Asn-Trp-Leu-Leu-Ala-Gln-Gly-Lys-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH_2

Formula: $C_{228}H_{348}N_{48}O_{68}$ Length: **39 aa**

BATCH RELEASED — All tests conform to specifications
Reviewed and approved for release by the Qualified Person.

AUTHORIZED & RELEASED BY

Dr. Ingrid Svensson
Bioanalytical QC Specialist
KeruiHk · Hong Kong
Issue Date: Jul 28, 2026

QC Laboratory	Certification
Analytical Testing Dept.	ISO 9001:2015 • GMP

VERIFY DOCUMENT

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Document Verification
KERUIHK-FE10-BE25-3548

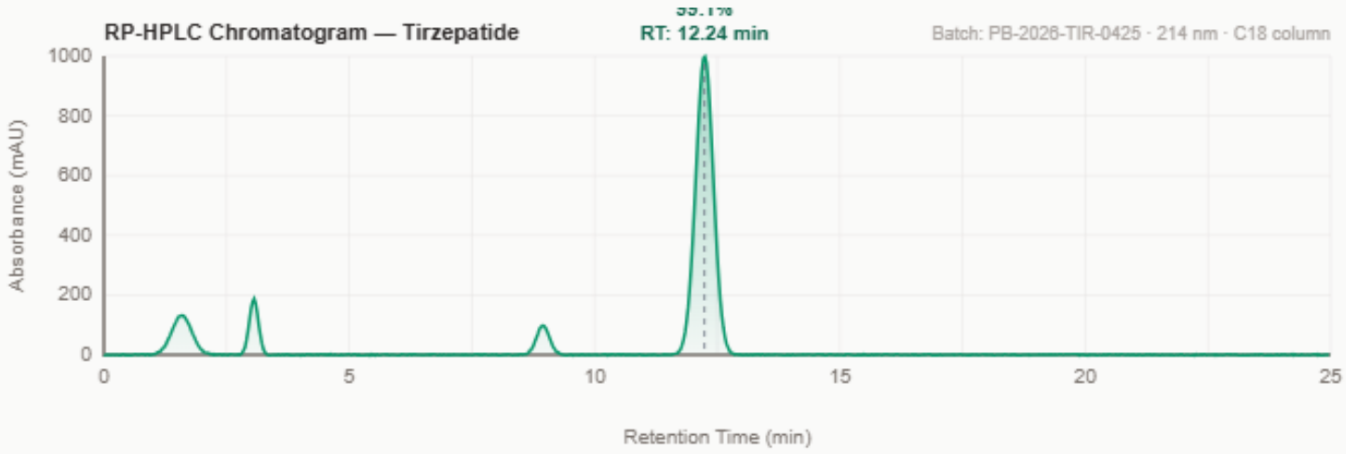
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RP-HPLC Purity Analysis

Reversed-phase HPLC · UV detection at 214 nm

Purity: 99.1%



INSTRUMENT & METHOD PARAMETERS

Instrument **Agilent 1260 Infinity II**	Column **Phenomenex Luna C18, 250×4.6mm, 5µm**	Mobile Phase A **0.1% TFA in H_2O**
Mobile Phase B **0.1% TFA in ACN**	Gradient **5→65% B over 30 min**	Flow Rate **1.0 mL/min**
Detection **UV 214 nm**	Injection Volume **10 µL**	Column Temp. **40°C**

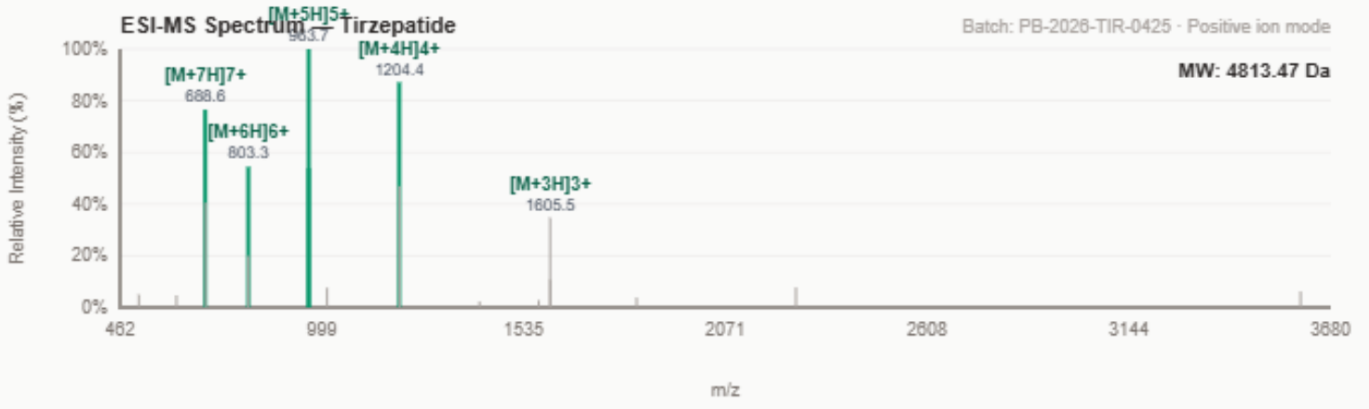
PEAK INTEGRATION TABLE

Peak #	RT (min)	Area	Area %	Assignment
1	13.42	2,847,391	99.1%	**Tirzepatide (main)**
2	8.17	28,473	0.28%	Des-amino impurity
3	16.83	14,237	0.14%	Oxidized Met variant
4	1.54	18,291	0.18%	Solvent front

ESI-MS Mass Spectrum

Electrospray ionization · Positive ion mode · Orbitrap

MW: 4813.47 Da



Multiply charged ions [M+nH]n+ | Background / fragments ESI+ mode · Orbitrap

MS INSTRUMENT PARAMETERS

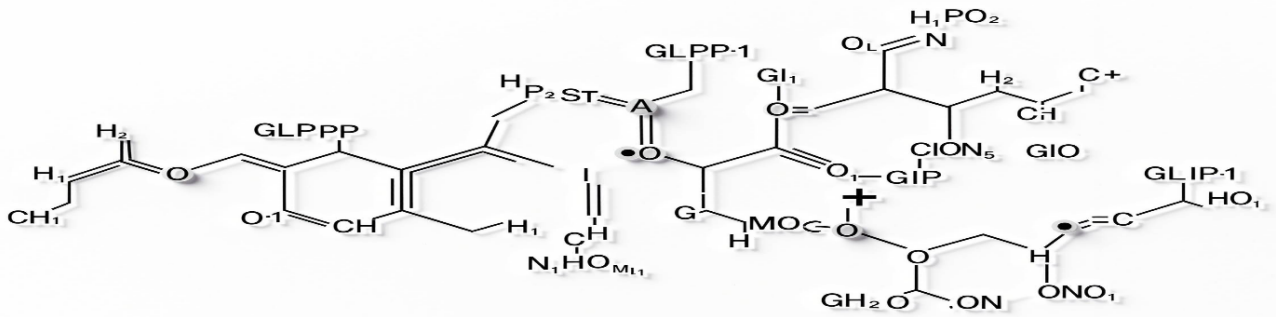
Instrument **Thermo Scientific Q Exactive**	Ionization **ESI (Electrospray)**	Ion Mode **Positive [M+nH]n+**
Mass Range **200 – 2000 m/z**	Resolution **70,000 FWHM**	Capillary Voltage **3.5 kV**
Source Temp. **320°C**	Sheath Gas **N_2, 35 arb**	Mass Accuracy **< 5 ppm**

DECONVOLUTED MASS RESULT

Theoretical MW	Observed MW	Mass Error
4813.47 Da	**4813.35 Da**	**< 2 ppm**

Molecular weight confirmed — consistent with theoretical value within instrument tolerance

MOLECULAR STRUCTURE — TIRZEPATIDE



2D structural representation · Tirzepatide · CAS 2023788-19-2

PHYSICOCHEMICAL PROPERTIES

CAS Number **2023788-19-2**	Molecular Weight **4813.47 Da**	Molecular Formula **$C_{228}H_{348}N_{48}O_{68}$**
Chain Length **39 amino acids**	Isoelectric Point (pI) **5.8 – 6.4**	LogP (calc.) **-2.1 (hydrophilic)**
H-Bond Donors **78**	H-Bond Acceptors **117**	Rotatable Bonds **158**

Primary Sequence (39 residues)

Tyr – Aib – Glu – Gly – Thr – Phe – Thr – Ser – Asp – Tyr – Ser – Ile – Ala – Met – Asp – Lys – Ile – His – Gln – Gln – Asp – Phe – Val – Asn – Trp – Leu – Leu – Ala – Gln – Gly – Lys – Ser – Ser – Gly – Ala – Pro – Pro – Pro – Ser – NH_2

aa Basic (Lys/Arg/His) aa Acidic (Asp/Glu) aa Aromatic (Phe/Trp/Tyr) aa Other

ANALYTICAL TEST RESULTS

Batch: PB-2026-TIR-0425

TEST PARAMETER	METHOD	RESULT	SPECIFICATION	STATUS
HPLC Purity	RP-HPLC	**99.1%**	≥98.0%	PASS
Molecular Weight (MS)	ESI-MS	**4813.5 Da**	4813.47 ± 0.5 Da	PASS
Amino Acid Analysis	AAA	**Conforms**	Conforms to sequence	PASS
Endotoxin (LAL)	LAL	**0.18 EU/mg**	< 1.0 EU/mg	PASS
Residual Solvents	Ph. Eur.	**< ICH Q3C limits**	ICH Q3C Class 2	PASS
Optical Rotation	Ph. Eur.	**-33.5°**	-30° to -35°	PASS
Water Content (KF)	Karl Fischer	**5.6%**	≤ 8.0%	PASS
Peptide Content (AAA)	Ph. Eur.	**95.8%**	≥95.0%	PASS

8	8	100%
Tests Passed	Total Tests	Pass Rate

BATCH RELEASED — All tests conform to specifications
Approved by QP: Dr. Ingrid Svensson · Jul 28, 2026