

ALC-PROOF-TIRZEPATIDE-10-55 · Rev 1

Catalog reference: tirzepatide-10

Search code: ALC-PROOF-TIRZEPATIDE-10-55

Received: 2026-09-28

Analyzed: 2026-09-29

Reported: 2026-09-30

Lot: SYN-00055

Sample Summary

Product: Tirzepatide - 10 mg

Principal peak purity: 99.21 % (area)

Identity evidence: Mass assignment supplied

Net content: 10.224 mg

Molecular formula: C225H348N48O68

Neutral mass: 4,810.52486 Da (monoisotopic; calculated)

Appearance: Lyophilized material

Chemical reference: [PubChem CID 156588324](#)

Analytical Results

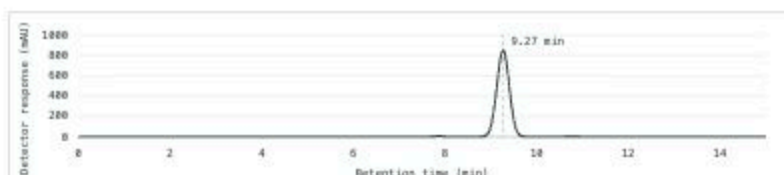
Review required

Profile profile-tirzepatide-10 v1.

Determination / method	Result	Specification	Decision
Principal peak purity HPLC-01 · area basis Peak area percent. This is not a mass fraction.	99.21 % U = 0.08 %, k = 2	98 to 100 %	Pass simple
Net content QNT-01 · mass basis Specification applies to the declared label claim.	10.224 mg U = 0.15 mg, k = 2	9 to 11 mg	Pass guard-band

Methods: Quantitative assay; RP-HPLC with UV detection; LC-MS mass assignment. Conditions, limits and calculated checks are included in the supporting pages.

Chromatogram



Mass Confirmation



Charge state	m/z (observed)	Mass error (ppm)
[M+2H] ²⁺	2406.26994	0.10
[M+3H] ³⁺	1604.51771	1.34
[M+4H] ⁴⁺	1203.63756	-0.77

monoisotopic mass convention; configured tolerance 10 ppm. Full acquisition values follow.

Paul Gütse

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Reviewed by

Scan report code

Local design proof

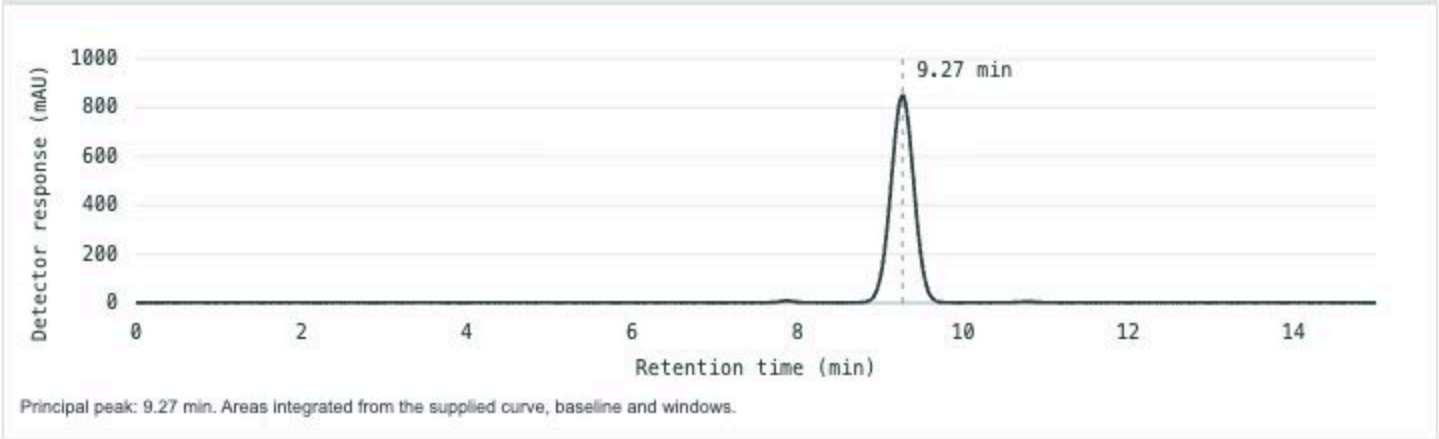
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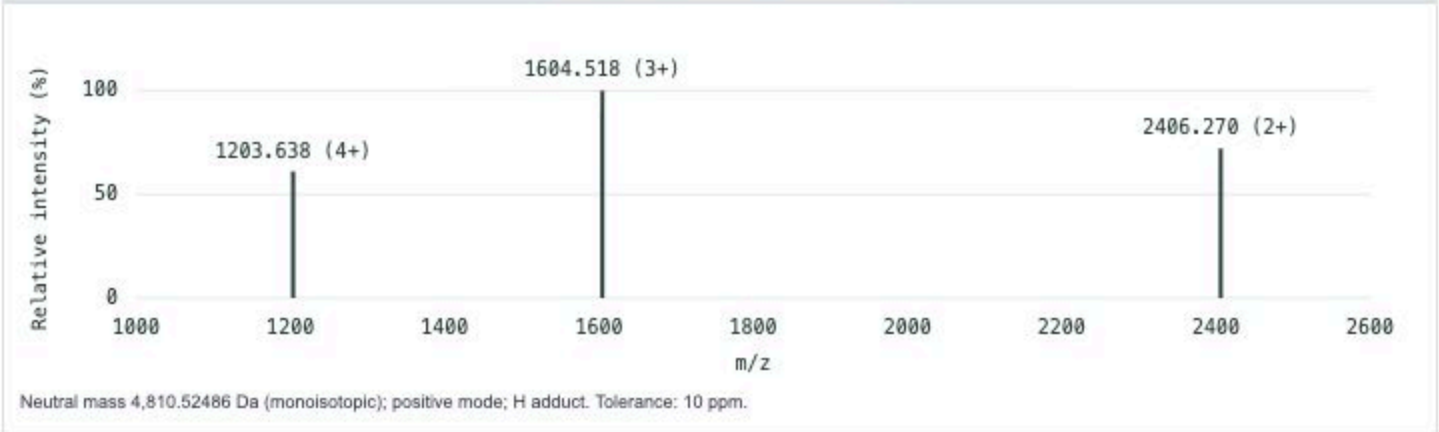
Results apply only to the submitted sample and the methods listed in this report. Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.

Chromatographic evidence

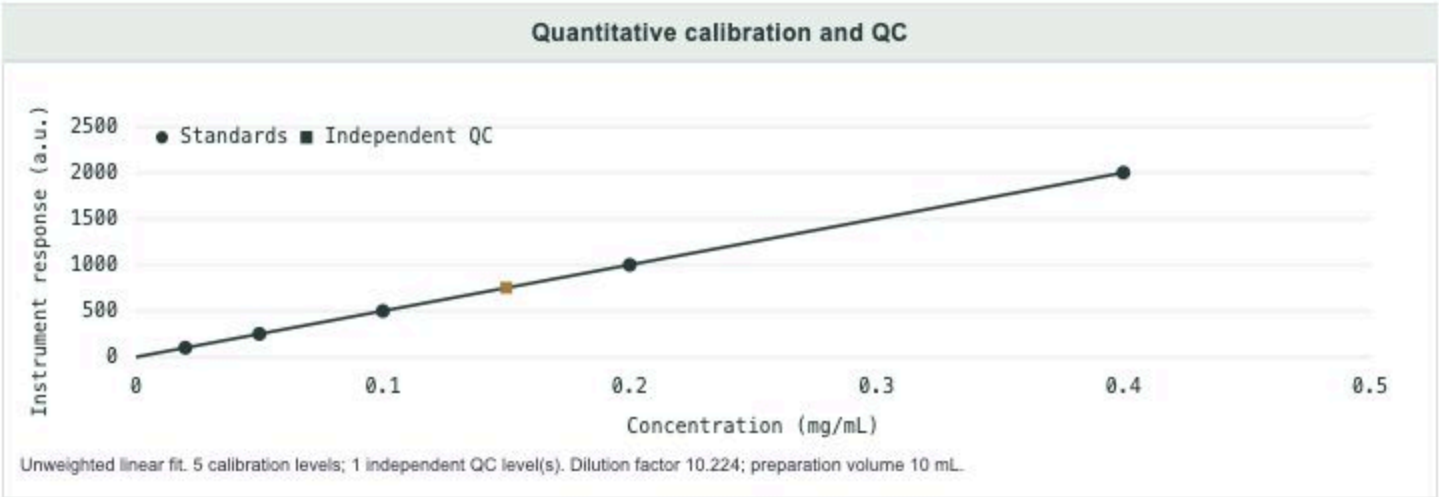


Integrated peak	Area (detector unit x min)	Area %
Principal peak	276.90203	99.21
Early impurity	1.42156	0.51
Late impurity	0.77256	0.28

Mass spectrometric evidence



Charge	Observed m/z	Predicted m/z	Error (ppm)
2+	2406.26994	2406.26971	0.10
3+	1604.51771	1604.51556	1.34
4+	1203.63756	1203.63849	-0.77



Calculated checks and system suitability			
Analysis check	Value	Configured criterion	Assessment
Expected neutral monoisotopic mass	4810.524858 Da	Chemical reference	informational
Principal peak purity	99.21 % area	Minimum 98; caution below 99	pass
Assay relative to label claim	102.24 %	90 to 110	pass
Total integrated impurities	0.7862 % area	Maximum 2	pass
Largest integrated impurity	0.5093 % area	Maximum 1.5	pass
Retention time	9.27 min	9.27 +/- 0.2	pass
Principal peak width at half height	0.3068 min	0.306 +/- 30%	pass
Theoretical plates	5056	Minimum 2000	pass
Resolution to Early impurity	3.335	Minimum 1.5	pass
Resolution to Late impurity	3.4	Minimum 1.5	pass
Tailing factor at 5% height	0.97	Maximum 2	pass
Principal signal to baseline noise	19185.3	Minimum 50	pass
Calibration R squared	0.999999	Minimum 0.995	pass
Independent QC bias	0.168 %	Absolute maximum 5	pass
Calibration-derived content	10.224 mg	Agrees with reported content within uncertainty	informational

Assessment observations

WARNING · impurity-detected

Early impurity: 0.509% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.277% area meets the configured impurity reporting threshold 0.05%.

Methods and decision rules

QNT-01 · Quantitative assay 1

Instrument: analytical balance

Calibration and replicate measurement. Expanded uncertainty uses $k = 2$.

Expanded measurement uncertainty uses a coverage factor of 2.

HPLC-01 · RP-HPLC with UV detection 1

Instrument: HPLC-UV

C18 column, 150 x 4.6 mm, 5 μ m; 0.1% formic acid in water/acetonitrile; 5 to 60% B over 15 min; 1.0 mL/min; 25 C; 214 nm; 10 μ L injection.

Trapezoidal integration against the declared baseline and windows.

MS-01 · LC-MS mass assignment 1

Instrument: ESI mass spectrometer

Positive ionization; protonated species; monoisotopic mass convention.

Neutral analyte formula: linked PubChem reference.

Simple acceptance compares the result with the stated limits. Guard band acceptance requires the full expanded uncertainty interval to fall within the limits; overlap is indeterminate. A failed specification remains a reportable result.

Scope and observations

Calculated from the configured neutral formula using monoisotopic atomic masses. This is a theoretical value, not an observed MS result.

Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.

Sample reference: Catalog identity and nominal content supplied by the client.

Chemical form: Neutral tirzepatide analyte

Chemical reference: [PubChem CID 156588324](#)

Prepared by: alchemlabs