

ALC-PROOF-MT2-10-56 · Rev 1

Catalog reference:	mt2-10
Search code:	ALC-PROOF-MT2-10-56
Received:	2026-09-28
Analyzed:	2026-09-29
Reported:	2026-09-30
Lot:	SYN-00056

Sample Summary

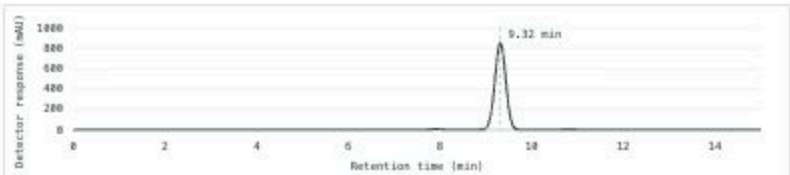
Product:	Melanotan II - 10 mg	Principal peak purity:	98.95 % (area)
Identity evidence:	Mass assignment supplied	Net content:	9.979 mg
Molecular formula:	C50H69N15O9	Neutral mass:	1,023.54027 Da (monoisotopic; calculated)
Appearance:	Lyophilized material	Chemical reference:	PubChem CID 92432

Analytical Results

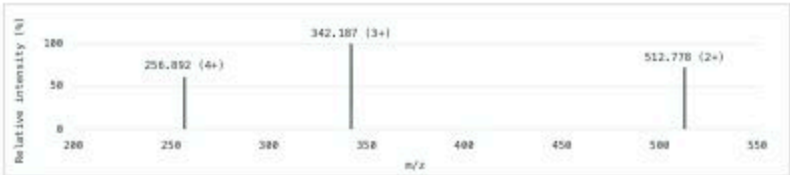
Review required		Profile profile-mt2-10 v1.	
Determination / method	Result	Specification	Decision
Principal peak purity	98.95 %	98 to 100 %	Pass
HPLC-01 · area basis	U = 0.08 %, k = 2		simple
Peak area percent. This is not a mass fraction.			
Net content	9.979 mg	9 to 11 mg	Pass
QNT-01 · mass basis	U = 0.15 mg, k = 2		guard-band
Specification applies to the declared label claim.			

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+	512.77752	0.21
[M+3H]3+	342.18739	0.07
[M+4H]4+	256.89243	0.34

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

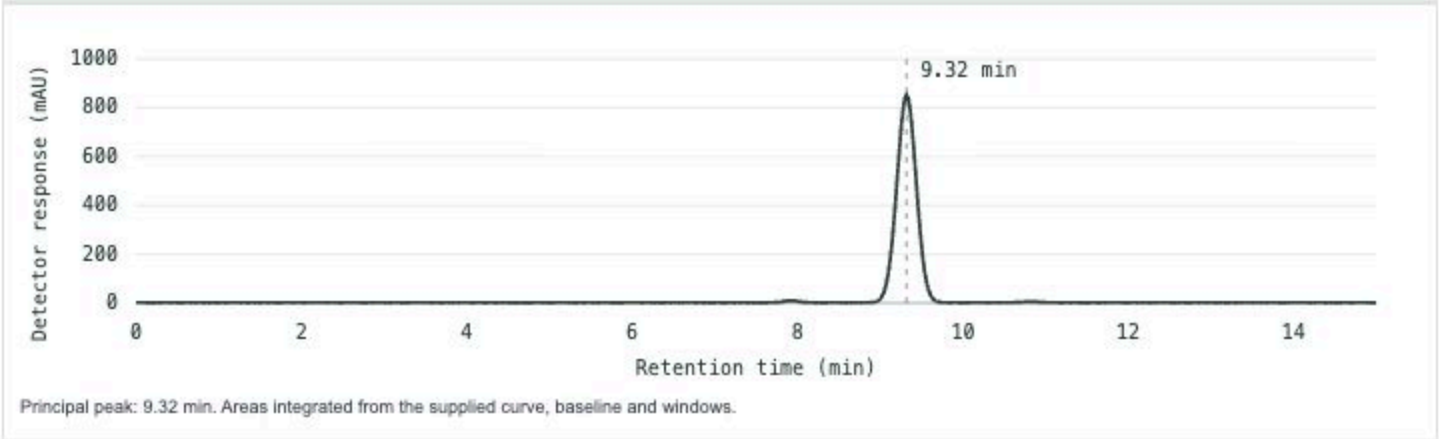
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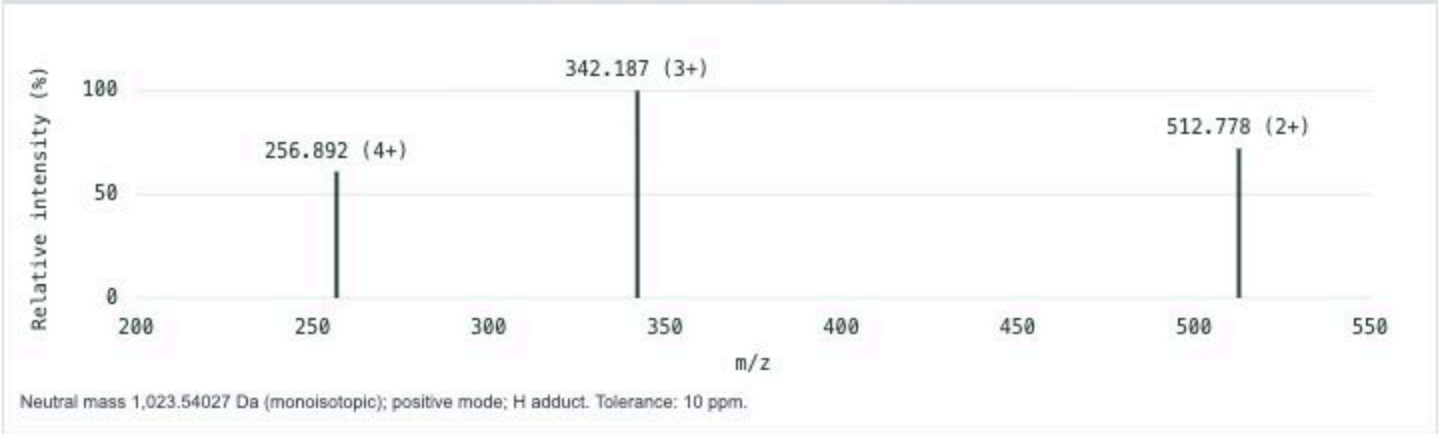
Results apply only to the submitted sample and the methods listed in this report. Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.

Chromatographic evidence

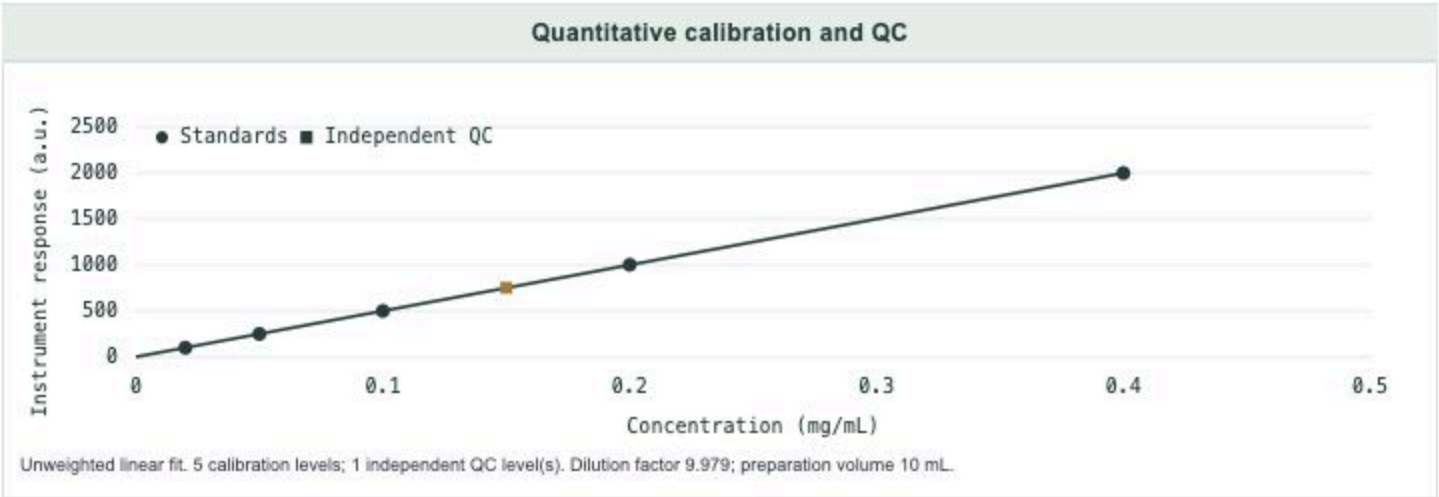


Integrated peak	Area (detector unit x min)	Area %
Principal peak	238.44081	98.95
Early impurity	1.64807	0.68
Late impurity	0.89417	0.37

Mass spectrometric evidence



Charge	Observed m/z	Predicted m/z	Error (ppm)
2+	512.77752	512.77741	0.21
3+	342.18739	342.18737	0.07
4+	256.89243	256.89234	0.34



Calculated checks and system suitability			
Analysis check	Value	Configured criterion	Assessment
Expected neutral monoisotopic mass	1023.540269 Da	Chemical reference	informational
Principal peak purity	98.95 % area	Minimum 98; caution below 99	review
Assay relative to label claim	99.79 %	90 to 110	pass
Total integrated impurities	1.0549 % area	Maximum 2	pass
Largest integrated impurity	0.6839 % area	Maximum 1.5	pass
Retention time	9.32 min	9.32 +/- 0.2	pass
Principal peak width at half height	0.2638 min	0.2635 +/- 30%	pass
Theoretical plates	6915	Minimum 2000	pass
Resolution to Early impurity	3.644	Minimum 1.5	pass
Resolution to Late impurity	3.702	Minimum 1.5	pass
Tailing factor at 5% height	1	Maximum 2	pass
Principal signal to baseline noise	19466.9	Minimum 50	pass
Calibration R squared	0.999997	Minimum 0.995	pass
Independent QC bias	0.234 %	Absolute maximum 5	pass
Calibration-derived content	9.979 mg	Agrees with reported content within uncertainty	informational

Assessment observations

WARNING · purity-caution

Purity is below the configured caution bar. Review impurity distribution.

WARNING · impurity-detected

Early impurity: 0.684% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.371% 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 cyclic Melanotan II analyte

Chemical reference: [PubChem CID 92432](#)

Prepared by: alchemlabs