

ALC-PROOF-MT1-10-61 · Rev 1

Catalog reference: mt1-10

Search code: ALC-PROOF-MT1-10-61

Received: 2026-09-28

Analyzed: 2026-09-29

Reported: 2026-09-30

Lot: SYN-00061

Sample Summary

Product: Melanotan I - 10 mg

Principal peak purity: 99.31 % (area)

Identity evidence: Not established by this report

Net content: 10.125 mg

Molecular formula: C78H111N21O19 (reference)

Neutral mass: 1,645.83651 Da (monoisotopic; calculated)

Appearance: Lyophilized material

Chemical reference: [PubChem CID 16197727](#)

Analytical Results

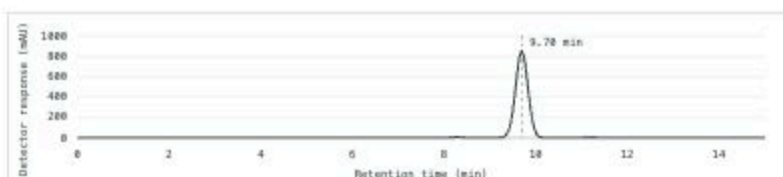
Review required

Profile profile-mt1-10 v1.

Determination / method	Result	Specification	Decision
Principal peak purity HPLC-01 · area basis Peak area percent. This is not a mass fraction.	99.31 % U = 0.08 %, k = 2	98 to 100 %	Pass simple
Net content QNT-01 · mass basis Specification applies to the declared label claim.	10.125 mg U = 0.15 mg, k = 2	9 to 11 mg	Pass guard-band

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

Chromatogram



Paul Gütse

Paul Gütse

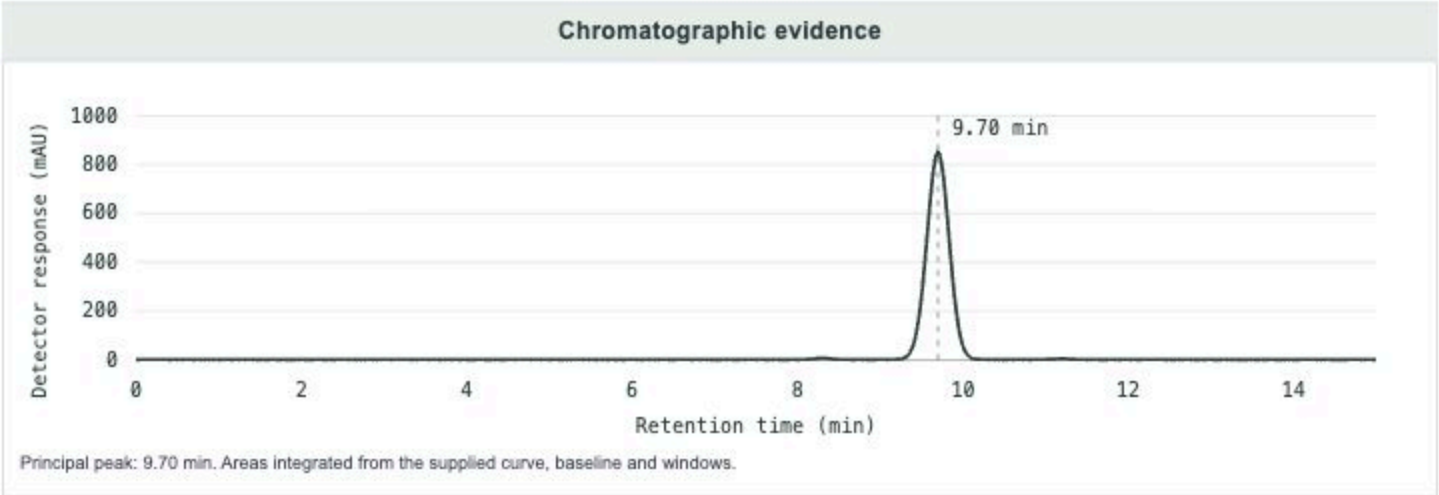
Reviewed by

Scan report code
Local design proof
ALC-PROOF-MT1-10-61

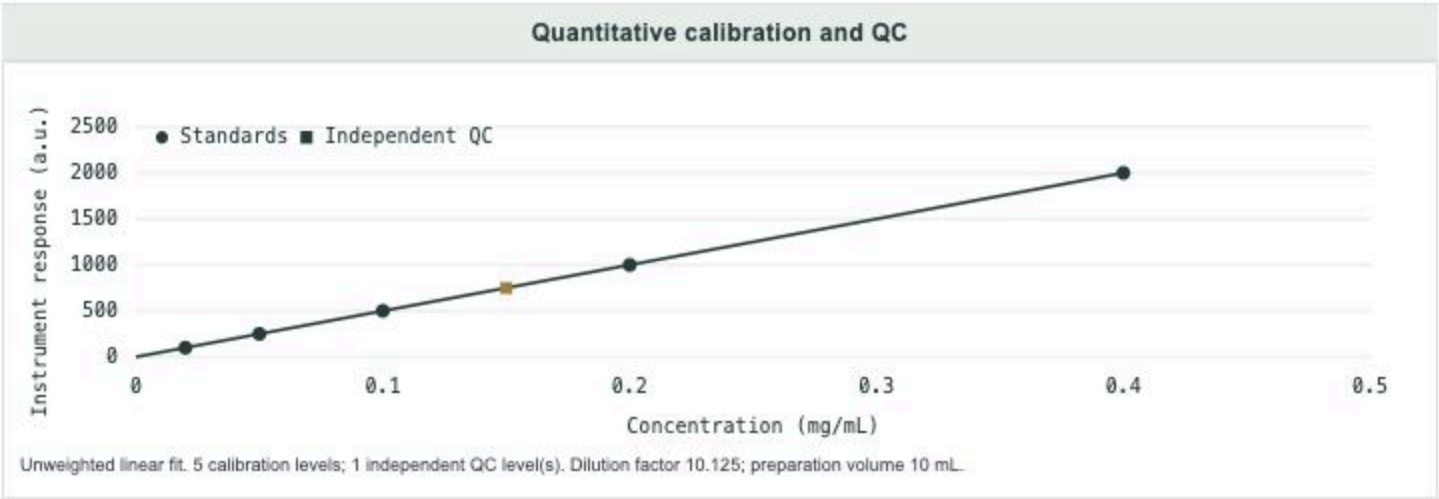


alchemlabs.org

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.



Integrated peak	Area (detector unit x min)	Area %
Principal peak	275.4051	99.31
Early impurity	1.22896	0.44
Late impurity	0.67092	0.24



Calculated checks and system suitability			
Analysis check	Value	Configured criterion	Assessment
Principal peak purity	99.31 % area	Minimum 98; caution below 99	pass
Assay relative to label claim	101.25 %	90 to 110	pass
Total integrated impurities	0.6851 % area	Maximum 2	pass
Largest integrated impurity	0.4432 % area	Maximum 1.5	pass
Retention time	9.7 min	9.7 +/- 0.2	pass
Principal peak width at half height	0.3046 min	0.3044 +/- 30%	pass
Theoretical plates	5618	Minimum 2000	pass
Resolution to Early impurity	3.36	Minimum 1.5	pass
Resolution to Late impurity	3.399	Minimum 1.5	pass
Tailing factor at 5% height	1	Maximum 2	pass
Principal signal to baseline noise	19371.1	Minimum 50	pass
Calibration R squared	1	Minimum 0.995	pass
Independent QC bias	-0.198 %	Absolute maximum 5	pass
Calibration-derived content	10.125 mg	Agrees with reported content within uncertainty	informational

Assessment observations

WARNING · impurity-detected

Early impurity: 0.443% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.242% 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.

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

Normalized from mt1. Confirm exact compound and salt.

Afamelanotide reference for Melanotan I; excludes acetate and other counterions. Sample sequence, terminal groups and salt form are not confirmed. Reference form: Afamelanotide reference peptide, acetylated and C-terminally amidated. Reference formula source: [PubChem CID 16197727](#).

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: Chemical form and sequence require a laboratory reference.

Chemical reference: [PubChem CID 16197727](#)

Prepared by: alchemlabs