

ALC-PROOF-OXYTOCIN-10-62 · Rev 1

Catalog reference: oxytocin-10

Search code: ALC-PROOF-OXYTOCIN-10-62

Received: 2026-09-28

Analyzed: 2026-09-29

Reported: 2026-09-30

Lot: SYN-00062

Sample Summary

Product: Oxytocin acetate - 10 mg

Principal peak purity: 99.51 % (area)

Identity evidence: Mass assignment supplied

Net content: 9.818 mg

Molecular formula: C43H66N12O12S2

Neutral mass: 1,006.43646 Da (monoisotopic; calculated)

Appearance: Lyophilized material

Chemical reference: [PubChem CID 439302](#)

Analytical Results

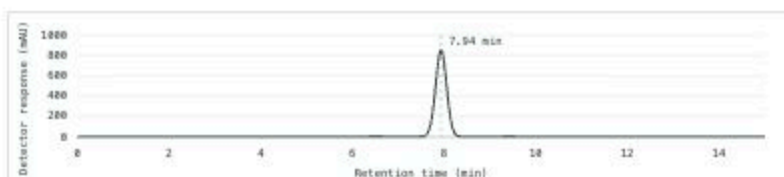
Review required

Profile profile-oxytocin-10 v1.

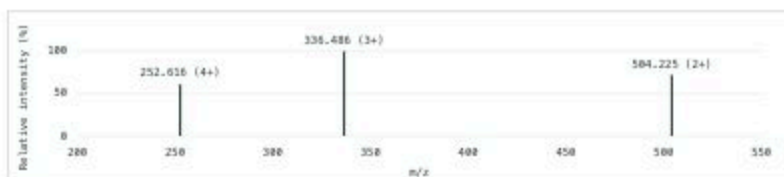
Determination / method	Result	Specification	Decision
Principal peak purity HPLC-01 · area basis Peak area percent. This is not a mass fraction.	99.51 % U = 0.08 %, k = 2	98 to 100 %	Pass simple
Net content QNT-01 · mass basis Specification applies to the declared label claim.	9.818 mg U = 0.15 mg, k = 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+	504.22485	-1.30
[M+3H]3+	336.48590	-0.58
[M+4H]4+	252.61638	-0.04

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

Paul Gütse

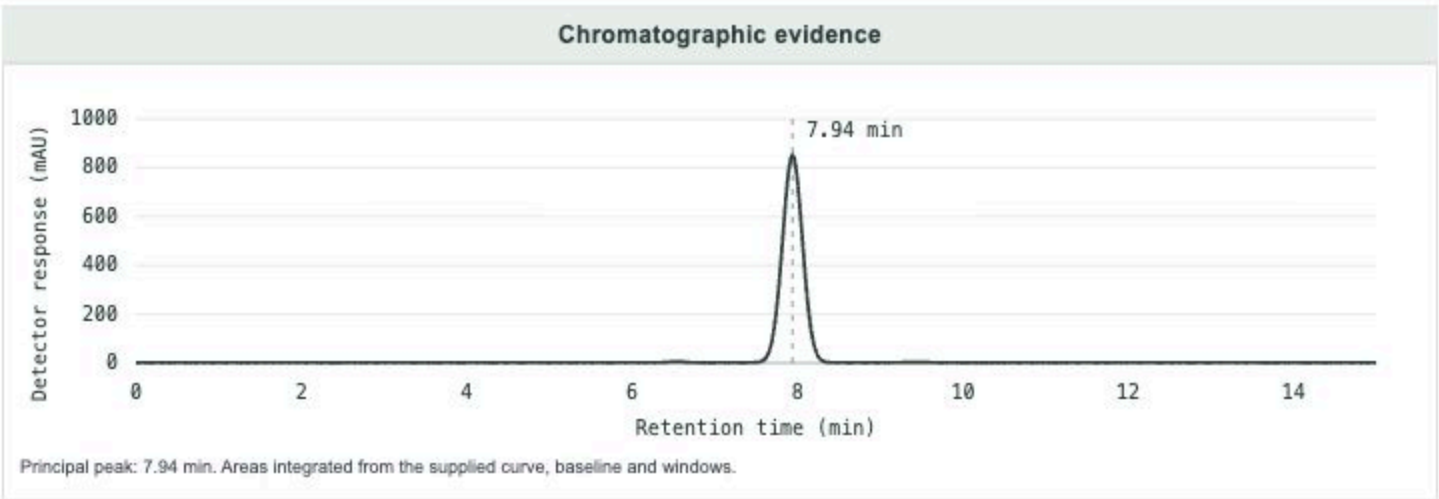
Paul Gütse
Reviewed by

Scan report code
Local design proof
ALC-PROOF-OXYTOCIN-10-62

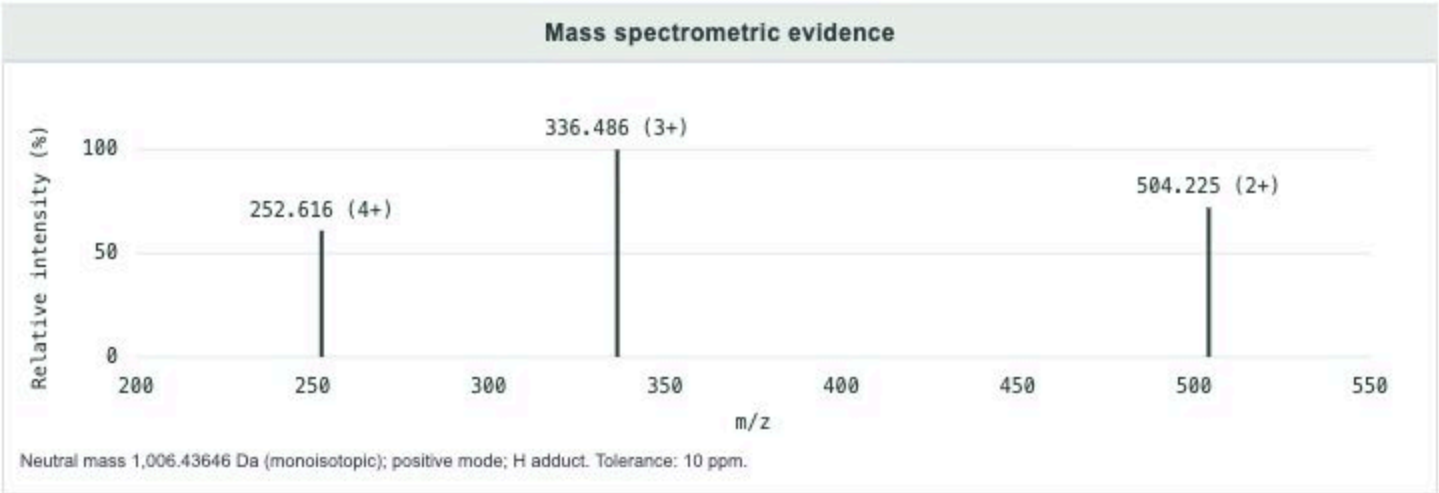


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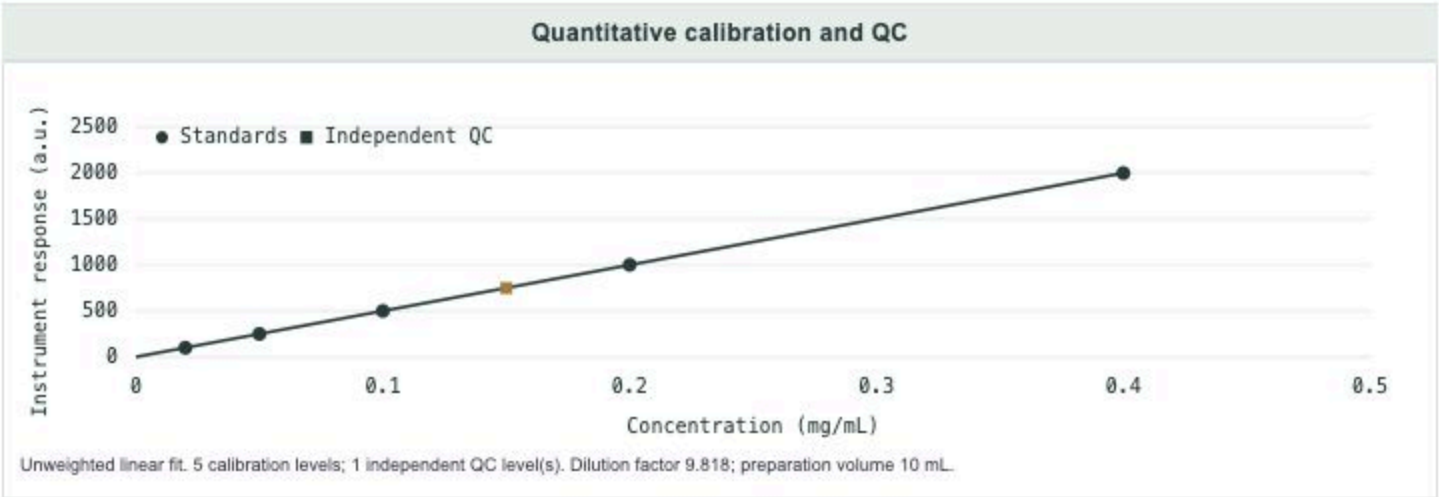
Results apply only to the submitted sample and the methods listed in this report. Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.



Integrated peak	Area (detector unit x min)	Area %
Principal peak	248.79072	99.51
Early impurity	0.79711	0.32
Late impurity	0.43067	0.17



Charge	Observed m/z	Predicted m/z	Error (ppm)
2+	504.22485	504.22551	-1.30
3+	336.48590	336.48610	-0.58
4+	252.61638	252.61639	-0.04



Calculated checks and system suitability			
Analysis check	Value	Configured criterion	Assessment
Expected neutral monoisotopic mass	1006.436458 Da	Chemical reference	informational
Principal peak purity	99.51 % area	Minimum 98; caution below 99	pass
Assay relative to label claim	98.18 %	90 to 110	pass
Total integrated impurities	0.4911 % area	Maximum 2	pass
Largest integrated impurity	0.3188 % area	Maximum 1.5	pass
Retention time	7.94 min	7.94 +/- 0.2	pass
Principal peak width at half height	0.2751 min	0.275 +/- 30%	pass
Theoretical plates	4616	Minimum 2000	pass
Resolution to Early impurity	3.586	Minimum 1.5	pass
Resolution to Late impurity	3.527	Minimum 1.5	pass
Tailing factor at 5% height	1	Maximum 2	pass
Principal signal to baseline noise	19267.5	Minimum 50	pass
Calibration R squared	0.999998	Minimum 0.995	pass
Independent QC bias	-0.171 %	Absolute maximum 5	pass
Calibration-derived content	9.818 mg	Agrees with reported content within uncertainty	informational

Assessment observations

WARNING · impurity-detected

Early impurity: 0.319% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.172% 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 oxytocin peptide; acetate is excluded from ion mass. Confirm assay basis and acetate content separately.

Chemical reference: [PubChem CID 439302](#)

Prepared by: alchemlabs