

ALC-PROOF-CEREBROLYSIN-60-64 · Rev 1

Catalog reference: cerebrolysin-60

Search code: ALC-PROOF-CEREBROLYSIN-60-64

Received: 2026-09-28

Analyzed: 2026-09-29

Reported: 2026-09-30

Lot: SYN-00064

Sample Summary

Product:	Cerebrolysin - 60 mg	Principal peak purity:	99.6 % (area)
Identity evidence:	Not established by this report	Net content:	59.733 mg
Molecular formula:	Not applicable: heterogeneous peptide mixture	Neutral mass:	Not applicable: molecular mass distribution
Appearance:	Lyophilized material	Chemical reference:	Manufacturer reference in supporting notes

Analytical Results

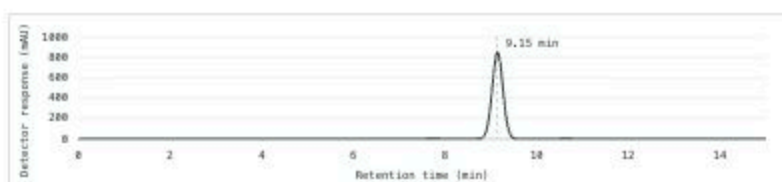
Review required

Profile profile-cerebrolysin-60 v1.

Determination / method	Result	Specification	Decision
Principal peak purity HPLC-01 · area basis Peak area percent. This is not a mass fraction.	99.6 % $U = 0.08 \%$, $k = 2$	98 to 100 %	Pass simple
Net content QNT-01 · mass basis Specification applies to the declared label claim.	59.733 mg $U = 0.9 \text{ mg}$, $k = 2$	54 to 66 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

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Reviewed by

Scan report code

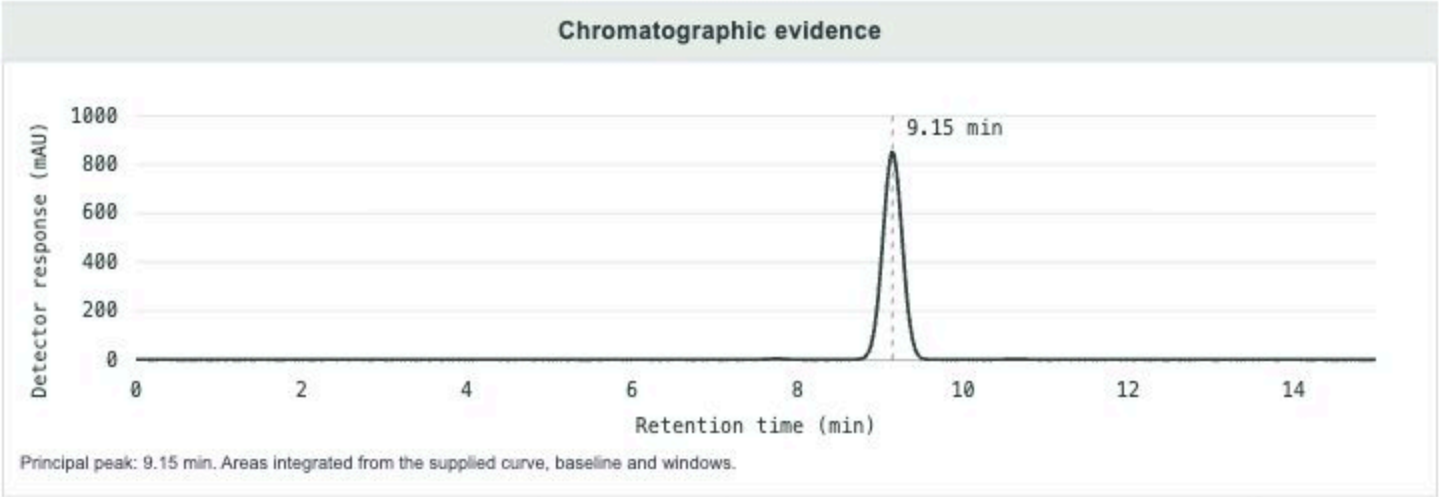
Local design proof

ALC-PROOF-CEREBROLYSIN-60-64

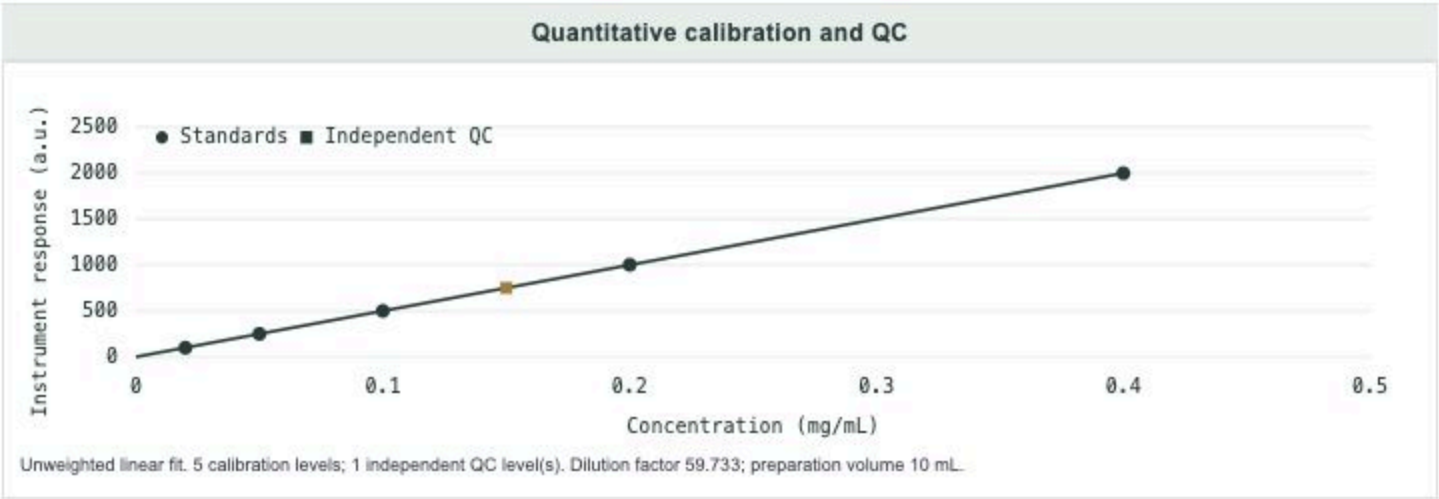


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Results apply only to the submitted sample and the methods listed in this report. Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.



Integrated peak	Area (detector unit x min)	Area %
Principal peak	239.22165	99.60
Early impurity	0.62743	0.26
Late impurity	0.34287	0.14



Calculated checks and system suitability			
Analysis check	Value	Configured criterion	Assessment
Principal peak purity	99.6 % area	Minimum 98; caution below 99	pass
Assay relative to label claim	99.555 %	90 to 110	pass
Total integrated impurities	0.404 % area	Maximum 2	pass
Largest integrated impurity	0.2612 % area	Maximum 1.5	pass
Retention time	9.15 min	9.15 +/- 0.2	pass
Principal peak width at half height	0.2653 min	0.2644 +/- 30%	pass
Theoretical plates	6590	Minimum 2000	pass
Resolution to Early impurity	3.71	Minimum 1.5	pass
Resolution to Late impurity	3.761	Minimum 1.5	pass
Tailing factor at 5% height	0.965	Maximum 2	pass
Principal signal to baseline noise	19010.1	Minimum 50	pass
Calibration R squared	0.999997	Minimum 0.995	pass
Independent QC bias	0.076 %	Absolute maximum 5	pass
Calibration-derived content	59.733 mg	Agrees with reported content within uncertainty	informational

Assessment observations

WARNING · impurity-detected

Early impurity: 0.261% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.143% 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

Complex mixture. Single molecular mass and single-component identity are not applicable.

Cerebrolysin is a heterogeneous peptide preparation. A single molecular formula or neutral mass does not describe the preparation. Characterization requires the actual composition and molecular mass distribution. [Manufacturer preparation information](#).

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: Manufacturer reference in supporting notes

Prepared by: alchemlabs