

ALC-PROOF-KLOW-80-57 · Rev 1

Catalog reference: klow-80

Search code: ALC-PROOF-KLOW-80-57

Received: 2026-09-28

Analyzed: 2026-09-29

Reported: 2026-09-30

Lot: SYN-00057

Sample Summary

Product: KLOW – 80 mg

Principal peak purity: 99.5 % (area)

Identity evidence: Not established by this report

Net content: 78.574 mg

Molecular formula: Composition not supplied

Neutral mass: No single molecular mass for a blend

Appearance: Lyophilized material

Chemical reference: Composition required

Analytical Results

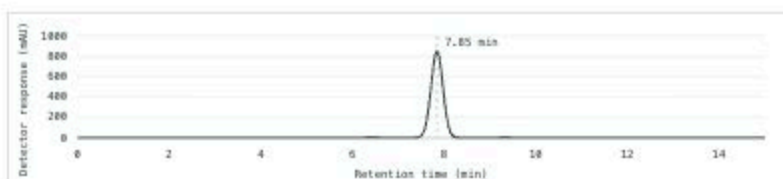
Review required

Profile profile-klow-80 v1.

Determination / method	Result	Specification	Decision
Principal peak purity HPLC-01 · area basis Peak area percent. This is not a mass fraction.	99.5 % U = 0.08 %, k = 2	98 to 100 %	Pass simple
Net content QNT-01 · mass basis Specification applies to the declared label claim.	78.574 mg U = 1.2 mg, k = 2	72 to 88 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

Evidence incomplete. Composition and component assay evidence must be resolved before issuance.

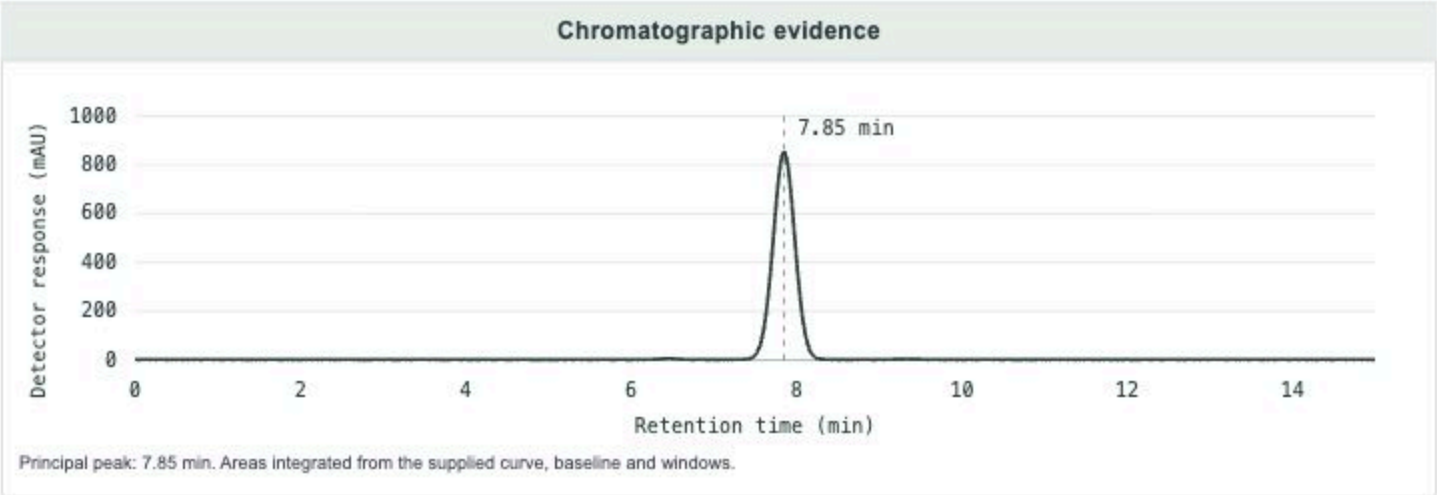
Scan report code

Local design proof
ALC-PROOF-KLOW-80-57

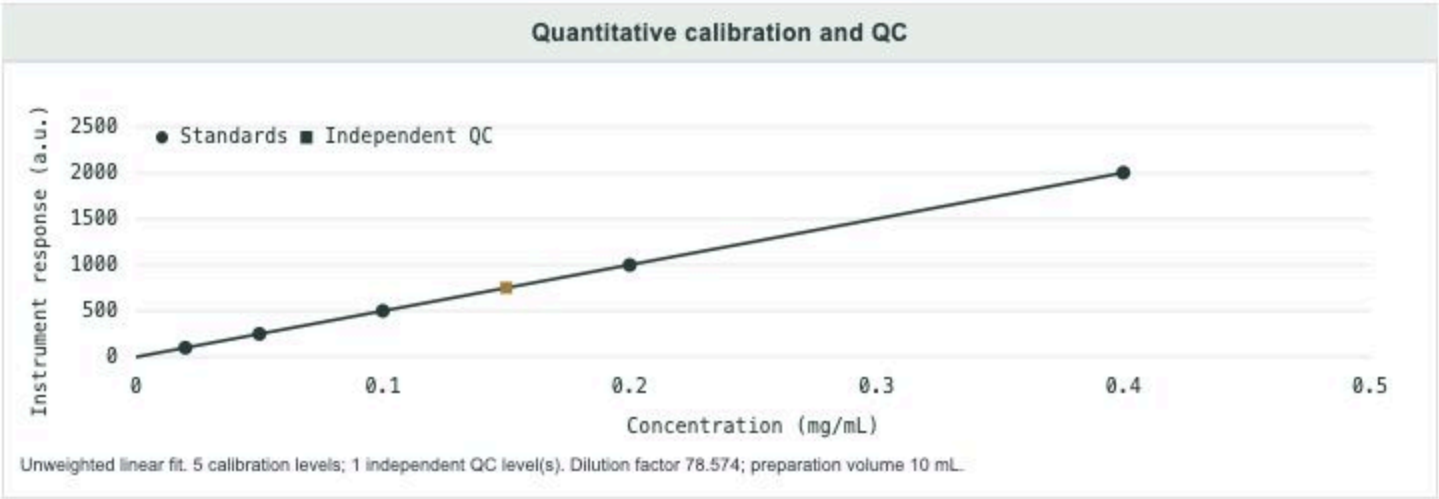


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Results apply only to the submitted sample and the methods listed in this report. Only the listed methods are covered. This report does not establish sterility, endotoxin content, biological activity or suitability for clinical use.



Integrated peak	Area (detector unit x min)	Area %
Principal peak	266.76556	99.50
Early impurity	0.87556	0.33
Late impurity	0.4779	0.18



Calculated checks and system suitability			
Analysis check	Value	Configured criterion	Assessment
Principal peak purity	99.5 % area	Minimum 98; caution below 99	pass
Assay relative to label claim	98.218 %	90 to 110	pass
Total integrated impurities	0.5048 % area	Maximum 2	pass
Largest integrated impurity	0.3266 % area	Maximum 1.5	pass
Retention time	7.85 min	7.85 +/- 0.2	pass
Principal peak width at half height	0.2956 min	0.2948 +/- 30%	pass
Theoretical plates	3907	Minimum 2000	pass
Resolution to Early impurity	3.469	Minimum 1.5	pass
Resolution to Late impurity	3.431	Minimum 1.5	pass
Tailing factor at 5% height	0.969	Maximum 2	pass
Principal signal to baseline noise	19771.2	Minimum 50	pass
Calibration R squared	0.999998	Minimum 0.995	pass
Independent QC bias	0.161 %	Absolute maximum 5	pass
Calibration-derived content	78.574 mg	Agrees with reported content within uncertainty	informational

Assessment observations

ERROR · blend-composition

Blend reports require at least two identified components.

WARNING · impurity-detected

Early impurity: 0.327% area meets the configured impurity reporting threshold 0.05%.

WARNING · impurity-detected

Late impurity: 0.178% area meets the configured impurity reporting threshold 0.05%.

ERROR · blend-area-purity

A single principal peak area cannot establish the purity or composition of a blend. Supply a dossier for each component.

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

Trade blend name. No composition inferred.

The trade name does not define a chemical composition. Supply component identities and proportions before assigning component formulas or reference masses.

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: Composition required

Prepared by: alchemlabs