

Scottsdale Police Department Crime Laboratory

Calibrators and Control Certificates for Samples Run

09/22/2025 -

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-20

Ethyl alcohol

Catalog Number: E-056
Solution Lot: FN03122113
Expiration: March 2026
Diluent: Water
Volume per Ampule: 1.2 mL
Storage: Refrigerate (Do Not Freeze)
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- ◆ Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- ◆ Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- ◆ For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|-----------------|-------------------------|
| Ethanol | > 99.9% | 20.00 ± 0.08 mg/dL |
| <ul style="list-style-type: none">◆ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.◆ When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval (k=2).◆ The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.◆ Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.◆ Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred. | | |

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date. Warranty applies to ampoules stored unopened and stored under the recommended storage conditions. Warranty and expiry do not extend to solutions into which this product has been incorporated. Establishment of shelf life of all such products is the responsibility of the user. This material is a product of Canada.



A handwritten signature in black ink, appearing to read 'D. Ellsworth'.

Darron Ellsworth, Quality Assurance Manager

July 27, 2021

Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
Sigma-Aldrich Production GmbH is a subsidiary of Merck KGaA, Darmstadt, Germany.



Traceability to SI through NIST:

- ◆ This standard has been prepared and certified under the ISO 17034 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- ◆ This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- ◆ Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- ◆ Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2891 mg/dL | Homogeneity % RSD |
|---|-------------------|--|------------------------------|
| New Lot | FN03122113 | 20.06 | 0.6 |
| Previous Lot | FN10051909 | 20.08 | 1.6 |
| Acceptance Criteria | | ± 2% | ≤ 2 |
| <ul style="list-style-type: none">◆ Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.◆ The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.◆ Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.◆ The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.◆ All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters. | | | |

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

| Material Characterization Summary | | |
|--|---------------------|---------------------------|
| Analytical Test | Method | Results |
| Chromatographic Purity by GC/FID Analysis | SP10-0101 | 99.9% |
| Residual Water Analysis by Karl Fischer Coulometry | AM1346 ¹ | 0.11% |
| Identity by GC/MS | SP10-0105 | Consistent with Structure |
| Mass Balance Purity Factor | | 99.81% |
| ¹ Validated analytical method | | |
| ♦ The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other. | | |

Spectral and Physical Data

Neat Material

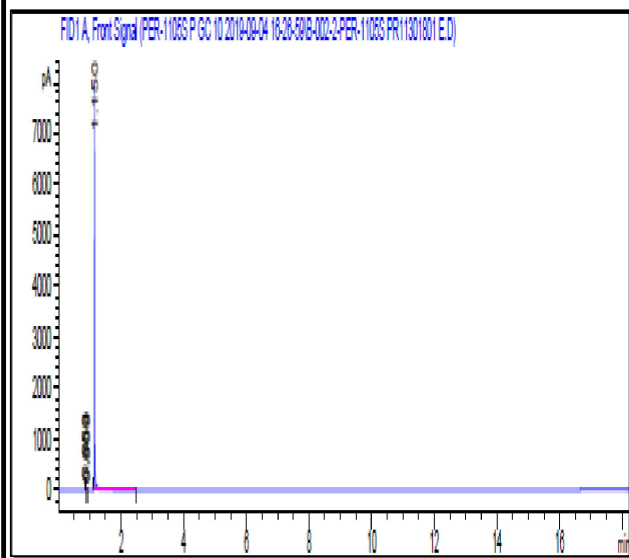
Analysis Method: GC/FID

Column: DB-5ms, 30 m x 0.53 mm ID,
1.5 µm film thickness

Temp Program: 35°C hold 5 min to 260°C at
20°C/min hold 2 min

Injector Temp: Cool-on-Column

Detector Temp: 325°C



Standard Solution

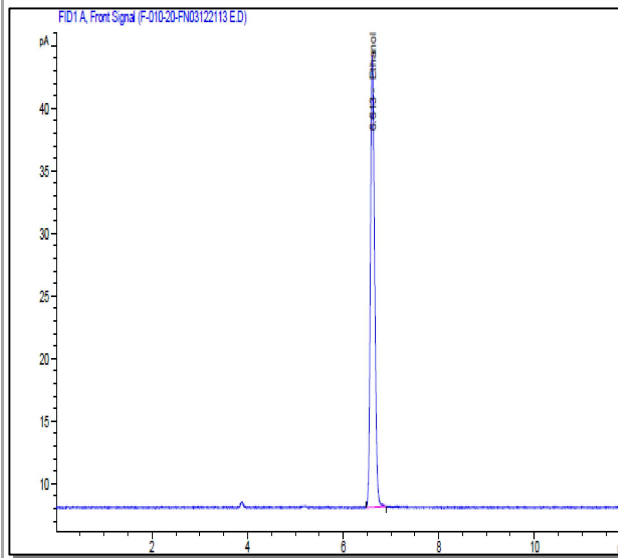
Analysis Method: GC/FID Headspace

Column: DB-ALC1 30 m x 0.53 mm ID,
3.0 µm film thickness

Temp Program: 40°C hold 12 min

Injector Temp: 200°C

Detector Temp: 250°C



COA Revision History

| Revision No. | Date | Reason for Revision |
|--------------|---------------|---------------------|
| 00 | July 27, 2021 | Initial version. |
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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-20

Ethyl alcohol

Catalog Number: E-056
Solution Lot: FN03062417
Expiration: September 2029
Diluent: Water
Volume per Ampule: 1.2 mL
Storage: Refrigerate (Do Not Freeze)
Country of Origin: Canada
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- ◆ Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- ◆ Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- ◆ For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|-----------------|-------------------------|
| Ethanol | > 99.9% | 20.00 ± 0.08 mg/dL |
| <ul style="list-style-type: none">◆ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of $k=2$ and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.◆ When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval ($k=2$).◆ The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.◆ Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.◆ Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred. | | |

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A handwritten signature in black ink, appearing to read 'J. Schmitt'.

James Schmitt, Quality Assurance Manager

January 24, 2025

Date

Cerilliant Corporation, 811 Paloma Drive, Round Rock, TX 78665, USA,
Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
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- ◆ Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- ◆ Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2891 mg/dL | Homogeneity % RSD |
|---|------------|---|----------------------|
| New Lot | FN03062417 | 19.83 | 1.3 |
| Previous Lot | FN03122113 | 19.83 | 0.8 |
| Acceptance Criteria | | ± 2% | ≤ 2 |
| <ul style="list-style-type: none">◆ Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.◆ The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.◆ Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.◆ The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.◆ All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters. | | | |

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary

| Analytical Test | Method | Results |
|--|-----------------------|---------|
| Chromatographic Purity by GC/FID Analysis | 20384346 | > 99.9% |
| Residual Water Analysis by Karl Fischer Coulometry | 20384212 ¹ | 0.15% |
| Mass Balance Purity Factor | | 99.85% |

¹ Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

Neat Material

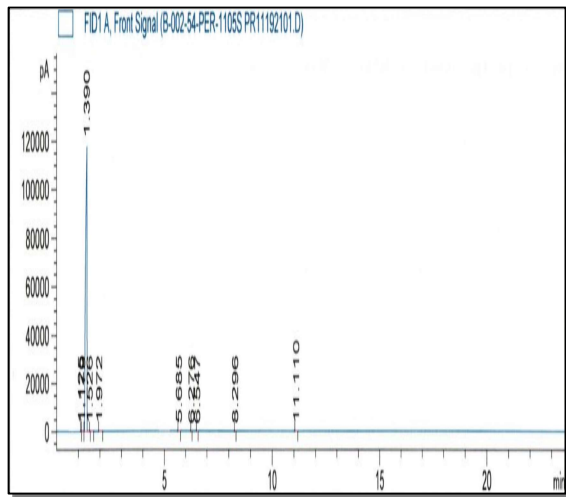
Analysis Method: GC/FID

Column: DB-5ms, 30 m x 0.53 mm ID,
1.5 µm film thickness

Temp Program: 35°C hold 5 min to 100°C at
40°C/min, 100°C to 280°C at
20°C/min hold 8 min

Injector Temp: Cool-on-Column

Detector Temp: 325°C



COA Revision History

| Revision No. | Date | Reason for Revision |
|--------------|------------------|---------------------|
| 00 | January 24, 2025 | Initial version. |
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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl alcohol


Catalog Number: E-031
Solution Lot: FN04042408
Expiration: April 2029
Diluent: Water
Volume per Ampule: 1.2 mL
Storage: Refrigerate (Do Not Freeze)
Country of Origin: Canada
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- ◆ Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- ◆ Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- ◆ For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|-----------------|-------------------------|
| Ethanol | > 99.9% | 100.0 ± 0.4 mg/dL |
| <ul style="list-style-type: none">◆ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.◆ When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval (k=2).◆ The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.◆ Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.◆ Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred. | | |

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James Schmitt, Quality Assurance Manager

June 27, 2024
Date

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- ◆ Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- ◆ Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

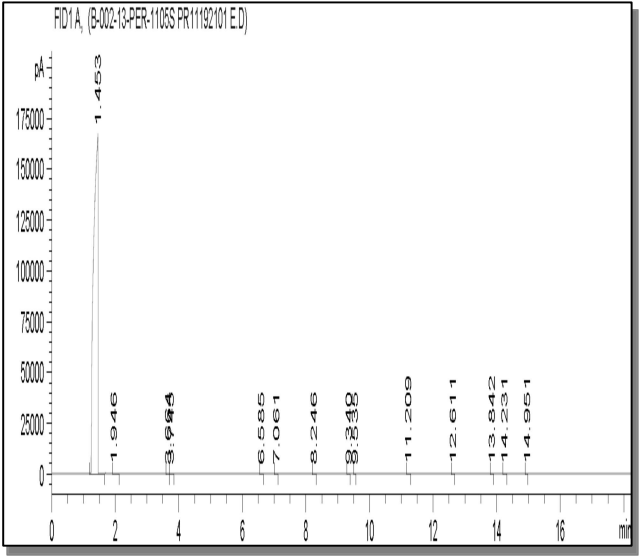
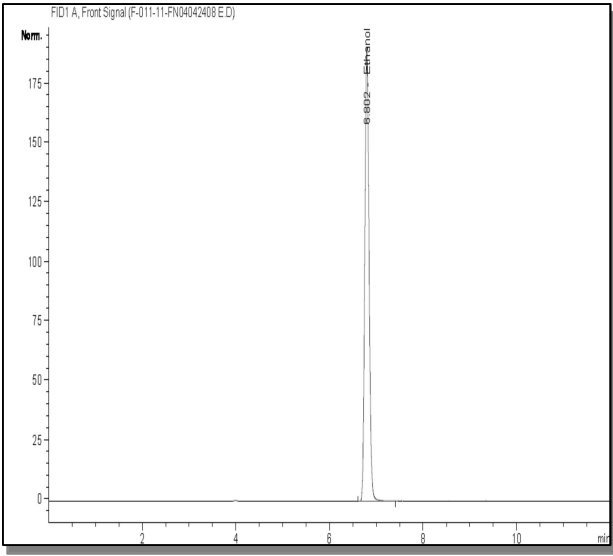
| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2894 mg/dL | Homogeneity % RSD |
|---|------------|---------------------------------------|-------------------|
| New Lot | FN04042408 | 99.1 | 0.3 |
| Previous Lot | FN03072301 | 99.1 | 1.2 |
| Acceptance Criteria | | ± 2% | ≤ 2 |
| <ul style="list-style-type: none">◆ Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.◆ The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.◆ Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.◆ The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.◆ All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters. | | | |

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

| Material Characterization Summary | | |
|--|-----------------------|---------------------------|
| Analytical Test | Method | Results |
| Chromatographic Purity by GC/FID Analysis | 20384346 | > 99.9% |
| Identity by GC/MS Analysis | 20384214 | Consistent with Structure |
| Residual Water Analysis by Karl Fischer Coulometry | 20384212 ¹ | 0.16% |
| Mass Balance Purity Factor | | 99.84% |
| ¹ Validated analytical method ♦ The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other. | | |

Spectral and Physical Data

| Neat Material | Standard Solution |
|--|--|
| Analysis Method: GC/FID Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min Injector Temp: Cool-on-Column Detector Temp: 325°C | Analysis Method: GC/FID Headspace Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness Temp Program: 40°C hold 12 min Injector Temp: 200°C Detector Temp: 250°C |
|  |  |

COA Revision History

| Revision No. | Date | Reason for Revision |
|--------------|---------------|---------------------|
| 00 | June 27, 2024 | Initial version. |
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The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada.

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-200

Ethyl alcohol

Catalog Number: E-032
Solution Lot: FN03132302
Expiration: March 2028
Diluent: Water
Volume per Ampule: 1.2 mL
Storage: Refrigerate (Do Not Freeze)
Country of Origin: Canada
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- ◆ Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- ◆ Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- ◆ For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|-----------------|-------------------------|
| Ethanol | > 99.9% | 200 ± 1 mg/dL |
| <ul style="list-style-type: none">◆ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.◆ When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.249% and the relative expanded uncertainty is 0.50% at the 95% confidence interval (k=2).◆ The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.◆ Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.◆ Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred. | | |

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Darron Ellsworth, Quality Assurance Manager

April 14, 2023
Date

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- ◆ Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- ◆ Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2895 mg/dL | Homogeneity % RSD |
|---|------------|---|----------------------|
| New Lot | FN03132302 | 199 | 1.3 |
| Previous Lot | FN02052101 | 199 | 0.9 |
| Acceptance Criteria | | ± 2% | ≤ 2 |
| <ul style="list-style-type: none">◆ Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.◆ The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.◆ Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.◆ The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.◆ All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters. | | | |

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The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary

| Analytical Test | Method | Results |
|--|-----------------------|---------|
| Chromatographic Purity by GC/FID Analysis | 20384346 | > 99.9% |
| Residual Water Analysis by Karl Fischer Coulometry | 20398075 ¹ | 0.09% |
| Mass Balance Purity Factor | | 99.90% |

¹ Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

Neat Material

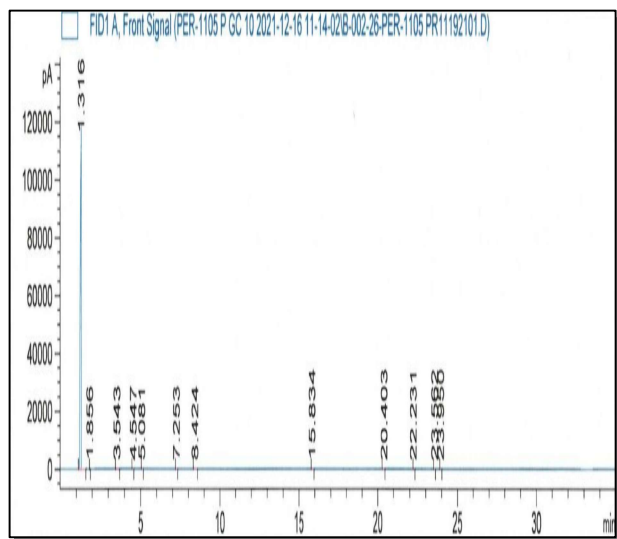
Analysis Method: GC/FID

Column: DB-5ms, 30 m x 0.53 mm ID,
1.5 µm film thickness

Temp Program: 35°C hold 5 min to 100°C at
40°C/min
100°C to 280°C at 20°C/min
hold 8 min

Injector Temp: Cool-on-Column

Detector Temp: 325°C



Standard Solution

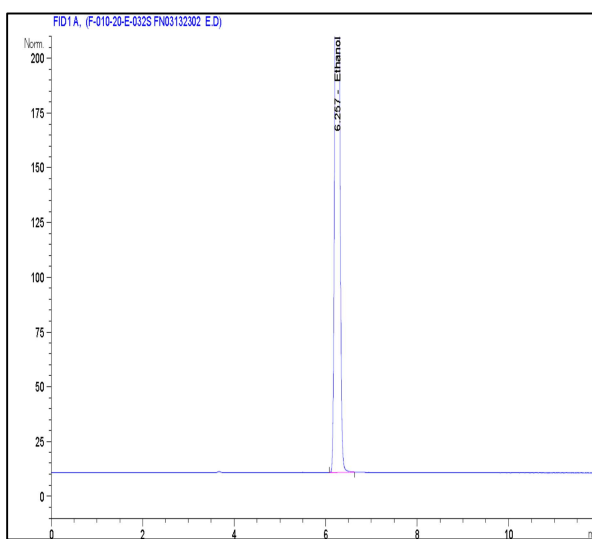
Analysis Method: GC/FID Headspace

Column: DB-ALC1 30 m x 0.53 mm ID,
3.0 µm film thickness

Temp Program: 40°C hold 12 min

Injector Temp: 200°C

Detector Temp: 250°C



COA Revision History

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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl alcohol

Catalog Number: E-036
Solution Lot: FN03052102
Expiration: March 2026
Diluent: Water
Volume per Ampule: 1.2 mL
Storage: Refrigerate (Do Not Freeze)
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- ◆ Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- ◆ Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- ◆ For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|-----------------|-------------------------|
| Ethanol | > 99.9% | 400 ± 2 mg/dL |
| <ul style="list-style-type: none">◆ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of $k=2$ and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.◆ When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval ($k=2$).◆ The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.◆ Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.◆ Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred. | | |

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date. Warranty applies to ampoules stored unopened and stored under the recommended storage conditions. Warranty and expiry do not extend to solutions into which this product has been incorporated. Establishment of shelf life of all such products is the responsibility of the user. This material is a product of the Canada.



A handwritten signature in black ink, appearing to read 'Dell'.

Darron Ellsworth, Quality Assurance Manager

April 14, 2021
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
Sigma-Aldrich Production GmbH is a subsidiary of Merck KGaA, Darmstadt, Germany.



Traceability to SI through NIST:

- ◆ This standard has been prepared and certified under the ISO 17034 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- ◆ This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- ◆ Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- ◆ Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

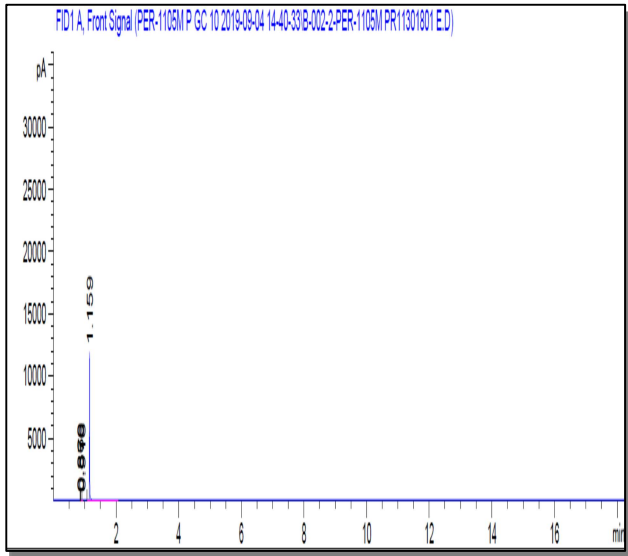
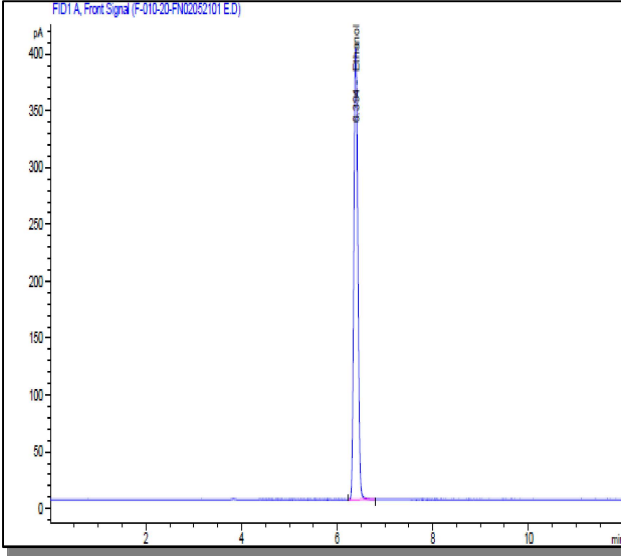
| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2896 mg/dL | Homogeneity % RSD |
|---|-------------------|--|------------------------------|
| New Lot | FN03052102 | 397 | 0.8 |
| Previous Lot | FN10051906 | 400 | 1.7 |
| Acceptance Criteria | | ± 2% | ≤ 2 |
| <ul style="list-style-type: none">◆ Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.◆ The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.◆ Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.◆ The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.◆ All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters. | | | |

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

| Material Characterization Summary | | |
|--|---------------------|---------|
| Analytical Test | Method | Results |
| Chromatographic Purity by GC/FID Analysis | SP10-0101 | 99.9% |
| Residual Water Analysis by Karl Fischer Coulometry | AM1346 ¹ | 0.11% |
| Mass Balance Purity Factor | | 99.81% |
| ¹ Validated analytical method | | |
| ♦ The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other. | | |

Spectral and Physical Data

| Neat Material | Standard Solution |
|---|--|
| Analysis Method: GC/FID | Analysis Method: GC/FID Headspace |
| Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness | Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness |
| Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min | Temp Program: 40°C hold 12 min |
| Injector Temp: Cool-on-Column | Injector Temp: 200°C |
| Detector Temp: 325°C | Detector Temp: 250°C |
|  |  |

COA Revision History

| Revision No. | Date | Reason for Revision |
|---------------------|----------------|----------------------------|
| 00 | April 14, 2021 | Initial version. |
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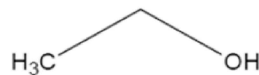
Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl alcohol

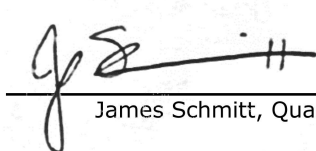
Catalog Number: E-036
Solution Lot: FN04092401
Expiration: April 2029
Diluent: Water
Volume per Ampule: 1.2 mL
Storage: Refrigerate (Do Not Freeze)
Country of Origin: Canada
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.



- ◆ Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- ◆ Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- ◆ For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|-----------------|-------------------------|
| Ethanol | > 99.9% | 400 ± 2 mg/dL |
| <ul style="list-style-type: none">◆ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.◆ When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval (k=2).◆ The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.◆ Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.◆ Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred. | | |

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date. Warranty applies to ampoules stored unopened and stored under the recommended storage conditions. Warranty and expiry do not extend to solutions into which this product has been incorporated. Establishment of shelf life of all such products is the responsibility of the user.



James Schmitt, Quality Assurance Manager

August 01, 2024
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
Sigma-Aldrich Production GmbH is a subsidiary of Merck KGaA, Darmstadt, Germany.



Traceability to SI through NIST:

- ◆ This standard has been prepared and certified under the ISO 17034 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- ◆ This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- ◆ Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- ◆ Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2896 mg/dL | Homogeneity % RSD |
|---|------------|---|----------------------|
| New Lot | FN04092401 | 397 | 1.0 |
| Previous Lot | FN03052102 | 399 | 1.1 |
| Acceptance Criteria | | ± 2% | ≤ 2 |
| <ul style="list-style-type: none">◆ Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.◆ The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.◆ Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.◆ The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.◆ All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters. | | | |

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary

| Analytical Test | Method | Results |
|--|-----------------------|---------|
| Chromatographic Purity by GC/FID Analysis | 20384346 | > 99.9% |
| Residual Water Analysis by Karl Fischer Coulometry | 20384212 ¹ | 0.04% |
| Mass Balance Purity Factor | | 99.96% |

¹ Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

Spectral and Physical Data

Neat Material

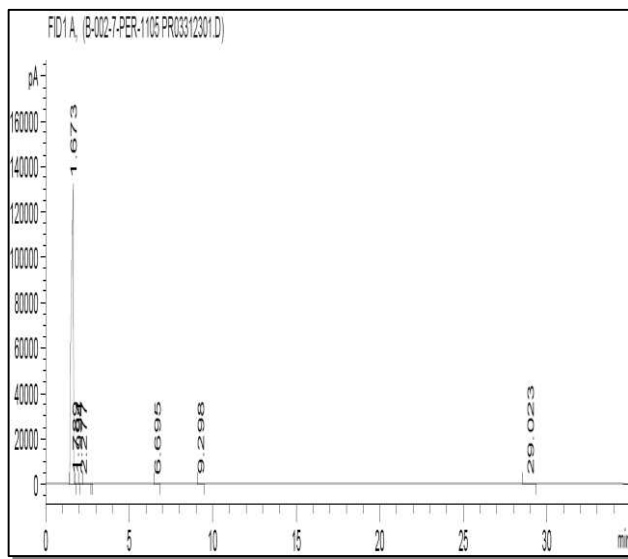
Analysis Method: GC/FID

Column: DB-5ms, 30 m x 0.53 mm ID,
1.5 µm film thickness

Temp Program: 35°C hold 5 min to 100°C at
40°C/min, 100°C to 280°C at
20°C/min, hold 8 mins

Injector Temp: Cool-on-Column

Detector Temp: 325°C



Standard Solution

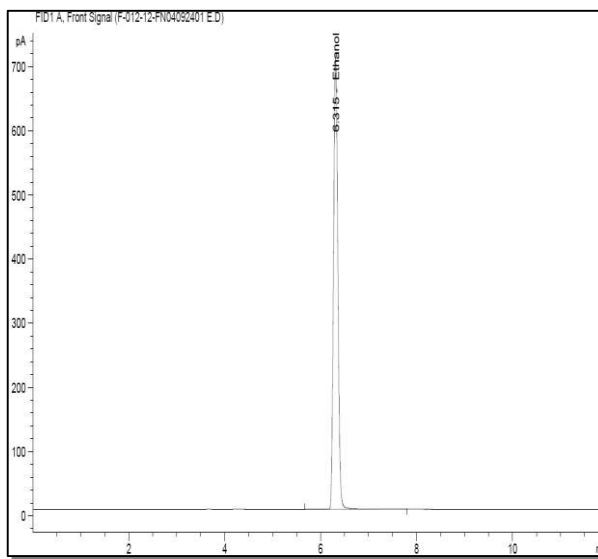
Analysis Method: GC/FID Headspace

Column: DB-ALC1 30 m x 0.53 mm ID,
3.0 µm film thickness

Temp Program: 40°C hold 12 min

Injector Temp: 200°C

Detector Temp: 250°C



COA Revision History

| Revision No. | Date | Reason for Revision |
|---------------------|-----------------|----------------------------|
| 00 | August 01, 2024 | Initial version. |
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The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada.

Certificate of Analysis

Certified Reference Material

Aqueous Ethanol Standard Solution 400 mg/dL

Description Ethanol diluted in Water
400 mg EtOH / dL Water (0.400 % by mass)
1 mL / ampoule

Certified Concentration **Ethanol 400.0 mg/dL \pm 0.209 mg/dL**

Expanded uncertainty of the certified concentration is in accordance with ISO/IEC 17025 at the 95% confidence interval using a coverage factor of $k=2$.

Metrological traceability

The certified reference material was produced in own facilities by weight of used solvent on calibrated balance(s) and traceable, following ISO/IEC 17025 guideline, to SI units.

The expanded uncertainty has been calculated and incorporates the following contributors:

- Mass of the solvent(s), including the calibration and repeatability uncertainties of the balance.
- Purity of the solvent(s), measured on pure solvent(s) including water content and GC/FID purity.
- Volume of the dilution, including uncertainties of volumetric measurement and temperature effects.

Procedure

The pure solvent is weighed into a volumetric flask, further diluted and the procedure is temperature monitored. The resulting dilution is filled into ampoules with a sufficient excess to allow complete volume withdrawal of the above given volume.

Homogeneity of the solution for the dilution of small amounts into a suitable diluent is ensured through adequate production conditions and therefore excluded from the uncertainty calculation.

Stability is ensured through real time stability studies on concentrations between 10 mg/dL and 700 mg/dL and found negligible inside the limits of the used analytical method and is therefore excluded from the uncertainty calculation.

Intended Use

The product is intended to be used for chromatographic analytic methods.

For analytical purposes only – not for human or animal use!

Storage Conditions

Store unopened below 30°C protected from light. Do not freeze. Opened ampoules must be used up in between 24 hours.

Lipomed certifies and warrants that this product conforms to the specifications stated in this certificate under the above storage conditions until its expiry date.

This certificate is issued electronically by Dr. L. Prévot (*Responsible Person Reference Materials*) on 21-Jun-2023 at Arlesheim and valid without signature.

Art. No: **ETH-400-1ML**

Lot No: **12052023-B**

Expiry Date: **May 2028**

CoA No: **QC-COA-ETH-400-12052023-B.1**

Information on used solvent(s)

Name: Ethanol
Mol Weight: 46.07 g/mol
CAS number: 64-17-5
Purity: 100.0 %
Water content: 0.01 %

The control is based on GC/FID and Karl-Fischer-Titration.

History (CoA)

| Version | Change | Date |
|---------|-------------|-------------|
| 001 | New version | 21-Jun-2023 |

Certificate of Analysis

Certified Reference Material

Description: 40 mg/dL Aqueous Ethanol Standard Solution 1 mL

Lot No.: 518018

Expiration Date: 3/20/2027

Catalog No.: ETH-040-1ML

Original issue date: 3/20/2024

Bulk Product Information: ethanol

Chemical Formula: C₂H₆O

CAS Registry No: 64-17-5

Water Content: <1%



Certified Values:

The certified value is based on gravimetric and volumetric preparation of this CRM. This CRM has been confirmed by gas chromatography (GC) or gas chromatograph/mass spectrometry (GC/MS) using an internally developed method against an independent source. The uncertainty value is calculated for a 95% confidence interval with a *k* value of 2.

| Compound | CAS No. | Purity (%) | Neat Material Lot No. | Concentration, mg/dL |
|----------|---------|------------|-----------------------|----------------------|
| ethanol | 64-17-5 | 99.9 | 202.9.7P | 39.96 ± .47 |

Packaging and Storage:

The solution should be stored according to the following storage requirements: 4°C +/- 4°C

Once the product is opened, it should be transferred to a vial with minimum head space if the product was in a seal ampule.

Once opened, the expiration is determined by user specifications.

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Intended Uses:

This Certified Reference material (CRM) is intended for use as a calibration standard or a quality control standard for Chromatography Equipment such as GC, GC/MS, HPLC, and HPLC/MS. It may also be used for various USEPA, NIOSH, EN, ISO, EPA and ASTM methods.

Recommended storage container for ampuled products after opening is a 12mmx32mm amber vial with screw cap Teflon

lined silicon septum. The modeled % change per day can be calculated using the following:

$$\% \text{ Change} = (-0.018 \ln(x+31) + 0.1157) + 636.54y^{-3.202}$$

where x = boiling point of the most volatile analyte in the mix (degrees K)
y = boiling point of the solvent (degrees K)

This model assumes the container is stored at -10 °C and is unopened during storage. The user should determine what the acceptable error for their process is and calculate the maximum number of days the opened ampule should be stored.

NIST Standard Solutions for Concentration Verification:

| Solution | Concentration | Position of Samples | Concentration (mg/dL) |
|-----------------------------|---------------|---------------------|-----------------------|
| Reference 1 (NIST 2892) | 39.00 mg/dL | Start | 41.0 |
| Reference 2 (NIST 2893a) | 76.63 mg/dL | Middle | 41.2 |
| | | End | 41.0 |

Concentration Verification/ Lot to Lot Consistency (HPLC analysis):

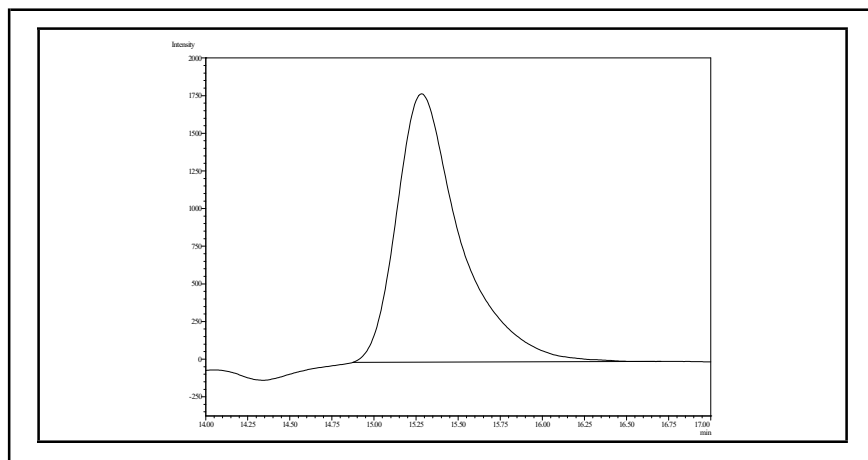
| Standard Solution | Lot Number | Concentration mg/dL (+/- 2%) Compared to NIST SRM 2892, 2893a | Ampule to Ampule Consistency (<3%) |
|-------------------|------------|--|-------------------------------------|
| Actual Lot | 518018 | 41.1 | 0.8 |
| Previous lot | N/A | | |

Random replicate samples of the final packaged CRM have been analyzed to prove homogeneity in accordance with internal procedure O2-QS-011. This is consistent with the intended use of this CRM. The homogeneity of this product has been confirmed by procedures consistent with ISO/IEC 17025:2017 and ISO 17034:2016.

Supportive Data:

| Parameter | Specification | Result |
|--------------------|--|----------|
| Appearance | Clear / colorless | Conforms |
| Identity | HPLC analysis Rt corresponds to Rt of reference standard (+/- 0.5 min) | Conforms |
| Solution Purity | Ethanol, HPLC >99% | Conforms |
| Solvent Purity | Water, HPLC grade | Conforms |
| Extractable Volume | > 1 mL | Conforms |

Chromatography:



Method Conditions:

Instrument
HPLC/RID

Detection
RID

Column/Flow
Phenomenex Rezex ROA - Organic Acid H+
(8%) 300mm x 7.8mm ID / 0.8 mL/min

Method Details
0.005 N H2SO4

Isocratic

Inj.-Vol
10 μ L

General Information:

Accreditation:

This CRM was manufactured by an ISO 17025:2017 chemical testing lab (Certificate number 3031.01) and ISO 17034:2016 Reference Material Producer (Certificate number 3031.02) accredited by The American Association of Laboratory Accreditation (A2LA).

Expiration Information:

The stability of this product is based upon rigorous short term and long term testing of the solution for the certified value. These tests include the effect of temperature and packaging on the product. This standard is guaranteed until the following date: 20-Mar-2027

Method of Preparation:

All weights are traceable through N. I. S. T. Test No. 822/264157-00. Concentration (correct for purity) and uncertainty (95% confidence) values listed are determined gravimetrically.

Glassware Calibration:

Only Class A glassware is used in the manufacture and quality control of Standards. All glassware is calibrated using NIST traceable weights.

Calculation of Uncertainty:

The following equations are used to calculate the value of the expanded uncertainty: $u = k u_c$; u = Expanded Uncertainty, k = the coverage factor at the 95% confidence level, $k=2$, u_c = the combined uncertainty $u_c = \sqrt{\sum u_i^2}$ where u_i are the individual uncertainty components for characterization, transportation, homogeneity, and shelf life.

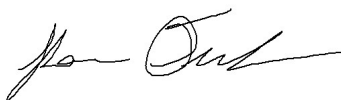
Weights and Balance Calibration:

Weights used perform daily checks on balances calibrated annually by the State of South Carolina Department of Agriculture Metrology Laboratory and are traceable to N.I.S.T. Balances are checked daily in accordance to in house procedure O2-LB-G-002. Balances are calibrated annually by an ISO/IEC 17025:2017 and ISO 17034:2016 accredited metrology service.

Hazardous Information:

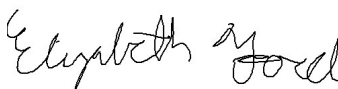
Refer to MSDS

Manufactured By:



Shane Overcash
Team Leader, Semi-Volatiles

Certified By:



Elizabeth Ford
Quality Control Chemist III

Released By:



Susan Mathews
Quality Control Team Lead

LGC Group
7290-B Investment Drive
North Charleston, SC 29418
United States
T | +1 843 763 4884
F | +1 866 509 5146
E | dr.ehrenstorfer@lgcgroup.com

The producer of this reference material is registered to ISO 9001:2015 under 56 100 19560019 by TUV USA and accredited to ISO 17025:2017 and ISO 17034:2016 by A2LA with the certification numbers 3031.01 and 3031.02.



ISO Guide 34 Accredited
Reference Material Producer
Cert. No. 3031.02

EtOH WH 2,0 g/L – In vitro diagnosticum

Ethanolkontrollen im Vollblut

Anwendung

Die Probe ist als Richtigkeitskontrolle oder Kalibrator für die Ethanolbestimmung einsetzbar.

Gebrauchsanweisung

Die Probe ist gebrauchsfertig und entsprechend der eigenen Laborvorschriften einzusetzen.

Zielwert

Die Zielwerte wurden unter der organisatorischen Leitung der ARVECON GmbH im Rahmen ihres Ringversuchsprogramms im Ringversuch EtB 2/24 B – Ethanol in Vollblut bestimmt. Die Analysen wurden von den Teilnehmern mit GC durchgeführt. Die Zielwerte wurden durch die Ringversuchsleitung der ARVECON freigegeben.

Lagerung und Haltbarkeit

Lagerung: + 2 °C bis + 8 °C

Haltbarkeit:

- Original verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.
- Dicht verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.

Vorsichtsmaßnahmen

Alle Materialien humanen Ursprungs sind grundsätzlich mit derselben Sorgfalt wie potentiell infektiöse Patientenproben zu behandeln. Jede zur Herstellung verwendete Bluteinheit wurde auf Antigen und Antikörper geprüft und für negativ befunden: HBsAg, anti-HIV-1, anti-HIV-2, anti-HBc und anti-HCV.

Ch.-B / Lotto: 4130622206
Best.-Nr. / Codice: WH20-015 (10 x 1,5 mL)
WH20-115 (100 x 1,5 mL)
WH20-030 (10 x 3,0 mL)
FG.Nr.: 24-08
Version / Versione: 2 – 202407

EtOH WH 2,0 g/L – Uso diagnostico in vitro

Controllo d'etanolo in sangue intero

Applicazione

Utilizzabile nelle procedure definite da ciascun laboratorio come calibratore o come materiale di controllo.

Utilizzo

Pronto all'uso.

Valori attesi

I valori attesi sono stati assegnati tramite l'attività di proficiency test della ARVECON: "EtB 2/24 B – Ethanol in sangue intero" sotto la direzione organizzativa di ARVECON GmbH. Le analisi sono state eseguite dai partecipanti tramite GC. I valori attesi sono stati forniti dal coordinatore dell'attività di proficiency test del ARVECON.

Conservazione e stabilità

Conservazione: + 2 °C fino a + 8 °C

Stabilità:

- Flacone non aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza.
- Flacone aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza in etichetta.

Precauzioni

Tuttavia, poiché nessuna analisi può offrire sicurezza completa che gli agenti infettivi siano assenti, questo prodotto deve essere manipolato osservando le stesse precauzioni di sicurezza usate quando si manipola qualunque tipo di materiale potenzialmente infettivo. I componenti originari da cui questo prodotto è stato derivato, sono stati trovati negativi per HBsAg e per gli anticorpi contro HCV, HBc, HIV-1 e HIV-2 attraverso metodologie di analisi approvate.

Hersteller / Manufacturer / Produttore / Producteur

ACQ Science GmbH
Etzwiesenstraße 37
72108 Rottenburg-Hailfingen
Germany

Tel.: + 49 (0) 7457 94
Fax: + 49 (0) 7457 94
E-mail: info@acq-science.com

EtOH WH 2,0 g/L – For in vitro diagnostic use

Ethanol control in whole blood

Application

This material should be used in accordance with the laboratory's operating procedures for instrument calibration or as a control material

User guide

This ACQ Science EtOH WH requires no additional preparation and is ready for use.

Target value

This material was tested in the proficiency test EtB 2/24 B – Ethanol in whole blood, organized by ARVECON GmbH. The target values listed are the consensus values obtained from this trial. Quantitative analyses were performed by the participants using Gas Chromatography. The target values were released by the coordinator of proficiency testing of ARVECON.

Storage and stability

Storage: + 2 °C to + 8 °C

Stability:

- Sealed container, stored in the dark: see expiration date on the package.
- Stored in the dark tightly capped: see expiration date on package.

Precautions

All materials of human origin should be considered as potentially infectious and treated with the same care as patient specimens. Each individual blood unit used for the production of the control was tested for the following antigens and antibodies: HBsAg, anti-HIV-1, anti-HIV-2, anti-HBc and anti-HCV and found to be negative.

Lot / Lot: 4130622206
Best.-Nr. / Codice: WH20-015 (10 x 1,5 mL)
WH20-115 (100 x 1,5 mL)
WH20-030 (10 x 3,0 mL)
FG.Nr.: 24-08
Version / Versione: 2 – 202407

EtOH WH 2,0 g/L – Usage in vitro

Contrôle d'éthanol dans le sang total

Application

Standard dédié à la calibration pour techniques analytiques de détermination de concentration d'éthanol ou à utiliser comme contrôle d'exactitude.

Utilisation

Ce contrôle est prêt à l'emploi.

Valeur cible

Les valeurs cibles ont été déterminées lors d'un test inter-laboratoire de ARVECON: "EtB 2/24 B – Ethanol dans le sang total", organisé par la société ARVECON GmbH. Les participants ont utilisé la méthode GC. Les valeurs cibles ont été validées par le responsable des tests inter-laboratoires de ARVECON.

Conservation et stabilité

Conservation: + 2 °C jusqu'à + 8 °C

Stabilité:

- Scellé (à l'origine), à l'abri de la lumière: voir la date d'expiration indiquée sur l'étiquette.
- à stocker hermétiquement à l'abri de la lumière: voir la date d'expiration indiquée sur l'étiquette.

Précautions

Tout
infecti
patien
Chaque
testée
anti-H

IVD 10 x 1,5 mL (liq.)

REF WH20-015

EtOH Check WH 2,0 g/L

Ethanolkontrolle im Vollblut

Ethanol control in whole blood

Contrôle d'éthanol dans le sang total

LOT 4130622206/10 2029-05

2°C 8°C

CE



ACQ Science GmbH
Etzwiesenstraße 37
72108 Rottenburg
Germany



EtOH WH 2,0 g/L – Lot: 4130622206 – For in vitro diagnostic use

Ethanol control in whole blood

| Messverfahren Method Metodo Méthode | Zielwert Target value Valori attesi Valeur cible | Konfidenzbereiche / Confidence ranges / Intervallo di fiducia / Intervalle de confiance | | | Einheit Unit Unità Unité |
|--|---|--|--|---|-----------------------------------|
| | | statistisch / statistical ¹ statistico / statistique ¹ | forensisch / forensic ² forense / médecine légale ² | klinisch / clinical ³ clinico / clinique ³ | |
| GC | 1,963 | 1,821 – 2,105 | 1,865 – 2,061 | 1,786 – 2,140 | g/L |

¹ Konfidenzbereich – Analysenwerte

Der Konfidenzbereich gibt den Bereich an, in dem der Zielwert mit einer Wahrscheinlichkeit von 95% liegt.

² Konfidenzbereich – Deutsche forensische Richtlinie

[EtOH] ≤ 1,06 g/L → Konfidenzbereich ± 0,053 g/L von dem Zielwert
[EtOH] > 1,06 g/L → Konfidenzbereich ± 5% von dem Zielwert

Literatur:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

³ Konfidenzbereich – Richtlinie der deutschen Bundesärztekammer

Für 0,2 < [EtOH] ≤ 0,6 g/L → Konfidenzbereich ± 15% vom Zielwert
Für 0,6 < [EtOH] ≤ 5,0 g/L → Konfidenzbereich ± 9% vom Zielwert

Literatur:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

¹ Confidence ranges – measured values

The confidence interval indicates the range in which the target value is located with a significance level of 95%.

² Confidence ranges – German forensic directives

[EtOH] ≤ 1.06 g/L → ± 0.053 g/L from the target value
[EtOH] > 1.06 g/L → ± 5% from the target value

References:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

³ Confidence ranges – Directive of the German Medical Association

0.2 < [EtOH] ≤ 0.6 g/L → ± 15% from the target value
0.6 < [EtOH] ≤ 5.0 g/L → ± 9% from the target value

References:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

¹ Intervallo di fiducia - Valori di analisi

L'intervallo di fiducia indica l'intervallo entro il quale si trova il valore atteso con un livello di significatività del 95%.

² Intervallo di fiducia – Direttiva Forense Tedesca

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L del valore atteso
[EtOH] > 1,06 g/L → ± 5% del valore atteso

Bibliografia:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

³ Intervallo di fiducia – Direttiva dell' Ordine Nazionale Tedesca dei Medici

0,2 < [EtOH] ≤ 0,6 g/L → ± 15% del valore atteso
0,6 < [EtOH] ≤ 5,0 g/L → ± 9% del valore atteso

Bibliografia:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

¹ Intervalle de confiance – Valeurs des analyses

La marge de confiance est la marge dans laquelle la valeur cible se trouve avec une probabilité de 95%.

² Intervalle de confiance – Directives allemandes de la Médecine Légale

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L de la valeur cible
[EtOH] > 1,06 g/L → ± 5% de la valeur cible

Littérature:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

³ Intervalle de confiance – Directives allemandes cliniques

0,2 < [EtOH] ≤ 0,6 g/L → ± 15% de la valeur cible
0,6 < [EtOH] ≤ 5,0 g/L → ± 9% de la valeur cible

Littérature:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

GI_EtOHWH_20_4130622206_20240708

Version 2 – 202407

Hersteller / Manufacturer / Produttore / Producteur

ACQ Science GmbH
Etzwiesenstraße 37
72108 Rottenburg-Hailfingen
Germany

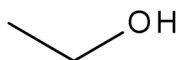
Tel.: + 49 (0) 7457 94 69 3 0
Fax: + 49 (0) 7457 94 69 3 69
E-mail: info@acq-science.de

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Certificate of Analysis Certified Reference Material

Product name: **100 mg/dL Aq. Ethanol Standard Solution**
 Lot number: C1455120
 Product code: LPM-ETH-100-1ML
 Long-term storage: below 30 °C, dark Do not freeze!
 Retest date: April 2029



| | | | |
|---------------------------|---------------------------------|------------------------|----------|
| Bulk product information: | Ethanol | Purity Ethanol GC/FID: | 100.00 % |
| CAS number: | 64-17-5 | Water content: | 0.19 % |
| Molecular formula: | C ₂ H ₆ O | | |
| Molecular weight: | 46.07 | | |

CERTIFIED CONCENTRATION

100.00 ± 0.88 mg/dL

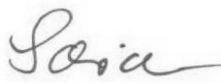
Uncertainty of the certified concentration is an expanded uncertainty in accordance with ISO/IEC 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the characterization, gravimetric preparation, homogeneity, storage stability and shipping stability according to U_c equation in the general information of this certificate. The uncertainty covers variability of the density in the range between 19 °C and 25 °C.

Metrological traceability:

Calibration and verification were carried out using standards traceable to SI-units.

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Producer confirms that this standard meets the specification stated in this certificate and warrants this product to meet the stated acceptance criteria through the retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

| | | | |
|---------------------|--------------------------|--|-----------------|
| Release by: | Date of Release: |  | Product Release |
| Dr. Sabine Schröder | Luckenwalde, 30 Jul 2024 | | |

Concentration verification using NIST standard solutions

| Standard | Verified Concentration (mg/dL) | Acceptance Criteria ($\pm 2\%$ to NIST) |
|---------------------------|--------------------------------|--|
| NIST 2894 100.84 mg/dL | 100.63 | conforms |
| NIST 2896 298.00 mg/dL | 101.04 | conforms |

Homogeneity of the lot is confirmed by analysis of 12 ampoules. These samples are representative of the batch from which they were taken.

The verified concentration of the ampoules is calculated from the distribution of 12 GC/FID analyses calibrated with 2 NIST SRM 2894 and 2896. During preparation, the content has been corrected to account for the purity of ethanol and residual water.

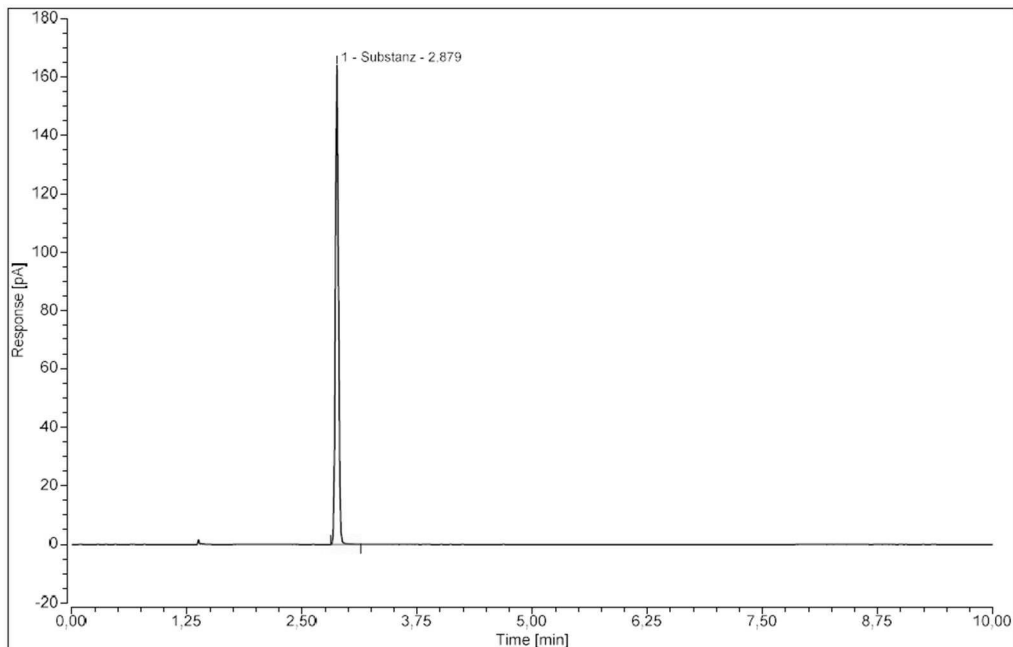
Lot to lot consistency

| Standard solution | Lot number | Concentration |
|-------------------|------------|---------------|
| Actual Lot | C1455120 | 100.00 mg/dL |
| Previous Lot | 25052023-A | 100.0 mg/dL |

Supportive data

| Test | Specification | Result 7/30/2024 |
|--------------------|---|--|
| Appearance | Clear colourless solution | conforms |
| Identity | GC/FID R_t corresponds to R_t (reference standard) (± 0.5 min) | R_t (NIST) = 2.879 min R_t (test) = 2.879 min |
| Solution Purity | Ethanol GC/FID > 99 % | 100.00 % |
| Extractable volume | > 1 ml | conforms |

GC/FID data: Verification



| GC Conditions: | | | |
|------------------------------------|---|---------------------------|--------------------------------|
| Column: | Injector and Flow: | Oven Program: | Detector: |
| USP G43 30 m × 0.32 mm × 1.8 µm | Split 10:1, 240 °C Nitrogen 2.5 ml/min | Isotherm 40 °C for 10 min | FID 35 to 550 amu 270 °C |

| Pk # | Time (min) | Area | Area % |
|--------|------------|---------|--------|
| 1 | 2.879 | 376.355 | 100.00 |
| Totals | | 376.355 | 100.00 |

Document history

| Revision | Date | Reason for Revision |
|----------|-------------|--|
| 00 | 30 Jul 2024 | Release of the Certificate – initial version |

GENERAL INFORMATION

Quality documentation:

This certificate is designed in accordance with ISO 33401 (Reference Materials – Contents of certificates, labels and accompanying documentation) and ISO 33405 (Reference Materials – Approaches for characterization and assessment of homogeneity and stability).

Quality standards:

| | |
|----------------------|--|
| ISO 9001 | Quality Management System. Development, production, analysis and distribution of reference materials |
| ISO/IEC 17025 | General requirements for the competence of testing and calibration laboratories |
| ISO 17034 | General requirements for the competence of reference material producers, Certificate number: DAkkS D-RM-14176-01-00 |

Intended use:

The product covered by this certificate is designed for calibration or for use in quality control procedures for the specified chemical compound listed on page 1. This product can be used for quantification and/or identification. If dilution is required, use only diluents compatible with all certified analytes in this preparation. All solutions should be thoroughly mixed prior to use.

Retest date:

The retest date of the unopened unit stored at the recommended storage condition is the last day of the month listed on page 1.

Uncertainty, concentration and retest date of the Reference Material are based on the unopened unit being stored according to the recommended condition found in the storage field.

Metrological traceability:

The neat material assay, preparation and verification were carried out using standards traceable to SI-units. All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed regularly with certified traceable weights. Each balance has been assigned a minimum weighing.

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: GC/FID, GC/FID Headspace, IR, NMR and Karl Fischer titration.
- Purity values are rounded up to the last decimal place given.
- The content is already corrected from the purity and residual water.

Uncertainty statistics and confidence limits:

The uncertainties are determined in accordance with ISO 17034 and 17025. Uncertainty is given for a minimum injection volume of 0.5 µl. The combined expanded uncertainty value includes uncertainty of preparation (with characterization, gravimetric and density uncertainty), homogeneity, storage stability and shipping stability and was calculated using the following formula:

$$Uc = k \sqrt{u_{preparation}^2 + u_{homogeneity}^2 + u_{storage\ stability}^2 + u_{shipping\ stability}^2}$$

k is a coverage factor of 2, which gives the level of confidence of approximately 95%.

The units are overfilled to ensure that the minimum packaged amount can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by analysis of 12 units. The samples are representative of the batch from which they are taken.

Stability:

The manufacturer guarantees the stability of this solution through the date stated on page 1 of the certificate when handled and stored according to the conditions stated on page 1.

Handling:

Before usage of the product, it should be allowed to warm to room temperature. For long-term storage please refer to page 1.

Legal notice and limit of liability:

This product is for routine laboratory analysis and research purposes only. Due to the hazardous nature, only trained personnel should handle this product. Please refer to the safety data sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.