Scottsdale Police Department Crime Laboratory

Calibrators and Control Certificates for Samples Run

12/11/2023 -

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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

- 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.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

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**

- 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%

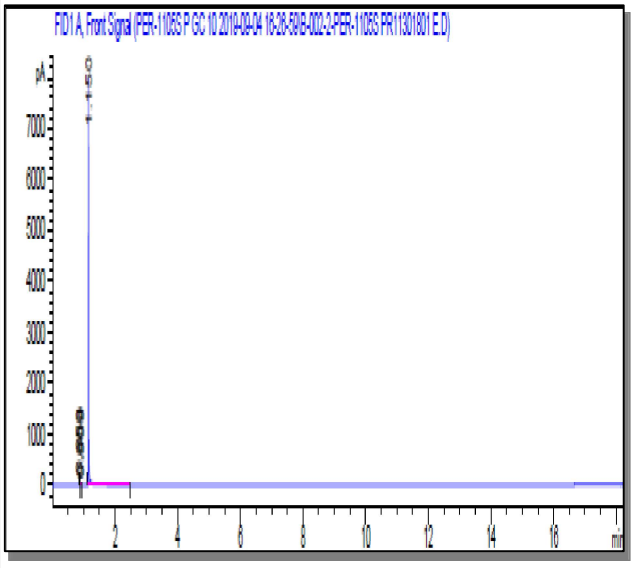
[1] Validated analytical method

- 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

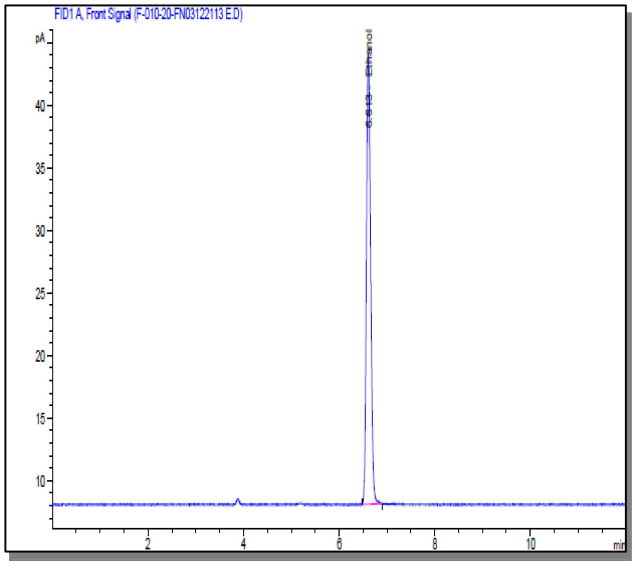
Neat Material

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-100

Ethyl alcohol

Catalog Number:	E-031
Solution Lot:	FN11172002
Expiration:	December 2025
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%	100.0 ± 0.4 mg/dL

- 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 USA.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

June 23, 2021
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com

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 2894 mg/dL	Homogeneity % RSD
New Lot	FN11172002	99.4	0.8
Previous Lot	FN05311902	99.5	0.6
Acceptance Criteria		**± 2%**	**≤ 2**

- 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]	0.05%
Mass Balance Purity Factor		99.94%

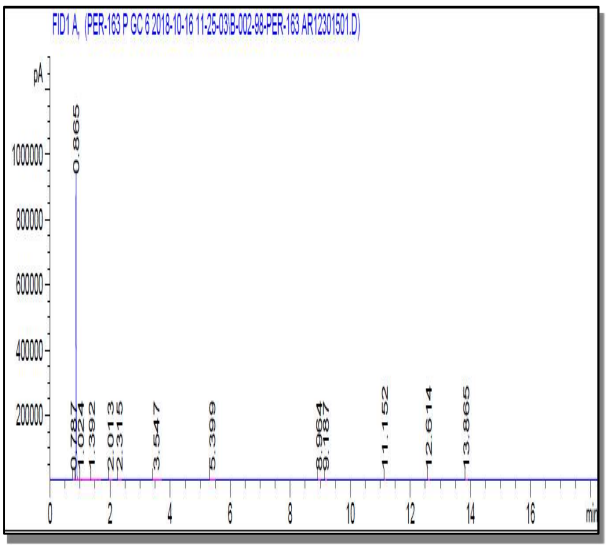
[1] Validated analytical method

- 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

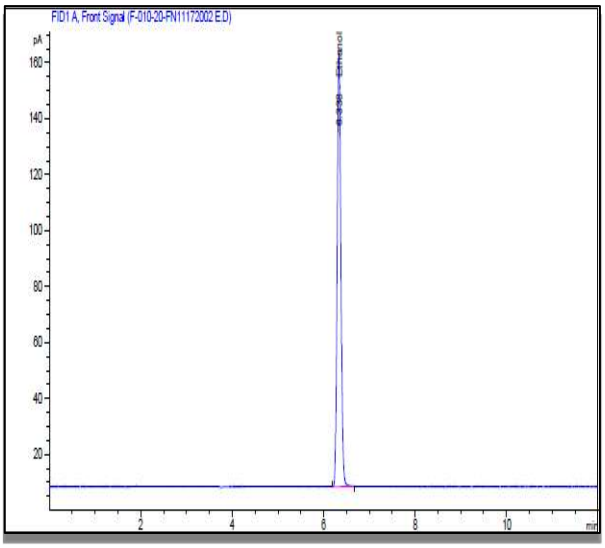
Neat Material

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	March 10, 2021	Initial version.
01	June 23, 2021	Corrected the revision number in the footer of CoA.

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www.sigmaaldrich.com

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl alcohol

Catalog Number:	E-031
Solution Lot:	FN03072301
Expiration:	March 2028
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%	100.0 ± 0.4 mg/dL

- 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.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darren Ellsworth, Quality Assurance Manager

May 10, 2023

Date

Cerilliant Corporation, 811 Paloma Drive, Suite A 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 2894 mg/dL	Homogeneity % RSD
New Lot	FN03072301	98.4	0.5
Previous Lot	FN11172002	99.0	1.0
Acceptance Criteria		**± 2%**	**≤ 2 %**

- 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	Consistant with Structure
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	0.16%
Mass Balance Purity Factor		99.84%

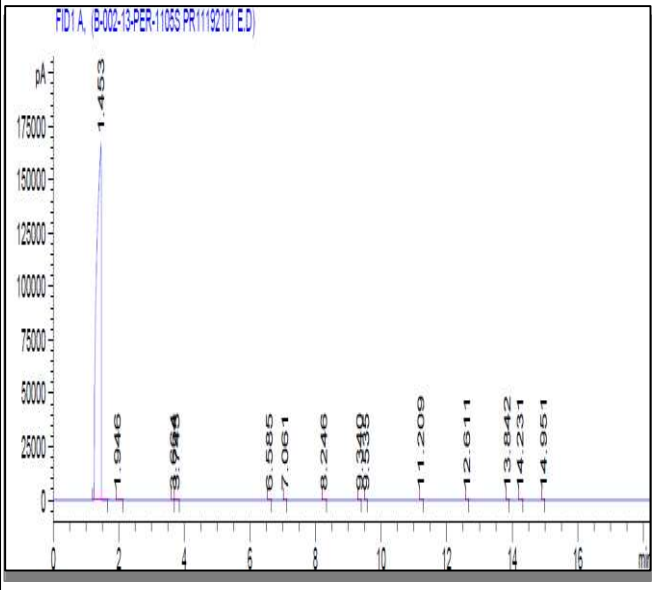
[1] Validated analytical method

- 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

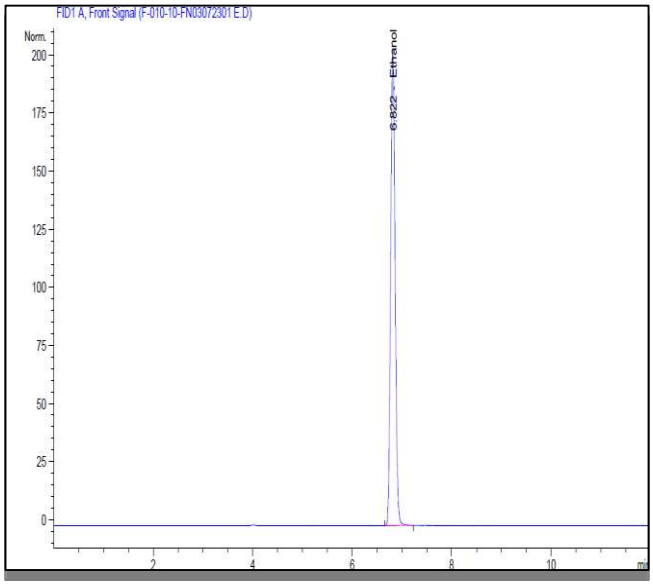
Neat Material

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	May 10, 2023	Initial version.

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www.sigmaaldrich.com

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

- 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.

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.

ANAB ANSI National Accreditation Board ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

April 14, 2023
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
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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.
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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**

- 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.
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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	20398075 [1]	0.09%
Mass Balance Purity Factor		99.90%

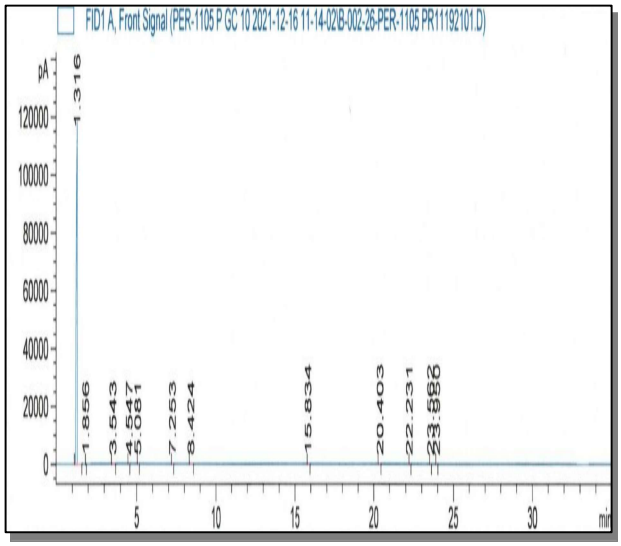
[1] Validated analytical method

- 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

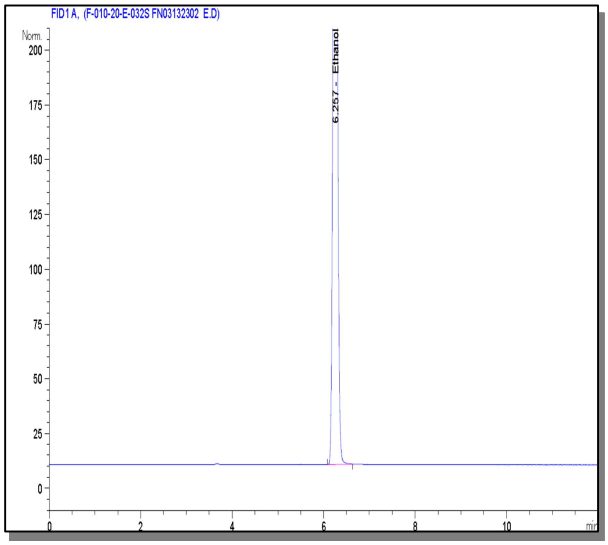
Neat Material

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

Revision No.	Date	Reason for Revision
00	April 14, 2023	Initial version.

The life science business of Merck KGaA, Darmstadt,
Germany operates as MilliporeSigma in the US and Canada.

Supelco®

www.sigmaaldrich.com

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

- 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.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

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**

- 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%

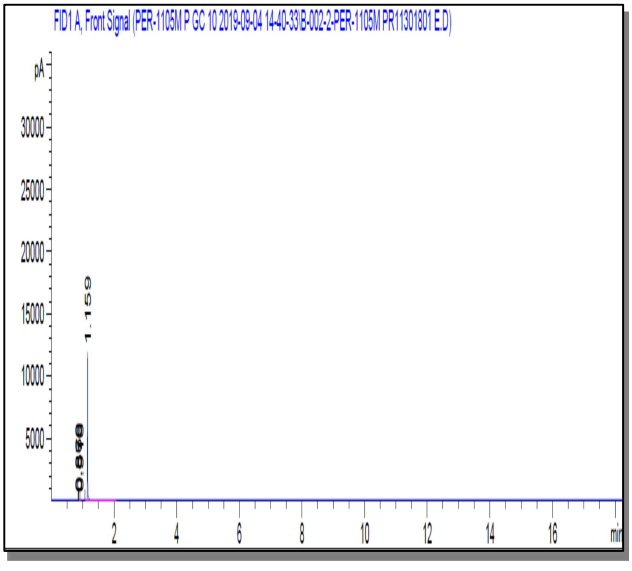
[1] Validated analytical method

- 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

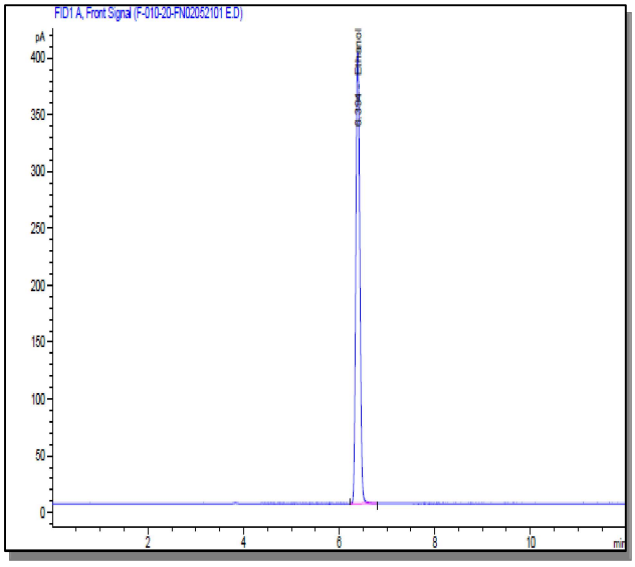
Neat Material

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	April 14, 2021	Initial version.

ACQ SCIENCE

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 des Ringversuchprogramms der GTFCh im Ringversuch EtB 2/20 - EtOH in Vollblut bestimmt. Die Analysen wurden von den Teilnehmern mit GC durchgeführt. Die Zielwerte wurden durch die Ringversuchsleitung der GTFCh freigegeben.

Lagerung und Haltbarkeit
Lagerung: + 2° 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.

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 2/20 - EtOH in whole blood, organized for the GTFCh 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 the GTFCh.

Storage and stability
Storage: + 2 ° 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.

Ch.-B / Lotto:	4110320133
Best.-Nr. / Codice:	WH20-015 (10 x 1,5 ml) WH20-115 (100 x 1,5 ml) WH20-030 (10 x 3,0 ml)
GTFCh-FG.Nr:	20-05
Version / Versione:	1 – 202006

Lot / Lot:	4110320133
Best.-Nr. / Codice:	WH20-015 (10 x 1,5 ml) WH20-115 (100 x 1,5 ml) WH20-030 (10 x 3,0 ml)
GTFCh-FG.Nr:	20-05
Version / Versione:	1 – 202006

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 Società Tedesca di Tossicologia e Chimica Forense (GTFCh) " EtB 2/20 – *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 GTFCh.

Conservazione e stabilità
Conservazione: + 2° 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.

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 l'Association Allemande de Toxicologie et de Médecine Légale (GTFCh) 'EtB 2/20 – *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 la GTFCh.

Conservation et stabilité
Conservation: + 2° jusqu'à + 8° C
Stabilité:
- Scellé (à l'origine), à l'abri de la lumière: voire la date d'expiration indiquée sur l'étiquette.
- à stocker hermétiquement à l'abri de la lumière: voire la date d'expiration indiquée sur l'étiquette.

Précautions
Tout matériel humain doit être considéré comme étant potentiellement infectieux et traité dans les mêmes conditions que des échantillons de patients.
Chaque unité de sang utilisée pour la préparation de ce contrôle a été testée et trouvée négatif pour les antigènes et anticorps suivants: AgHbS, anti-HIV-1, anti-HIV-2, anti-HBc et anti-HCV.

Hersteller / Manufacturer / Produttore / Producteur

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E-mail: info@acq-science.de

CE

ACQ SCIENCE

EtOH WH 2.0 g/L – Lot: 4110320133 - 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 /medicine légale[2]	klinisch / clinical[3] clinico / clinique[3]	
GC	1,99	1,89 – 2,09	1,891 – 2,090	1,811 – 2,169	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)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[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 (15.02.2008)

[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)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[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 (15.02.2008)

[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 Blutalkoholbestim-mung 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)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[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 (15.02.2008)

[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 Blutalkoholbestim-mung 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)
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[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

Litté
Rich
toriu

GI_EtOHWH_20_4110320133_20200623

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 4110320133/11 2029-05 2°C 8°C

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ACQ SCIENCE CE

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Etzwiesenstraße 37, 72108 Rottenburg-Hailfingen Germany, Tel. +49 (0) 7457 946 93-0

Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-ETH-040-1ML
Version: 003-13.Sep.2019 Supersedes: 002-21.Mar.2014

Product name: **40 mg/dL Aqueous Ethanol Standard Solution**
0.040 % by Mass (40 mg Ethanol / 1 dL Water) – 1 ml / ampoule
Ethyl alcohol

Lot No: 14082019-B
Art. No: ETH-040-1ML

Release date: August 14, 2019
Expiry date: **August 2024**

Bulk Product Information: Ethanol

Chemical formula:	C_2H_6O	Purity Ethanol GC/FID:	100 %
CAS Registry No:	64-17-5	Water content Karl Fischer:	0.08 %
Molwt:	46.07		

CERTIFIED CONCENTRATION **40.07 ± 0.05 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 purity factor, material density and mass measurement. The solution stability is established through real time stability studies and is, therefore, excluded from the uncertainty calculation.

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity (GC/FID analysis)	R_t corresponds to R_t of reference standard (± 0.1 min)	R_t standard = 2.9 min R_t test = 2.9 min
3. Extractable volume	> 1 ml	conforms
4. Water quality	Pharmaceutical water for injection	conforms

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

Storage conditions: For maximum stability store air-tight below 30 °C in a dark location. Do not freeze.

Lipomed certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiry date when stored unopened as recommended. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

Issued by Dr. L. Prévot

Date sign: Arlesheim,

September 13, 2019

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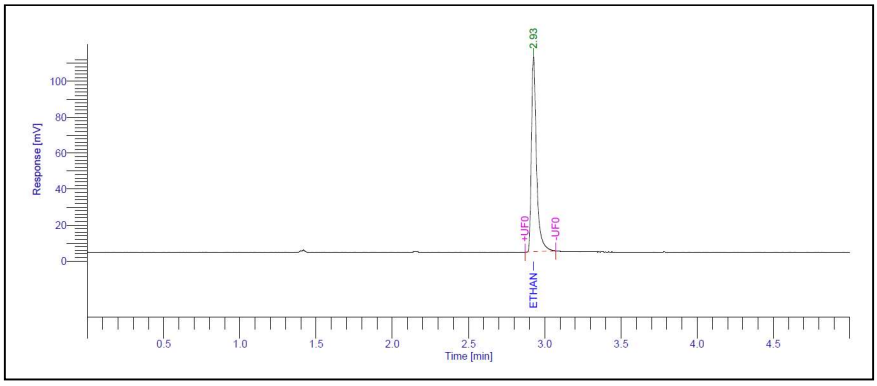
Concentration Verification / Lot to Lot Consistency (GC/FID analysis):

Standard solution	Lot Number	Concentration (± 2%) 39.20 – 40.80 mg/dL (Compared to NIST SRM 2892)	Ampoule to ampoule consistency (≤ 3%)
Actual Lot	14082019-B	39.51 mg/dL	1.1 %
Previous Lot	N/A	N/A	N/A

Homogeneity of the lot is confirmed by an analysis of 6 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 different freshly prepared ethanol solutions (triplicate injections of each solution) and compared with NIST SRM 2892 with a 95% level of confidence. During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

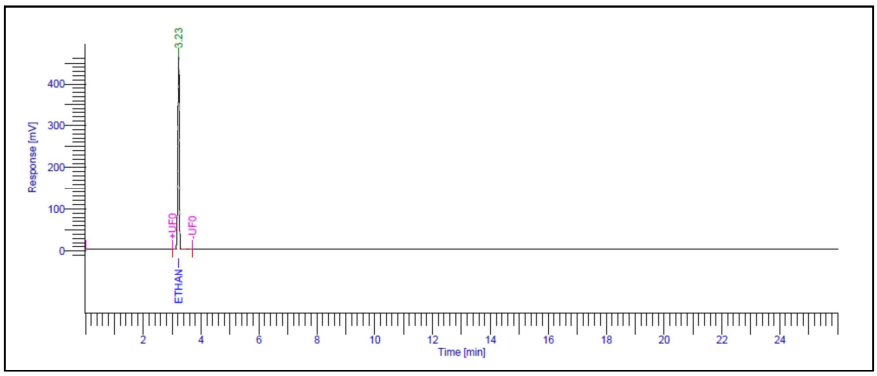
GC/FID Data: Calibration



Analytical conditions:

Column:
Rtx-624Sil-MS (30m x 0.32 mm * 1.8 um)
Injektionstechnik: Split: 1:5
Injector temp.: 240°C
Detector temp: 270°C
Säulenofen : 40°C / während 5min (isotherm)
Spritze: 0.5µl
Injektionsvolumen: 0.5µl
Attenuation am FID: -6

GC/FID Data: Ethanol purity



Analytical conditions:

column:
BAC 1, 30 m x 0.32 mm, 1.8 um
Injektor: 200 °C, split 20 ml/min
FID: 300 °C
Ofen:40 °C, 5 min isotherm
Helium 100 kPa (GC), 125 kPa (HS)
range 1, attenuation -6
pressurization time: 2 min
injection time: 0.05 min
withdrawal time: 0.5 min
needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 25 min

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GENERAL INFORMATION

Quality Documentation:

This certificate is designed in accordance with ISO Guide 31 (Reference Materials – Contents of Certificates and Labels) and ISO Guide 35 (Reference Materials – General and Statistical Principles for Certification).

Quality Standards:

ISO 9001 Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199

ISO/IEC 17025 General requirements for the competence of Testing Analytical Reference Standards. ANAB Certificate number: AT-1760

ISO 17034 General requirements for the competence of Reference Material Producer. ANAB Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by regularly performed analytical control tests/retests.

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 the first page. This product can be used for quantification and/or identification. All solutions should be thoroughly mixed prior to use. If dilution is required, use only diluent compatible with the substance and solvent in this preparation.

Expiration/Retest Date:

Expiration/retest date of the unopened ampoule stored at the recommended storage conditions is the last day of the month.

A retest will be performed 6 months prior to the stated retest date. Upon successful retesting, a new retest date or expiration date is set for the product. The certificate of analysis is then updated and made available on our website. For our products, the extension of the shelf life is capped to 10 years after release as the maximum period.

Gravimetric Preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly with certified and traceable weights. For each balance, a minimum weighing value has been assigned.

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: HPLC, GC/FID, LC/MS, IR, UV, NMR, Karl Fischer, melting point, and optical rotation if applicable
- Purity of isomeric compounds is reported as the sum of the isomers
- Purity values are rounded to the last decimal place given
- The salt form, purity, residual water, and residual solvents are already taken into account for the given content value.

Uncertainty Statistics:

The uncertainties are determined in accordance with ISO 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. The certified uncertainty value (including characterization uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) is combined using the following formula:

$$U(y) = \sqrt{U^2_{characterization} + U^2_{homogeneity} + U^2_{storage\ stability} + U^2_{shipping\ stability}}$$

The filling volume is the minimum sample size for which the uncertainty is valid. The ampoules are over-filled to ensure that the minimum filling volume can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of 12 ampoules. 4 ampoules are taken at start, middle and end of the filling process. The analyzed concentration at each position is the average value obtained from duplicate analysis of 4 ampoules.

Stability:

The manufacturer guarantees the stability of this product throughout its intended shelf life, when handled and stored accordingly to the given storage conditions.

Legal and Safety Notice:

This product is for routine laboratory analysis and research purposes only. Due to the hazardous nature, only trained personnel should handle this product. The General Terms and Conditions of Lipomed apply.

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Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-ETH-080-1ML
Version: 002-10.Mar.2020 Supersedes: 001-01.Dec.2016

Product name: **80 mg/dL Aqueous Ethanol Standard Solution**
0.080 % by Mass (80 mg Ethanol / 1 dL Water) – 1 ml / ampoule
Ethyl alcohol

Lot No: 20012020-B Release date: February 28, 2020
Art. No: ETH-080-1ML Expiry date: **January 2025**

Bulk Product Information: Ethanol

Chemical formula:	C_2H_6O	Purity Ethanol GC/FID:	100 %
CAS Registry No:	64-17-5	Water content Karl Fischer:	0.08 %
Molwt:	46.07		

CERTIFIED CONCENTRATION **80.01 ± 0.10 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 purity factor, material density and mass measurement. The solution stability is established through real time stability studies and is, therefore, excluded from the uncertainty calculation.

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity (GC/FID analysis)	R_t corresponds to R_t of reference standard (± 0.1 min)	R_t standard = 2.9 min R_t test = 2.9 min
3. Extractable volume	> 1 ml	conforms
4. Water quality	Pharmaceutical water for injection	conforms

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

Storage conditions: For maximum stability store air-tight below 30 °C in a dark location. Do not freeze.

Lipomed certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiry date when stored unopened as recommended. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

Issued by Dr. L. Prévot

Date sign: Arlesheim,

March 10, 2020

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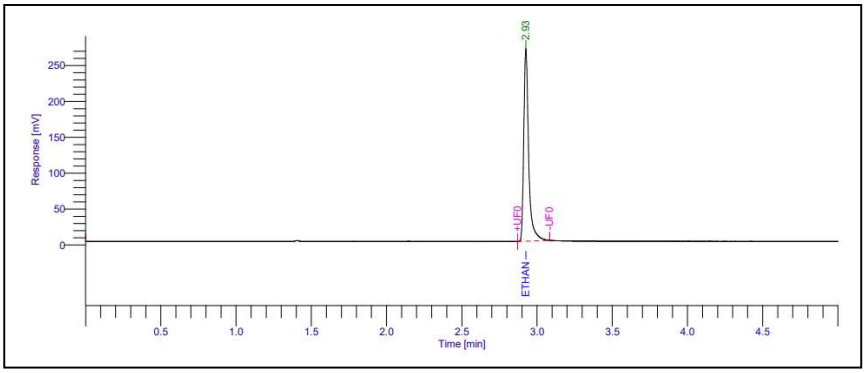
Concentration Verification / Lot to Lot Consistency (GC/FID analysis):

Standard solution	Lot Number	Concentration (± 2%) 78.40 – 81.60 mg/dL (Compared to NIST SRM 2893a)	Ampoule to ampoule consistency (≤ 3.0%)
Actual Lot	20012020-B	80.15 mg/dL	1.3 %
Previous Lot	N/A	N/A	N/A

Homogeneity of the lot is confirmed by a duplicate analysis of 21 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 21 GC/FID analyses calibrated with 2 different freshly prepared ethanol solutions (triplicate injections of each solution) and compared with NIST SRM 2893a with a 95% level of confidence. During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

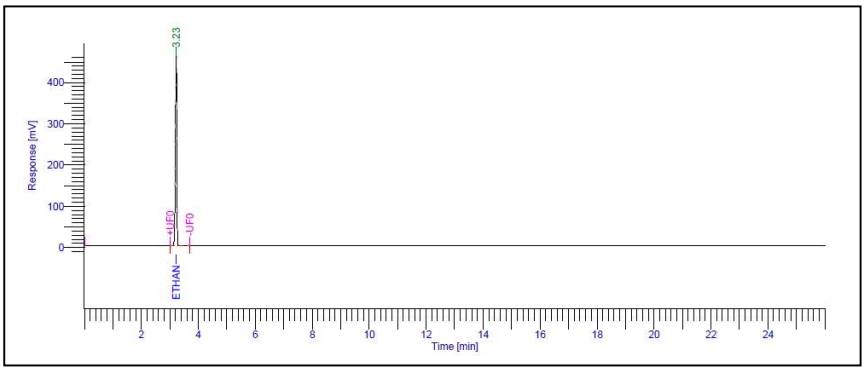
GC/FID Data: Calibration



Analytical conditions:

Column:
Rxi-624Sil-MS (30m x 0.32 mm * 1.8 um)
Split: 1:10
Injector temp.: 240°C
Detector temp: 270°C
Säulenofen : 40°C / während 5min (isotherm)
Spritze: 5.0µl
Injektionsvolumen: 1.0µl
Attenuation am FID: -6

GC/FID Data: Ethanol purity



Analytical conditions:

column:
BAC 1, 30 m x 0.32 mm, 1.8 um
Injektor: 200 °C, split 20 ml/min
FID: 300 °C
Ofen:40 °C, 5 min isotherm
Helium 100 kPa (GC), 125 kPa (HS)
range 1, attenuation -6
pressurization time: 2 min
injection time: 0.05 min
withdrawal time: 0.5 min
needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 25 min

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GENERAL INFORMATION

Quality Documentation:

This certificate is designed in accordance with ISO Guide 31 (Reference Materials – Contents of Certificates and Labels) and ISO Guide 35 (Reference Materials – General and Statistical Principles for Certification).

Quality Standards for Arlesheim production site:

ISO 9001 Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199

ISO/IEC 17025 General requirements for the competence of Testing Analytical Reference Standards. ANAB Certificate number: AT-1760

ISO 17034 General requirements for the competence of Reference Material Producer. ANAB Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by regularly performed analytical control tests/retests.

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 the first page. This product can be used for quantification and/or identification. All solutions should be thoroughly mixed prior to use. If dilution is required, use only diluent compatible with the substance and solvent in this preparation.

Expiration/Retest Date:

Expiration/retest date of the unopened ampoule stored at the recommended storage conditions is the last day of the month.

A retest will be performed 6 months prior to the stated retest date. Upon successful retesting, a new retest date or expiration date is set for the product. The certificate of analysis is then updated and made available on our website. For our products, the extension of the shelf life is capped to 10 years after release as the maximum period.

Gravimetric Preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly with certified and traceable weights. For each balance, a minimum weighing value has been assigned.

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: HPLC, GC/FID, LC/MS, IR, UV, NMR, Karl Fischer, melting point, and optical rotation if applicable
- Purity of isomeric compounds is reported as the sum of the isomers
- Purity values are rounded to the last decimal place given
- The salt form, purity, residual water, and residual solvents are already taken into account for the given content value.

Uncertainty Statistics:

The uncertainties are determined in accordance with ISO 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. The certified uncertainty value (including characterization uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) is combined using the following formula:

$$U(y) = \sqrt{U^2_{characterization} + U^2_{homogeneity} + U^2_{storage\ stability} + U^2_{shipping\ stability}}$$

The filling volume is the minimum sample size for which the uncertainty is valid. The ampoules are over-filled to ensure that the minimum filling volume can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of 12 ampoules. 4 ampoules are taken at start, middle and end of the filling process. The analyzed concentration at each position is the average value obtained from duplicate analysis of 4 ampoules.

Stability:

The manufacturer guarantees the stability of this product throughout its intended shelf life, when handled and stored accordingly to the given storage conditions.

Legal and Safety Notice:

This product is for routine laboratory analysis and research purposes only. Due to the hazardous nature, only trained personnel should handle this product. The General Terms and Conditions of Lipomed apply.

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Art. No: **ETH-100-1ML**
Lot No: **25052023-A**
Expiry Date: **May 2028**
CoA No: **QC-COA-ETH-100-25052023-A.1**

Certificate of Analysis

Certified Reference Material

Aqueous Ethanol Standard Solution 100 mg/dL

Description	Ethanol diluted in Water 100 mg EtOH / dL Water (0.100 % by mass) 1 mL / ampoule
Certified Concentration	**Ethanol 100.0 mg/dL ± 0.052 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.

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Art. No: **ETH-100-1ML**
Lot No: **25052023-A**
Expiry Date: **May 2028**
CoA No: **QC-COA-ETH-100-25052023-A.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

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Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-ETH-400-1ML
Version: 003-01.Nov.2018 Supersedes: 002-24.Mar.2014

Product name: **400 mg/dL Aqueous Ethanol Standard Solution**
0.400 % by Mass (400 mg Ethanol / 1 dL Water) – 1 ml / ampoule
Ethyl alcohol

Lot No: 30012020-A
Art. No: ETH-400-1ML

Release date: October 16, 2020
Expiry date: **January 2025**

Bulk Product Information: Ethanol

Chemical formula:	C_2H_6O	Purity Ethanol GC/FID:	100 %
CAS Registry No:	64-17-5	Water content Karl Fischer:	0.08 %
Molwt:	46.07		

CERTIFIED CONCENTRATION **400.04 ± 0.49 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 purity factor, material density and mass measurement. The solution stability is established through real time stability studies and is, therefore, excluded from the uncertainty calculation.

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity (GC/FID analysis)	R_t corresponds to R_t of reference standard (± 0.1 min)	R_t standard = 2.6 min R_t test = 2.6 min
3. Extractable volume	> 1 ml	conforms
4. Water quality	Pharmaceutical water for injection	conforms

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

Storage conditions: For maximum stability store air-tight below 30 °C in a dark location. Do not freeze.

Lipomed certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiry date when stored unopened as recommended. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

Issued by Dr. L. Prévot

Date sign: Arlesheim,

October 30, 2020

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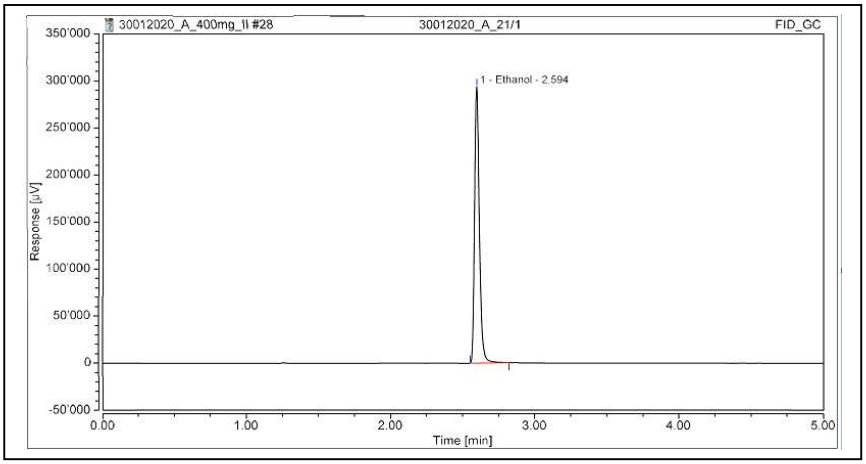
Concentration Verification / Lot to Lot Consistency (GC/FID analysis):

Standard solution	Lot Number	Concentration (± 2%) 392.00 – 408.00 mg/dL (Compared to NIST SRM 2896 / 2897a)	Ampoule to ampoule consistency (≤ 3.0%)
Actual Lot	30012020-A	398.90 mg/dL	0.7 %
Previous Lot	N/A	N/A	N/A

Homogeneity of the lot is confirmed by a duplicate analysis of 21 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 21 GC/FID analyses calibrated with 2 different freshly prepared ethanol solutions (duplicate injections of each solution) and compared with NIST SRM 2896 and 2897a with a 95% level of confidence. During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

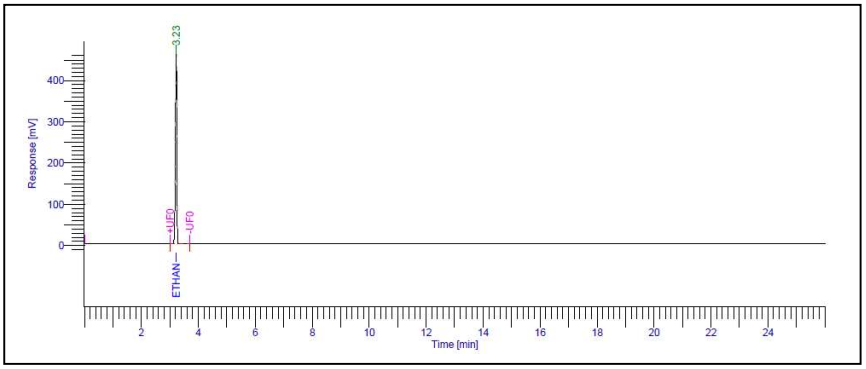
GC/FID Data: Calibration



Analytical conditions:

Column:
Rxi-624Sil-MS (30m x 0.32 mm * 1.8 um)
Split ratio 50.0
Makeup flow: 24.0 mL/min (N_2)
H_2 flow: 32.0 mL/min
Air flow: 200.0 mL/min
Injector temp.: 240°C
Detector temp: 270°C
Säulenofen : 40°C / während 5min (isotherm)
Injektionsvolumen: 1.0µl

GC/FID Data: Ethanol purity



Analytical conditions:

column:
BAC 1, 30 m x 0.32 mm, 1.8 um
Injektor: 200 °C, split 20 ml/min
FID: 300 °C
Ofen:40 °C, 5 min isotherm
Helium 100 kPa (GC), 125 kPa (HS)
range 1, attenuation -6
pressurization time: 2 min
injection time: 0.05 min
withdrawal time: 0.5 min
needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 25 min

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ISO 17034 General requirements for the competence of Reference Material Producer. ANAB Certificate number: AR-1761

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- Purity of isomeric compounds is reported as the sum of the isomers
- Purity values are rounded to the last decimal place given
- The salt form, purity, residual water, and residual solvents are already taken into account for the given content value.

Uncertainty Statistics:

The uncertainties are determined in accordance with ISO 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. The certified uncertainty value (including characterization uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) is combined using the following formula:

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Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of 12 ampoules. 4 ampoules are taken at start, middle and end of the filling process. The analyzed concentration at each position is the average value obtained from duplicate analysis of 4 ampoules.

Stability:

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Legal and Safety Notice:

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