Scottsdale Police Department
Crime Laboratory

Calibrators and Control Certificates for Samples Run

03/22/2021 -

Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-20

Ethyl Alcohol

Cerilliant Quality
ISO GUIDE 34
ISO/IEC 17025
ISO 13485
ISO 15194
ISO 9001
GMP/GLP

Catalog Number: E-056
Solution Lot: FN06141806
Expiration Date: August 2023
Diluent: Water
Volume per Ampoule: 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 Chromatographic 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 Guide 34 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.
- 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 2.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

Traceability to SI through NIST:

- This standard has been prepared and certified under the ISO Guide 34 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. See page 2.

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 ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

May 22, 2020
Date

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2891 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN06141806	19.93	1.9%
Prior Lot	FN03241604	19.98	1.1%
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 Prior Lot represents system suitability on the date of analysis. Triplicate injections of the Prior 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.

Solution Standard Assay Parameters

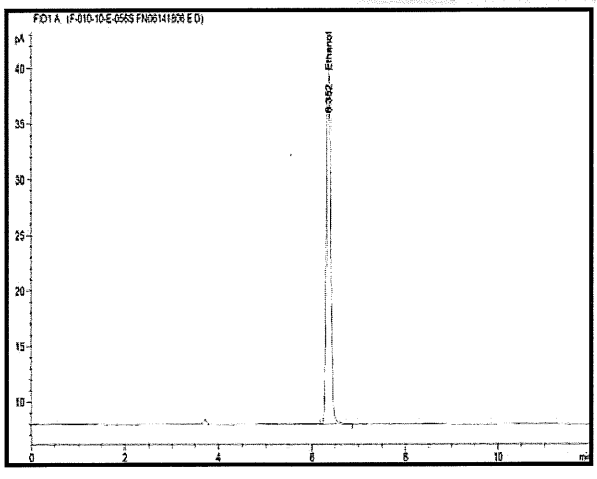
Analysis Method: GC/FID Headspace

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

Temp Program: 40°C hold for 12 min

Injector Temp: 200°C

Detector Temp: 250°C



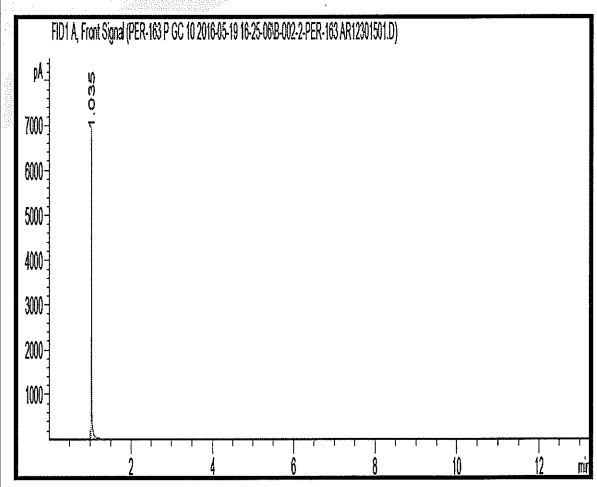
Neat Material Analysis

Purity by GC/FID Analysis: > 99.9%

Water Content by Karl Fischer: 0.0%

Purity Factor: 99.95%

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.



COA Revision History

Revision No.	Date	Reason for Revision
00	October 11, 2018	Initial version
01	May 22, 2020	Removed the Relative Standard Uncertainty Statement on page 1.

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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl alcohol

Catalog Number:	E-031
Solution Lot:	FN05311902
Expiration:	October 2024
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.
- 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 ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

April 01, 2020
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 2894 mg/dL	Homogeneity % RSD
New Lot	FN05311902	99.2	1.2
Previous Lot	FN02271802	98.4	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	SP10-0101	> 99.9%
Residual Water Analysis by Karl Fischer Coulometry	AM1346 [1]	0.05%
Mass Balance Purity Factor		99.94%

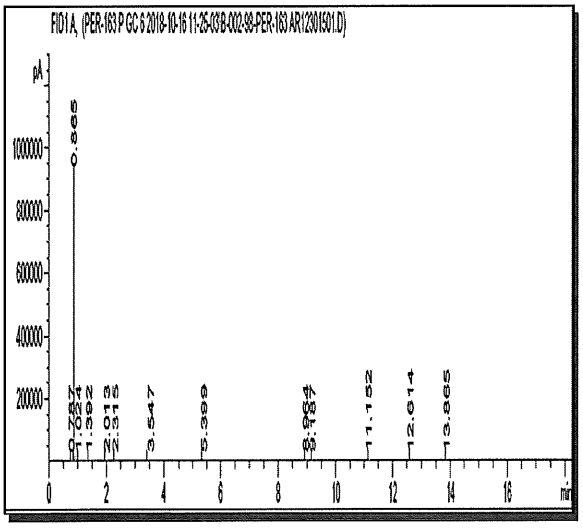
[1] Validated analytical method

- 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

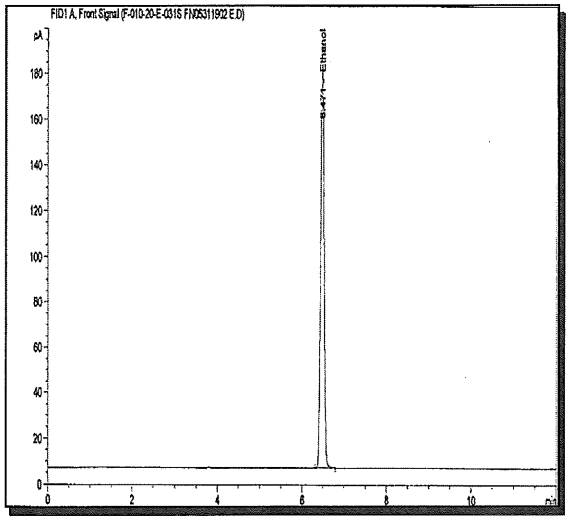
Neat Material

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	April 01, 2020	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:	FN05101903
Expiration:	September 2024
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%	200.0 ± 0.8 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.
- 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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ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

April 03, 2020
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.

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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	FN05101903	198.2	0.8
Previous Lot	FN06231704	198.3	0.8
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.
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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	SP10-0101	> 99.9%
Residual Water Analysis by Karl Fischer Coulometry	AM1346 [1]	0.05%
Mass Balance Purity Factor		99.94%

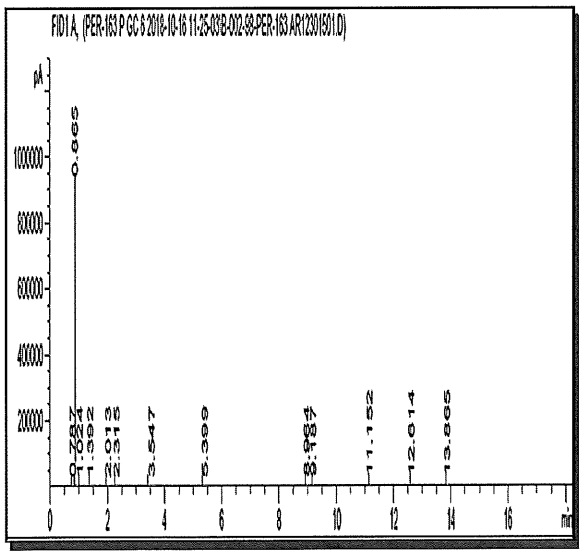
[1] Validated analytical method

- 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

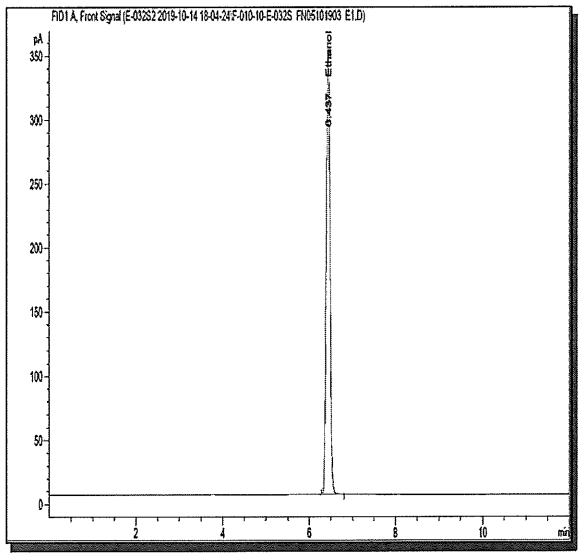
Neat Material

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	April 03, 2020	Initial version.

Supelco®

www.sigmaaldrich.com

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl alcohol

Catalog Number:	E-036
Solution Lot:	FN10051906
Expiration:	December 2024
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%	400.0 ± 1.6 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.
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ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

April 17, 2020
Date

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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 2896 mg/dL	Homogeneity % RSD
New Lot	FN10051906	403.6	0.7
Previous Lot	FN05131606	406.3	0.8
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	SP10-0101	99.9%
Residual Water Analysis by Karl Fischer Coulometry	AM1346 [1]	0.12%
Mass Balance Purity Factor		99.81%

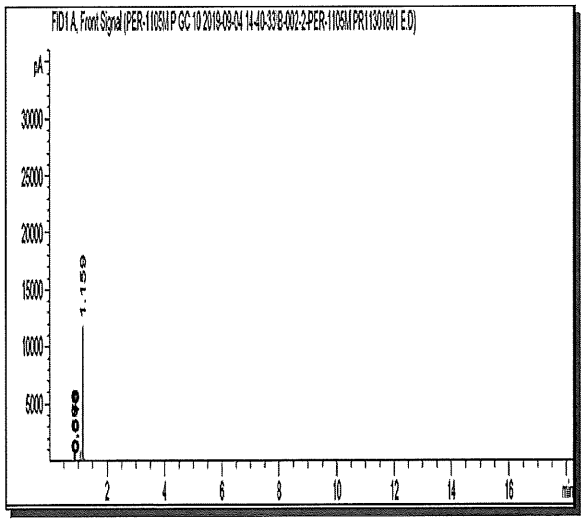
[1] Validated analytical method

- 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

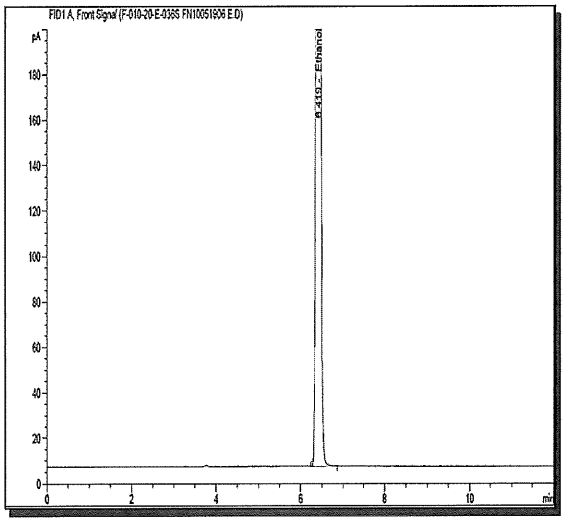
Neat Material

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 17, 2020	Initial version.

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 Ethanol-Konzentration wurde von 3 akkreditierten Laboratorien (DIN EN 17025) ermittelt. Es wurden jeweils Doppelbestimmungen mit zwei unterschiedlichen GC-Methoden pro Tag an 5 Tagen durchgeführt.

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.

Ch.-B: 4101018274
Best.-Nr.: WH20-015 (10 x 1,5 ml)
WH20-115 (100 x 1,5 ml)
WH20-030 (10 x 3,0 ml)
Version: 1 – 201812

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.

Assigned value
The assigned ethanol concentration was determined by 3 independent laboratories, each accredited to DIN EN 17025. Repeat determinations were carried out daily on 5 days using two independent analytical GC methods.

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 original 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: 4101018274
Order no.: WH20-015 (10 x 1.5 ml)
WH20-115 (100 x 1,5 ml)
WH20-030 (10 x 3.0 ml)
Version: 1 - 201812

Messverfahren / Method	Zielwert / Target value	Konfidenzbereiche / Confidence ranges			Einheit / Unit
		statistisch / statistical[1]	forensisch / forensic[2]	klinisch / clinical[3]	
GC	2,004	1,938 – 2,070	1,904 – 2,104	1,824 – 2,184	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 des Zielwerts.
[EtOH] > 1,06 g/L → Konfidenzbereich ± 5% des Zielwets

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)

GI_EtOHWH_20_4101018274_20181219.doc

[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)

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 4101018274/9 2026-10 2°C 8°C

Hersteller / Manufacturer / Produttore / Producteur
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SERVICES TO HEALTH

Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-ETH-080-1ML
Version: 001-01.Dec.2016 Supersedes: new

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 Nr: 03102016-A/1 Release date: November 29, 2016
Art. Nr: ETH-080-1ML Expiry date: **October 2021**

Bulk Product Information: Ethanol

Chemical formula:	C_2H_6O	Purity Ethanol GC/FID:	100 %
CAS Registry Nr:	64-17-5	Water content Karl Fischer:	0.08 %
Molwt:	46.07		

CERTIFIED CONCENTRATION **80.42 ± 0.10 mg/dL**

Uncertainty of the certified concentration is an expanded uncertainty in accordance with ISO 17025 and ISO Guide 34 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 Headspace)	R_t corresponds to R_t of NIST reference standard (± 0.1 min)	R_t standard = 1.4 min R_t test = 1.4 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,

December 01, 2016

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ANAB ACCREDITED ISO GUIDE 34 REFERENCE MATERIAL PRODUCER
ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY
CERTIFIED Management System ISO 9001

Ampoule to ampoule consistency:

	Specification	Result
% RSD	< 2 %	0.24 %

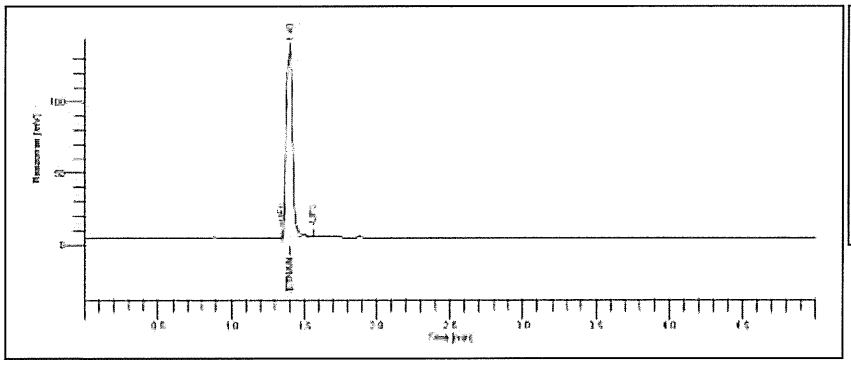
Homogeneity of the lot is confirmed by an analysis of 6 ampoules. These samples are representative of the batch from which they were taken.

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

Standard solution	Lot Number	Specification	Concentration (Compared to NIST SRM 2892; 2893; 2894; 2895)
Actual Lot	03102016-A/1	80.00 ± 1.60 mg/dL	79.17 ± 0.19 mg/dL
Previous Lot	N/A	N/A	N/A

The verified concentration of the ampoules is calculated from the distribution of 6 GC/FID Headspace analyses compared with the calibration curve of 2 ampoules of each NIST SRM 2892; 2893; 2894; 2895 with a 95% level of confidence. During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

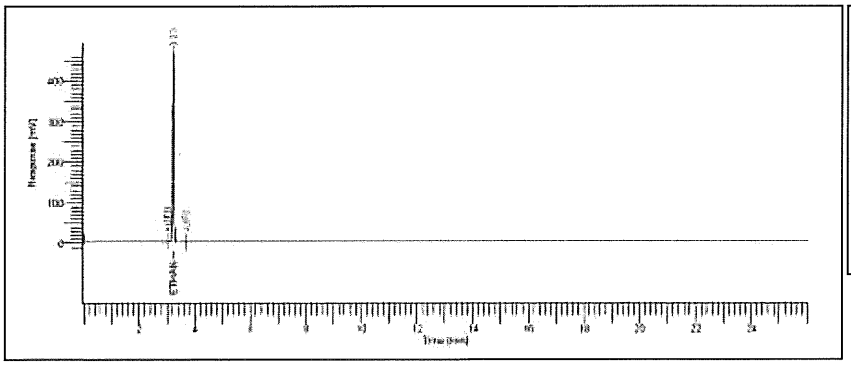
GC/FID Headspace Data: Calibration



Analytical conditions:

column:
Restek 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)
pressurization time: 2 min
injection time: 0.05 min
withdrawal time: 0.5 min
needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 15 min

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 9001:2015	Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199
ISO/IEC 17025:2005	General requirements for the competence of Testing Analytical Reference Standards. ANAB Certificate number: AT-1760
ISO Guide 34:2009	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 quality 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 page 1. This product can be used for quantification and/or identification. If dilution is required use only diluent compatible with all certified analyses in this preparation. All solutions should be thoroughly mixed prior to use.

Expiration/Retest dates:

Expiration date/Retest date of the unopened ampoule stored at the recommended storage condition is the last day of the month listed page 1.

A retest is 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 web-site. A maximum of 5 years after the release date is given. Upon successful retesting after these 5 years, an expiry date of 2 years is stated.

Uncertainty, concentration and Expiration/Retest dates of the Reference Material are based on the unopened ampoule being stored according to the recommended condition found in the storage field.

Gravimetric preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly 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: 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 up to the third decimal place
- The content is already corrected from the salt form, the purity, residual water and residual solvents.

Uncertainty Statistics and Confidence limits:

The uncertainties are determined in accordance with ISO Guide 34 and 17025. The certified combined stressed uncertainty value (includes gravimetric uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) were combined using the following formula:

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

K is a coverage factor of 2, which gives the level of confidence of approximately 95%.
The packaged amount is the minimum sample size for which uncertainty is valid. The ampoules are over-filled to ensure that the minimum packaged amount can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of 12 ampoules. 4 ampoules are taken in each early, middle and late fill position. The analyzed concentration in each early, middle and late fill position is the average value obtained from duplicate analysis of 4 ampoules

Stability:

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

Legal Notice and Limit of Liability:

This product is for routine laboratory analysis and research proposal only. Due to the hazardous nature, only trained personnel should handle this product. The company's liability will be limited to replacement of product or refund or purchase price. Notice of claims must be made within thirty (30) days from date of delivery.

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SERVICES TO HEALTH

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
Art. No: ETH-080-1ML

Release date: February 28, 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 **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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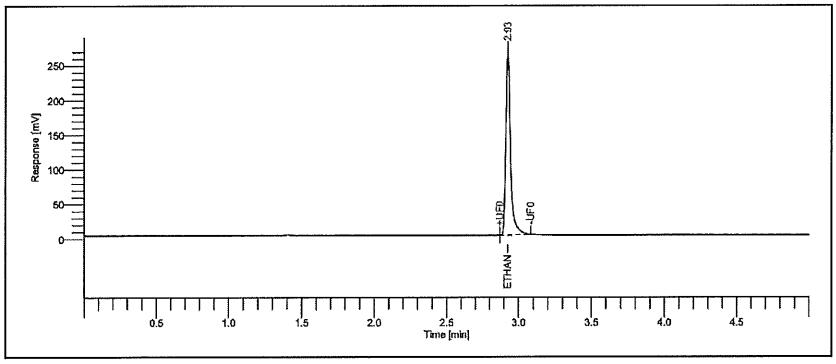
Concentration Verification / Lot to Lot Consistency (GC/FID analysis):

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.

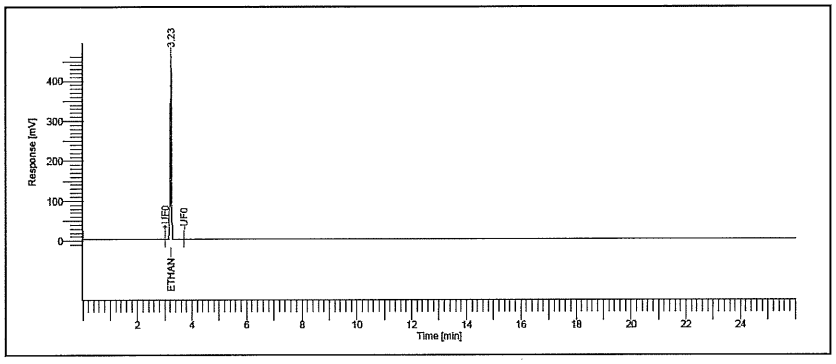
GC/FID Data: Calibration



Analytical conditions:

Column:
Rtx-624Sil-MS (30m x 0.32 mm * 1.8 um)
Injektionstechnik: 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:

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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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SERVICES TO HEALTH

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 Nr: 11092018-A
Art. Nr: ETH-400-1ML

Release date: October 31, 2018
Expiry date: **September 2023**

Bulk Product Information: Ethanol

Chemical formula: C_2H_6O
CAS Registry Nr: 64-17-5
Molwt: 46.07

Purity Ethanol GC/FID: 100 %
Water content Karl Fischer: 0.08 %

CERTIFIED CONCENTRATION **400.10 ± 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 = 2.9 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,

November 01, 2018

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

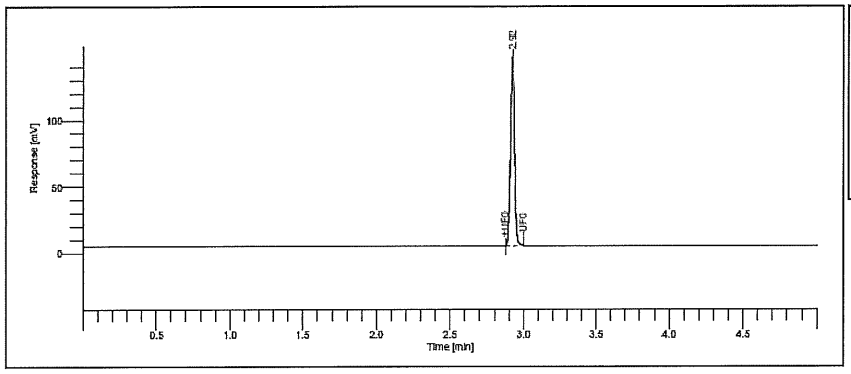
Standard solution	Lot Number	Concentration (± 2%) 392.00 – 408.00 mg/dL (Compared to NIST SRM 2896)	Ampoule to ampoule consistency (≤ 3%)
Actual Lot	11092018-B	399.13 mg/dL	2.6 %
Previous Lot	N/A	N/A	N/A

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 6 GC/FID analyses calibrated with 2 different freshly prepared ethanol solutions (triplicate injections of each solution) and compared with NIST SRM 2896 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 Headspace Data: Calibration

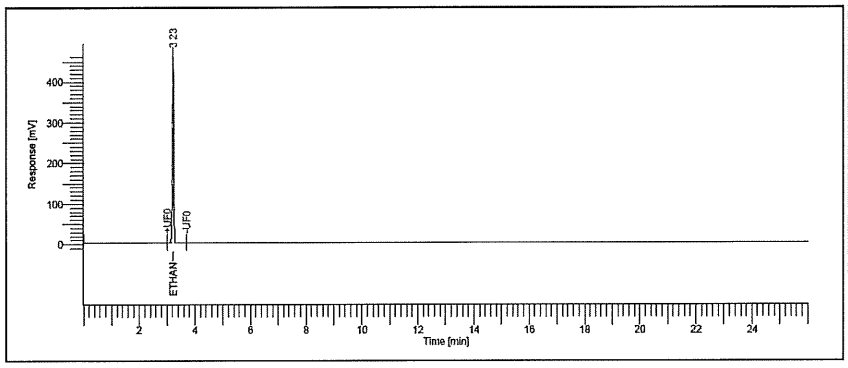
Analytical conditions:



Column:
Trx-624Sil-MS (30m x 0.32 mm * 1.8 um)
Injektionstechnik: Split: 1:5
Injektortemp: 240°C
Detektortemp: 270°C
Säulenofen : 40°C / während 5min (isotherm)
Spritze: 0.4µl
Injektionsvolumen: 0.4µl
Attenuation am FID: -3

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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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 quality 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 page 1. This product can be used for quantification and/or identification. If dilution is required use only diluent compatible with all certified analyses in this preparation. All solutions should be thoroughly mixed prior to use.

Expiration/Retest dates:

Expiration date/Retest date of the unopened ampoule stored at the recommended storage condition is the last day of the month listed page 1.

A retest is performed 6 months prior to the stated retest date. Upon successful retesting, a new retest date or expiration date is set for the product. A maximum shelf-life of 10 years after the release date can be stated. The certificate of analysis is then updated and made available on our web-site.

Uncertainty, concentration and Expiration/Retest dates of the Reference Material are based on the unopened ampoule being stored according to the recommended condition found in the storage field.

Gravimetric preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly 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: 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 up to the third decimal place
- The content is already corrected from the salt form, the purity, residual water and residual solvents.

Uncertainty Statistics and Confidence limits:

The uncertainties are determined in accordance with ISO 17034 and 17025. The certified combined stressed uncertainty value (includes gravimetric uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) were combined using the following formula:

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

K is a coverage factor of 2, which gives the level of confidence of approximately 95%.
The packaged amount is the minimum sample size for which uncertainty is valid. The ampoules are over-filled to ensure that the minimum packaged amount can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by an analysis of 6 ampoules. 2 ampoules are taken in each early, middle and late fill position. The analyzed concentration is the average value obtained from analysis of 6 ampoules

Stability:

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

Legal Notice and Limit of Liability:

This product is for routine laboratory analysis and research proposal only. Due to the hazardous nature, only trained personnel should handle this product. The company's liability will be limited to replacement of product or refund or purchase price. Notice of claims must be made within thirty (30) days from date of delivery.

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SERVICES TO HEALTH

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
CAS Registry No: 64-17-5
Molwt: 46.07

Purity Ethanol GC/FID: 100 %
Water content Karl Fischer: 0.08 %

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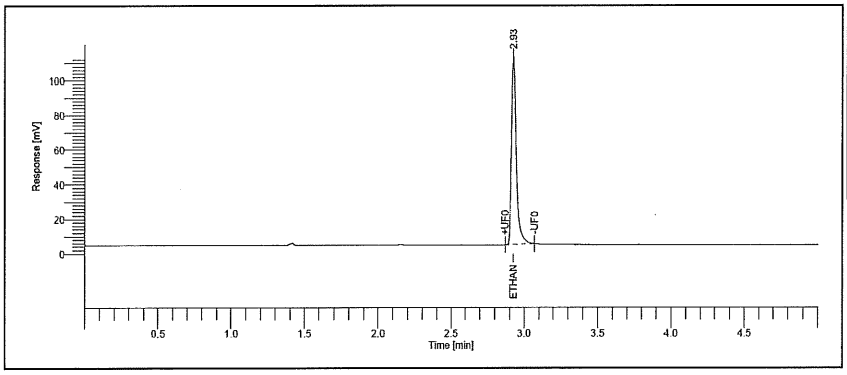
Concentration Verification / Lot to Lot Consistency (GC/FID analysis):

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.

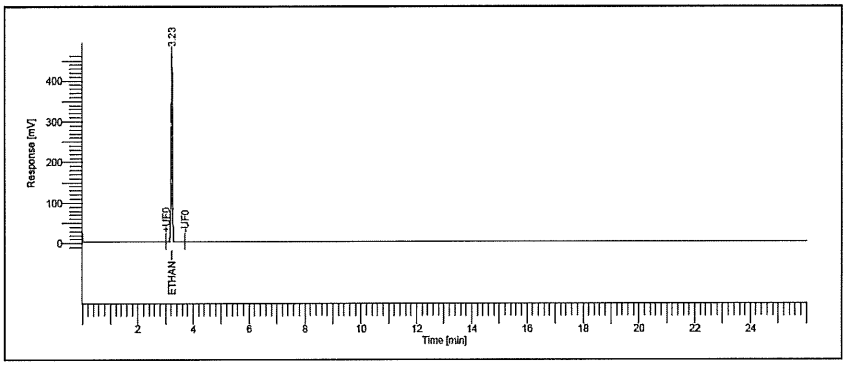
GC/FID Data: Calibration



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

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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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