Scottsdale Police Department Crime Laboratory

Calibrators and Control Certificates for Samples Run

12/28/18 -

Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

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

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-20

Ethyl Alcohol

Catalog Number: E-056
Solution Lot: FN03241604
Expiration Date: April 2021
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 ± 0.07 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.175% and the relative expanded uncertainty is 0.35% 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 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.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.10% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- 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 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

May 06, 2016
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	FN03241604	20.17	1.19%
Prior Lot	FN08101401	20.07	1.52%
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

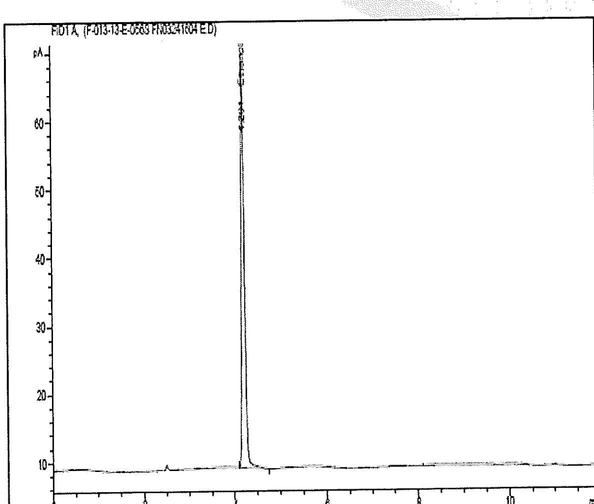
Analysis Method: GC/FID Headspace

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



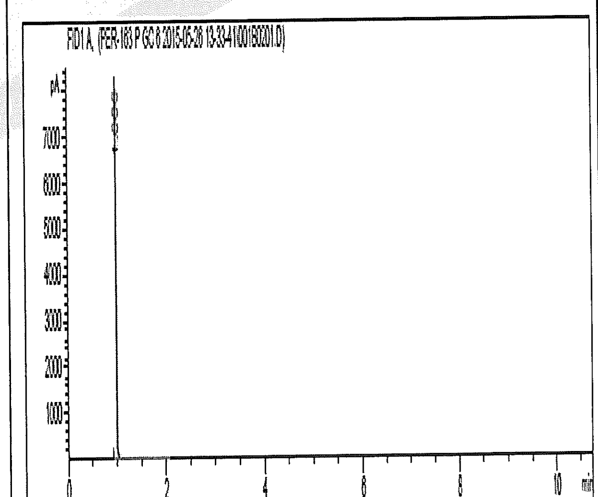
Neat Material Analysis

Purity by GC/FID Analysis: > 99.9%

Water Content by Karl Fischer: 1.1%

Purity Factor: 99.90%

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.



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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl Alcohol

Catalog Number:	E-031
Solution Lot:	FN06181501
Expiration Date:	June 2020
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 1 µL.

Component	Solution Chromatographic 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 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.175% and the relative expanded uncertainty is 0.35% 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 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.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.1% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- 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.

ACLASS ACCREDITED
REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

July 01, 2015
Date

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2894 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN06181501	97.86	0.68%
Prior Lot	FN02021403	97.83	0.79%
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

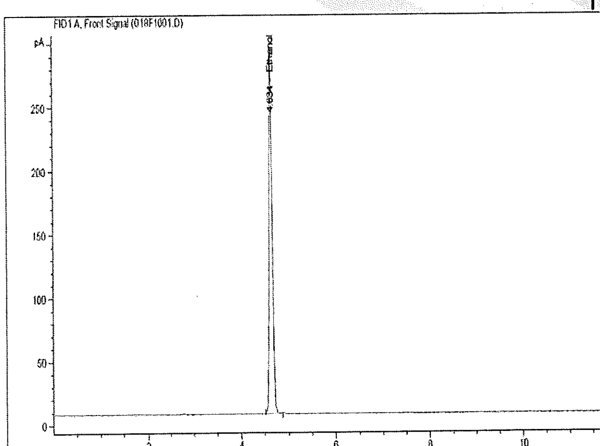
Analysis Method: GC/FID Headspace

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



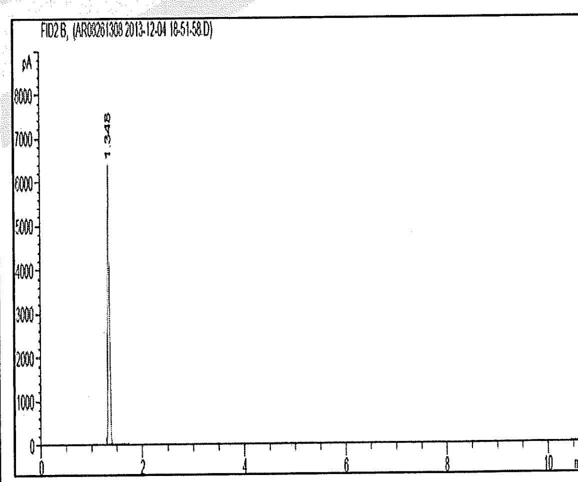
Neat Material Analysis

Purity by GC/FID Analysis: >99.9%

Water Content by Karl Fischer: 0.0%

Purity Factor: >99.9%

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.



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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl Alcohol

Catalog Number: E-031
Solution Lot: FN02271802
Expiration Date: April 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 1 μL.

Component	Solution Chromatographic 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 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.175% and the relative expanded uncertainty is 0.35% 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 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.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.1% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- 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

Darron Ellsworth, Quality Assurance Manager

July 05, 2018
Date

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Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2894 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN02271802	100.8	1.5%
Prior Lot	FN08101601	99.8	0.5%
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

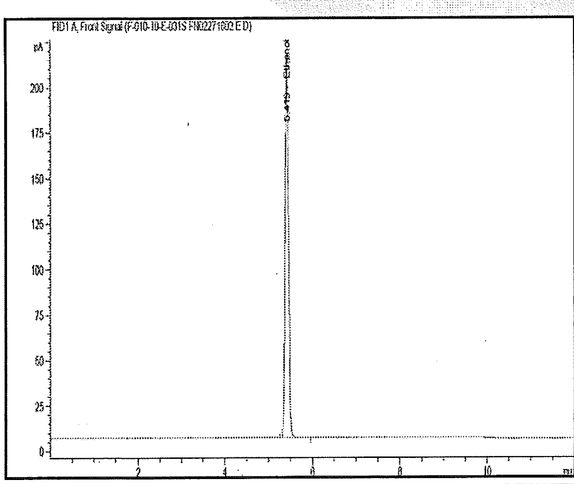
Analysis Method: GC/FID Headspace

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



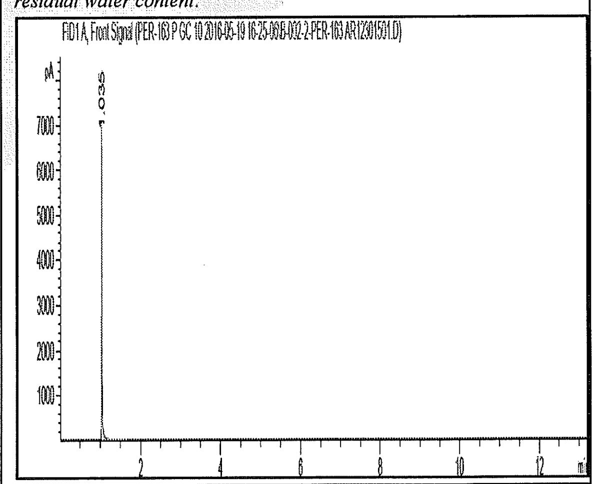
Neat Material Analysis

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.



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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-200

Ethyl Alcohol

Catalog Number:	E-032
Solution Lot:	FN07201502
Expiration Date:	October 2020
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%	200.0 ± 0.7 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.175% and the relative expanded uncertainty is 0.35% 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 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.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.1% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- 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.

ACLASS ACCREDITED REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

November 04, 2015
Date

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2895 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN07201502	199.5	0.7%
Prior Lot	FN12011401	198.4	0.7%
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 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

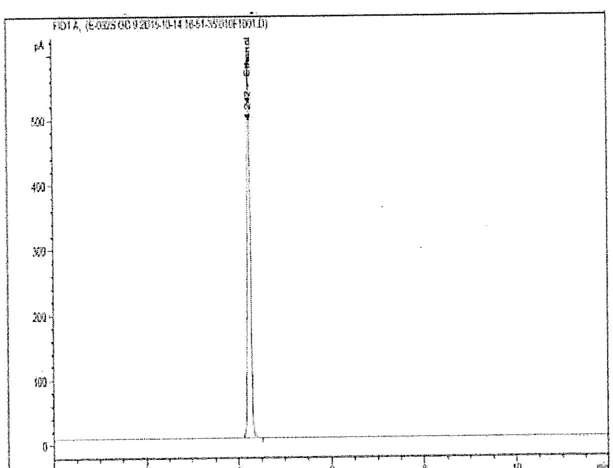
Analysis Method: GC/FID Headspace

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

Temp Program: 40°C hold for 12 min

Injector Temp: 200°C

Detector Temp: 250°C



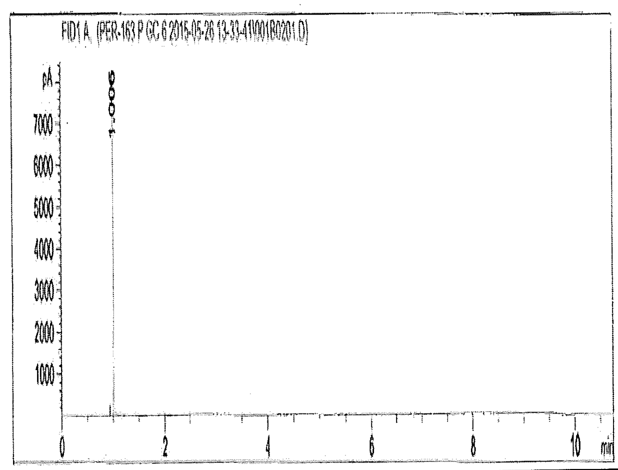
Neat Material Analysis

Purity by GC/FID Analysis: > 99.9%

Water Content by Karl Fischer: 0.09%

Purity Factor: 99.91%

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.



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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-200

Ethyl Alcohol

Catalog Number: E-032
Solution Lot: FN06231704
Expiration Date: August 2022
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%	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 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.181% 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 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 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

December 04, 2017
Date

Cerilliant®
Analytical Reference Standards
a SIGMA-ALDRICH company

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2895 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN06231704	199.6	0.5%
Prior Lot	FN03301601	198.8	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 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

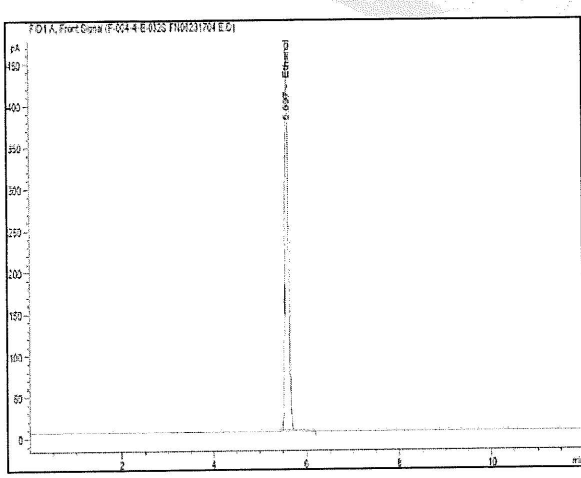
Analysis Method: GC/FID Headspace

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



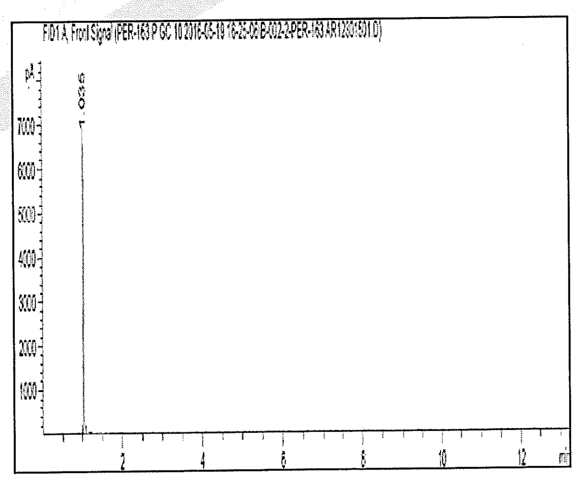
Neat Material Analysis

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.



Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

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

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl Alcohol

Catalog Number: E-036
Solution Lot: FN11191402
Expiration Date: February 2020
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%	400.0 ± 1.4 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.175% and the relative expanded uncertainty is 0.35% 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 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.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.1% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- 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.

ACLASS ACCREDITED
REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

June 25, 2015
Date

811 Paloma Drive. Suite A. Round Rock. TX 78665 800-848-7837 / 512-238-9974

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2896 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN11191402	399.2	0.54%
Prior Lot	FN012712-01	400.4	1.56%
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

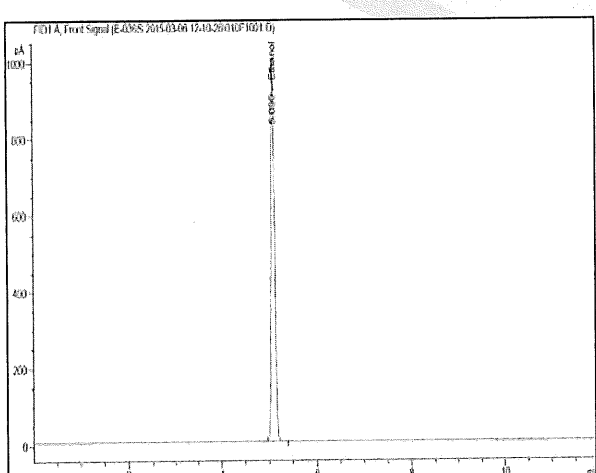
Analysis Method: GC/FID Headspace

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



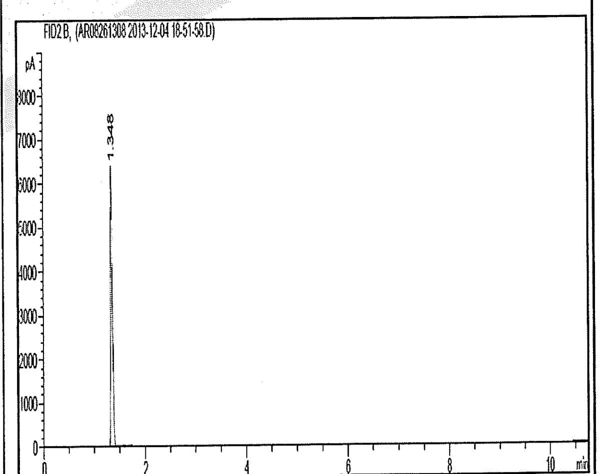
Neat Material Analysis

Purity by GC/FID Analysis: 100.0%

Water Content by Karl Fischer: 0.0%

Purity Factor: 100.0%

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.



Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

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

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl Alcohol

Catalog Number: E-036
Solution Lot: FN05131606
Expiration Date: June 2021
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%	400.0 ± 1.4 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.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.175% and the relative expanded uncertainty is 0.35% 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 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.
- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo to ISO 17025 requirements and using NIST traceable weights. Qualification of each balance includes the assignment of a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure each weighing complies with USP tolerances of NMT 0.10% relative uncertainty.
- Balance calibration adjustments are performed weekly utilizing the balance's internal adjustment mechanism and with NIST traceable weights.
- Balance calibration is verified prior to each use and is performed utilizing NIST traceable weights. Weigh tapes from the balance calibration are included in the production batch record for this standard. Production data package available upon request.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Weight sets used for all balance calibrations are calibrated externally by an ISO 17025 accredited calibration laboratory to NIST standards.
- 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 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

June 18, 2016
Date

811 Paloma Drive. Suite A. Round Rock. TX 78665 800-848-7837 / 512-238-9974

Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2896 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN05131606	404.0	0.9%
Prior Lot	FN11191402	402.0	2.3 %
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 0.352% 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

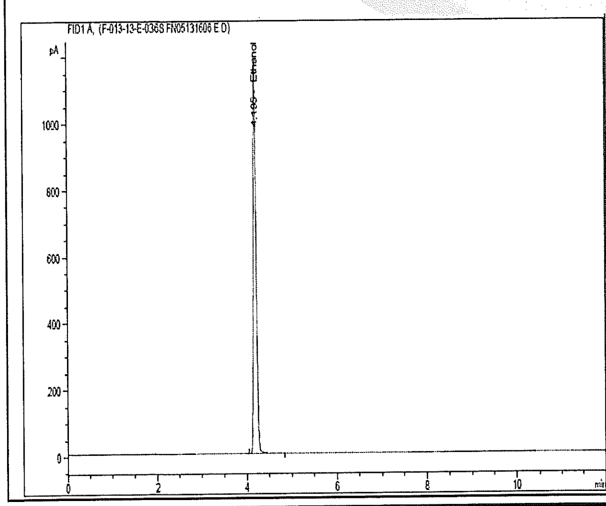
Analysis Method: GC/FID Headspace

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



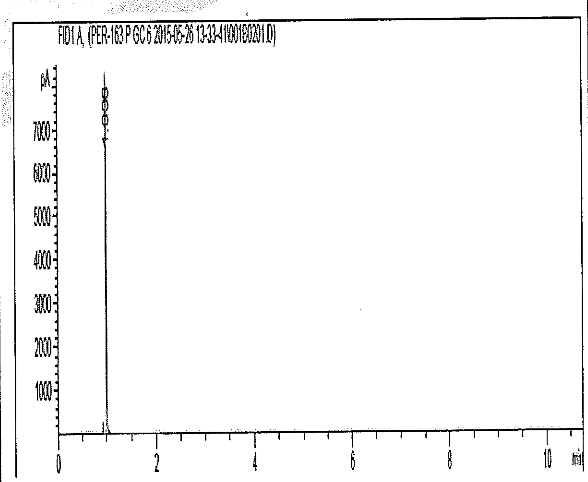
Neat Material Analysis

Purity by GC/FID Analysis: > 99.9%

Water Content by Karl Fischer: 0.1%

Purity Factor: 99.91%

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.



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SERVICES TO HEALTH

Certificate of Analysis
Reference Material

Lipomed Document QC-CA-ETH-40-1ML
Version: 002-21.Mar.2014 Supersedes: 001-13 Jan 2012

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 Nr: 09022015-A Art. Nr: ETH-40-1ML		Release date: March 23, 2015 Expiry date: **February 2020**

Bulk Product Information: Ethanol

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

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity	GC/FID Headspace R_t corresponds to R_t of NIST reference standard (± 0.10 min)	R_t standard = 1.63 min R_t test = 1.63 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	40.00 ± 0.80 mg/dL	**39.62 ± 0.25 mg/dL** [a] (mean value) (Compared to NIST SRM 2891; 2892; 2893; 2894)
4. Extractable volume	> 1 ml	conforms
5. Water quality	Pharmaceutical water for injection	conforms

a : The 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 2891; 2892; 2893; 2894 with a 95% level of confidence.
During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

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.

QC - Officer: Deputy: Dr. L. Prévot Date sign: Arlesheim,

Prévot

March 23, 2015

Lipomed AG is ISO 9001:2008 certified and ISO/IEC 17025:2005, ISO Guide 34:2009 accredited.

SWITZERLAND: LIPOMED AG, FABRIKMATTENWEG 4, CH-4144 ARLESHEIM · ☎ +41 61 702 02 00 · FAX +41 61 702 02 20
GERMANY: LIPOMED GmbH, HEGENHEIMER STRASSE 2, D-79576 WEIL AM RHEIN ☎ +49 7621 1693 473 FAX +49 7621 1693 474
USA: LIPOMED INC., ONE BROADWAY, CAMBRIDGE, MA 02142 · ☎ (617) 577 7222 · FAX (617) 577 1776
INTERNET: http://www.lipomed.com e-mail: lipomed@lipomed.com

Ampoule to ampoule consistency:

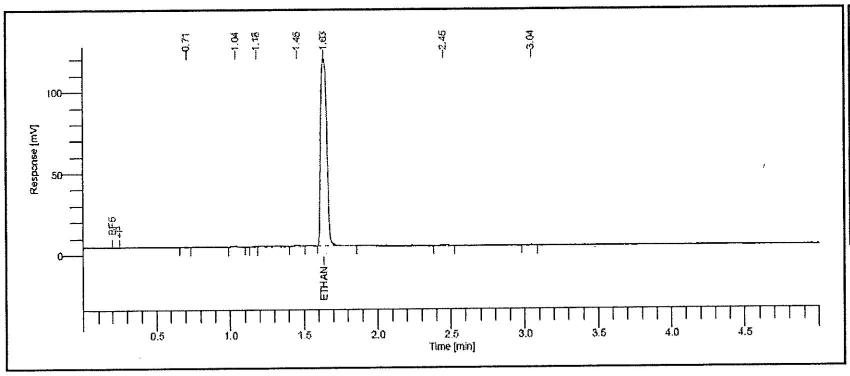
	Specification	Result
% RSD	< 2 %	0.6 %

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

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	09022015-A	39.62 ± 0.25 mg/dL
Previous Lot	30112011-B	39.29 ± 0.63 mg/dL

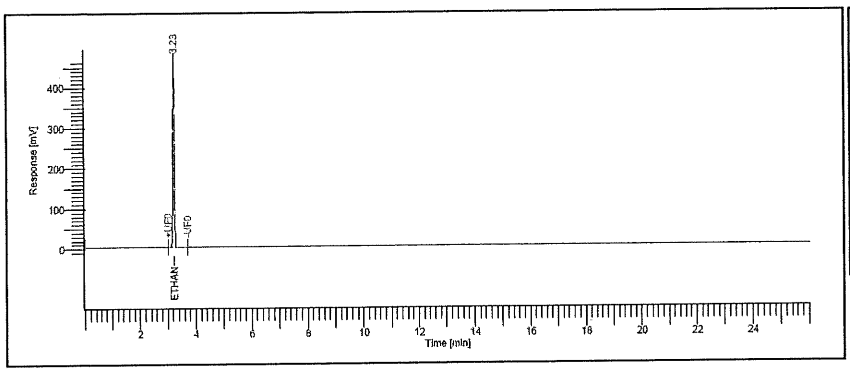
GC/FID Headspace Data: Calibration



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

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 9001:2008	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. ACLASS Certificate number: AT-1760
ISO Guide 34:2009	General requirements for the competence of Reference Material Producer. ACLASS Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by performed quality control tests with the calibration curve of 4 NIST standards during the release process.

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 date:

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

Uncertainty, concentration and expiration date 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: GC/FID, GC/FID Headspace, IR, NMR and Karl Fischer
- Purity values are rounded up to the third decimal place
- The content is already corrected from the purity and residual water.

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 3 ampoules. These samples are representative of the batch from which they are taken.

Stability:

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

SWITZERLAND: LIPOMED AG, FABRIKMATTENWEG 4, CH-4144 ARLESHEIM · ☎ +41 61 702 02 00 · FAX +41 61 702 02 20
GERMANY: LIPOMED GmbH, HEGENHEIMER STRASSE 2, D-79576 WEIL AM RHEIN ☎ +49 7621 1693 473 FAX +49 7621 1693 474
USA: LIPOMED INC., ONE BROADWAY, CAMBRIDGE, MA 02142 · ☎ (617) 577 7222 · FAX (617) 577 1776
INTERNET: http://www.lipomed.com e-mail: lipomed@lipomed.com

Certificate of Analysis
Reference Material

Lipomed Document QC-CA-ETH-080-1ML
Version: 002-21.Mar.2014 Supersedes: 001-22 Jun 2011

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: 28082014-B
Art. Nr: ETH-080-1ML

Release date: September 11, 2014
Expiry date: **August 2019**

Bulk Product Information: Ethanol

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

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity	GC/FID Headspace R_t corresponds to R_t of NIST reference standard (± 0.10 min)	R_t standard = 1.48 min R_t test = 1.48 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	80.00 ± 1.60 mg/dL	**81.30 ± 1.20 mg/dL** [a] (mean value) (Compared to NIST SRM 2891; 2892; 2893; 2894)
4. Extractable volume	> 1 ml	conforms
5. Water quality	Pharmaceutical water for injection	conforms

a : The 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 2891; 2892; 2893; 2894 with a 95% level of confidence.
During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

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.

QC - Officer: Deputy: Dr. L. Prévot

Date sign: Arlesheim,

Prévot

September 11, 2014

Lipomed AG is ISO 9001:2008 certified and ISO/IEC 17025:2005, ISO Guide 34:2009 accredited.

SWITZERLAND: LIPOMED AG, FABRIKMATTENWEG 4, CH-4144 ARLESHEIM · ☎ +41 61 702 02 00 · FAX +41 61 702 02 20
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INTERNET: http://www.lipomed.com e-mail: lipomed@lipomed.com

Ampoule to ampoule consistency:

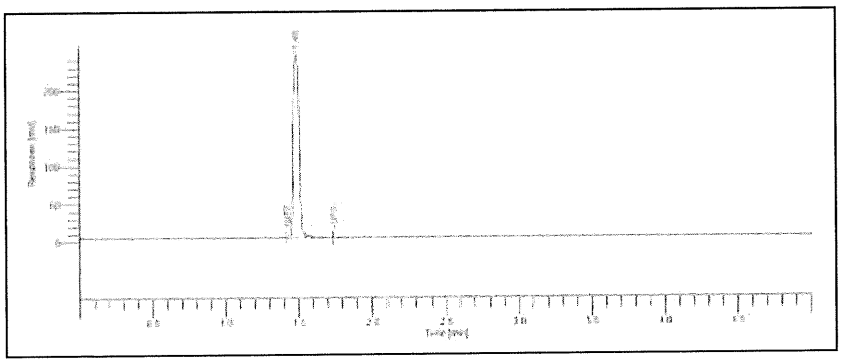
	Specification	Result
% RSD	< 2 %	1.48 %

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

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	28082014-B	81.30 ± 1.20 mg/dL
Previous Lot	14112011-A	79.92 ± 1.37 mg/dL

GC/FID Headspace Data: Calibration

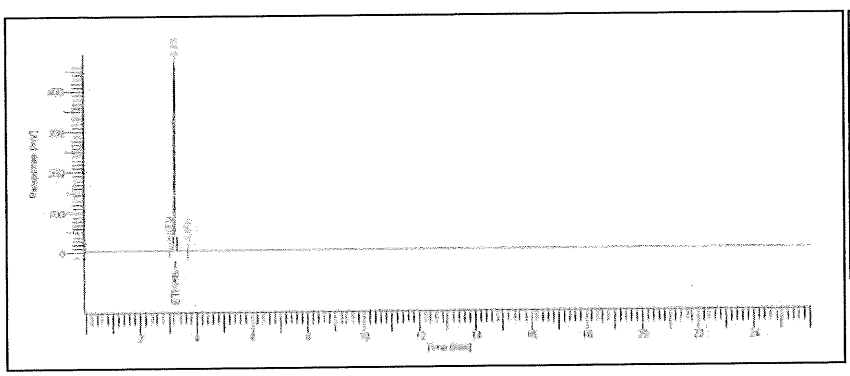


Analytical conditions:

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

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]	Area [%]
1		1.481	[illegible]	[illegible]	100.00

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

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:

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ISO/IEC 17025:2005	General requirements for the competence of Testing Analytical Reference Standards. ACLASS Certificate number: AT-1760
ISO Guide 34:2009	General requirements for the competence of Reference Material Producer. ACLASS Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by performed quality control tests with the calibration curve of 4 NIST standards during the release process.

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 date:

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

Uncertainty, concentration and expiration date 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: GC/FID, GC/FID Headspace, IR, NMR and Karl Fischer
- Purity values are rounded up to the third decimal place
- The content is already corrected from the purity and residual water.

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 3 ampoules. These samples are representative of the batch from which they are taken.

Stability:

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

SWITZERLAND: LIPOMED AG, FABRIKMATTENWEG 4, CH-4144 ARLESHEIM · ☎ +41 61 702 02 00 · FAX +41 61 702 02 20
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INTERNET: http://www.lipomed.com e-mail: lipomed@lipomed.com

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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
Art. Nr: ETH-080-1ML

Release date: November 29, 2016
Expiry date: **October 2021**

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 **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

Prévot

Date sign: Arlesheim,

December 01, 2016

Ampoule to ampoule consistency:

	Specification	Result
% RSD	< 2 %	0.24 %

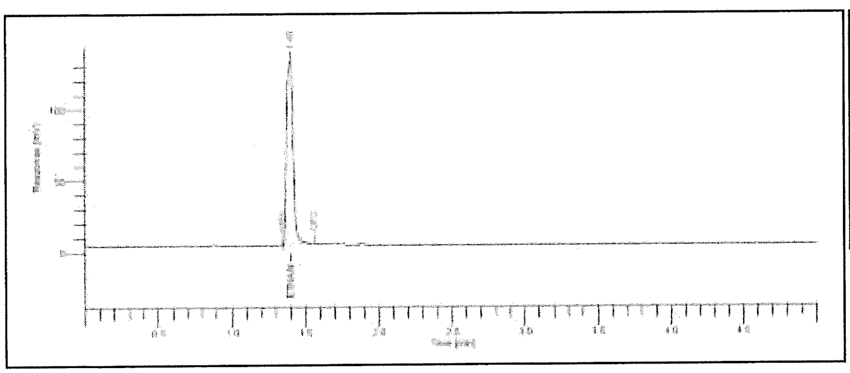
Homogeneity of the lot is confirmed by an analysis of 6 ampoules. These samples are representative of the batch from which they were taken.

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.

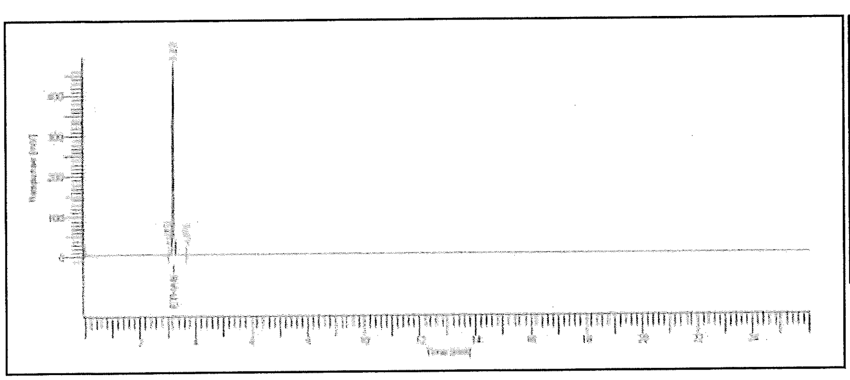
GC/FID Headspace Data: Calibration



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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lipomed@lipomed.com

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
Reference Material

Lipomed Document QC-CA-ETH-150-1ML
Version: 002-21.Mar.2014 Supersedes: 001-22 Jun 2011

Product name:	**150 mg/dL Aqueous Ethanol Standard Solution** 0.150 % by Mass (150 mg Ethanol / 1 dL Water) – 1 ml / ampoule Ethyl alcohol	

Lot Nr: 09022015-C Release date: March 23, 2015
Art. Nr: ETH-150-1ML Expiry date: **February 2020**

Bulk Product Information: Ethanol

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

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity	GC/FID Headspace R_t corresponds to R_t of NIST reference standard (± 0.10 min)	R_t standard = 1.63 min R_t test = 1.63 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	150.00 ± 3.00 mg/dL	**151.27 ± 1.04 mg/dL** [a] (mean value) (Compared to NIST SRM 2893; 2894; 2895; 2896)
4. Extractable volume	> 1 ml	conforms
5. Water quality	Pharmaceutical water for injection	conforms

a : The 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 2893; 2894; 2895; 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.

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.

QC - Officer: Deputy: Dr. L. Prévot Date sign: Arlesheim,

Prévot **March 23, 2015**

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INTERNET: http://www.lipomed.com e-mail: lipomed@lipomed.com

Ampoule to ampoule consistency:

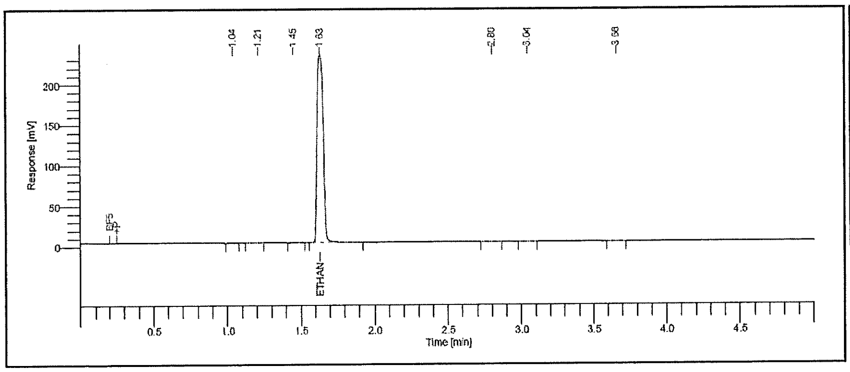
	Specification	Result
% RSD	< 2 %	0.7 %

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

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	09022015-C	151.27 ± 1.04 mg/dL
Previous Lot	11012012-C	150.07 ± 1.57 mg/dL

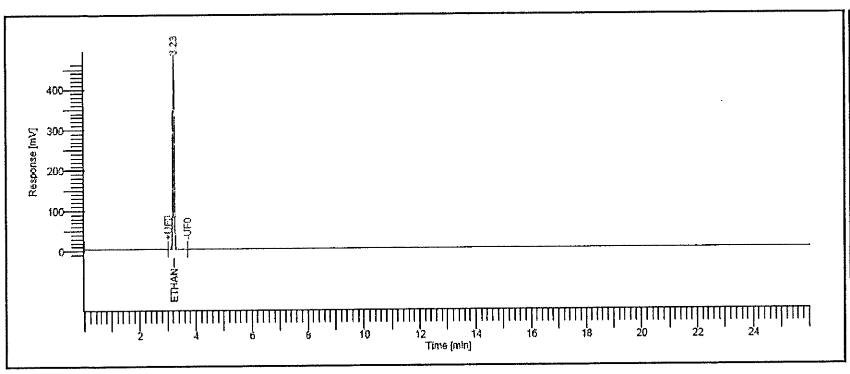
GC/FID Headspace Data: Calibration



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

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 9001:2008	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. ACLASS Certificate number: AT-1760
ISO Guide 34:2009	General requirements for the competence of Reference Material Producer. ACLASS Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by performed quality control tests with the calibration curve of 4 NIST standards during the release process.

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 date:

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

Uncertainty, concentration and expiration date 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: GC/FID, GC/FID Headspace, IR, NMR and Karl Fischer
- Purity values are rounded up to the third decimal place
- The content is already corrected from the purity and residual water.

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 3 ampoules. These samples are representative of the batch from which they are taken.

Stability:

The manufacturer guarantees the stability of this solution through the date stated on page 1 of the certificate when handled and stored 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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Certificate of Analysis
Reference Material

Lipomed Document QC-CA-ETH-400-1ML
Version: 002-24.Mar.2014 Supersedes: 001-22 Jun 2011

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: 08012015-C Release date: February 05, 2015
Art. Nr: ETH-400-1ML Expiry date: **January 2020**

Bulk Product Information: Ethanol

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

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity	GC/FID Headspace R_t corresponds to R_t of NIST reference standard (± 0.10 min)	R_t standard = 1.56 min R_t test = 1.56 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	400.00 ± 8.00 mg/dL	**400.67 ± 4.68 mg/dL** [a] (mean value) (Compared to NIST SRM 2893; 2894; 2895; 2896)
4. Extractable volume	> 1 ml	conforms
5. Water quality	Pharmaceutical water for injection	conforms

a : The 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 2893; 2894; 2895; 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.

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.

QC - Officer: Deputy: Dr. L. Prévot Date sign: Arlesheim,

Prévot

February 05, 2015

Lipomed AG is ISO 9001:2008 certified and ISO/IEC 17025:2005, ISO Guide 34:2009 accredited.

SWITZERLAND: LIPOMED AG, FABRIKMATTENWEG 4, CH-4144 ARLESHEIM · ☎ +41 61 702 02 00 · FAX +41 61 702 02 20
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Ampoule to ampoule consistency:

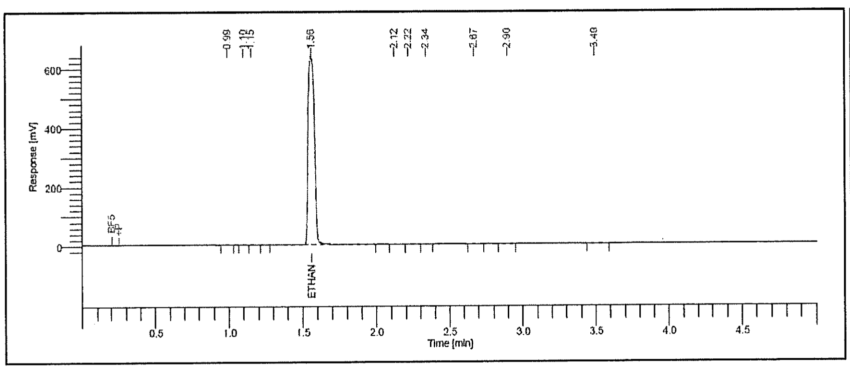
	Specification	Result
% RSD	< 2 %	1.17 %

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

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	08012015-C	400.67 ± 4.68 mg/dL
Previous Lot	05012012-C	400.73 ± 3.31 mg/dL

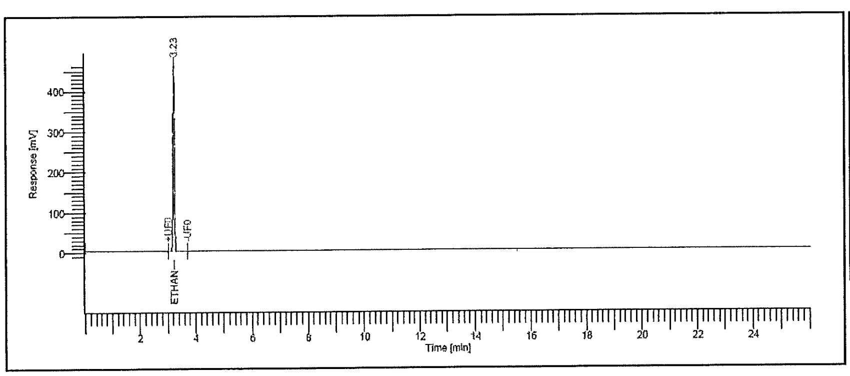
GC/FID Headspace Data: Calibration



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

Lipomed AG is ISO 9001:2008 certified and ISO/IEC 17025:2005, ISO Guide 34:2009 accredited.

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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:

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ISO Guide 34:2009	General requirements for the competence of Reference Material Producer. ACLASS Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by performed quality control tests with the calibration curve of 4 NIST standards during the release process.

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 date:

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

Uncertainty, concentration and expiration date 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: GC/FID, GC/FID Headspace, IR, NMR and Karl Fischer
- Purity values are rounded up to the third decimal place
- The content is already corrected from the purity and residual water.

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 3 ampoules. These samples are representative of the batch from which they are taken.

Stability:

The manufacturer guarantees the stability of this solution through the date stated on page 1 of the certificate when handled and stored 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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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 Ethanol-Konzentration wurde von 3 akkreditierten Laboratorien (DIN EN 17025) ermittelt. Es wurde eine Doppelbestimmung mit einer GC Methode 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:	407041529
Best.-Nr.:	WH20-015 (10 x 1,5 ml) WH20-115 (100 x 1,5 ml) WH20-030 (10 x 3,0 ml)
Version:	3 – 201707

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 Gas Chromatography.

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:	407041529
Order no.:	WH20-015 (10 x 1.5 ml) WH20-115 (100 x 1,5 ml) WH20-030 (10 x 3.0 ml)
Version:	3 – 201707

Messverfahren Method	Zielwert Target value	Konfidenzbereiche / Confidence ranges statistisch / statistical[1]	forensisch / forensic[2]	klinisch / clinical[3]	Einheit Unit
GC	1,982	1,906 – 2,058	1,883 – 2,081	1,804 – 2,160	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

Für [EtOH] ≤ 1,06 g/L → Konfidenzbereich ± 0,053 g/L von dem Zielwert
Für [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)

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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 407041529/13 2023-04 2°C 8°C

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