Scottsdale Police Department
Crime Laboratory

Vendor Control Inserts for Blood Samples Analyzed

July 7, 2014 ----- _____

Please make copies only, do not remove or mix these items with other time periods.

Whole Blood Ethanol Control Level 2

CE

INTENDED USE

FOR IN VITRO DIAGNOSTIC USE

LiquiSP$_x$™ Whole Blood Ethanol Control is an assayed quality control material intended for use in monitoring the accuracy and precision of the quantitative determination of ethanol in whole blood.

SUMMARY AND PRINCIPLE

This product is to be used exactly as directed for the patient sample in order to monitor, and thus minimize the potential for technical and performance errors in routine testing.

PRODUCT DESCRIPTION

LiquiSP$_x$ Whole Blood Ethanol Control is prepared from stabilized normal human whole blood with the addition of ethanol. This product has been assigned lot-specific ethanol values using quantitative analytical methods. This product is packaged 5.0 mL per vial.

2°C – 8°C

STORAGE AND STABILITY

LiquiSP$_x$ Whole Blood Ethanol Control is stable until the expiration date on the package when stored unopened at 2-8° C and 45 days after opening when stored at 2-8° C. Discard any contaminated material. Microbial contamination is evidenced by an increase in turbidity and/or a characteristic odor.

⚠ PRECAUTIONS

Human source material. Treat as potentially infectious.

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

PROCEDURE

Allow the refrigerated controls to warm to room temperature (18-25° C) and gently swirl the control material prior to use in order to ensure product homogeneity. QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

LIMITATIONS

This material is a control for methods listed in the ASSIGNED VALUES section; it is not to be used as a calibrator. Accurate and reproducible results are dependent upon properly functioning instruments, reagents, standardization, and proper laboratory techniques. Individual laboratories may not obtain the mean assigned value as listed.

VALUE ASSIGNMENT

The mean values and expected ranges printed in this insert were derived from extensive replicate analyses and are specific for this lot.

Values listed below were generated by Cliniqa, the reagent/instrument manufacturer and/or independent laboratories in accordance with an established protocol.

Procedural or assay modifications may alter the mean value obtained. Each laboratory should establish its own parameters of precision; use the mean assigned values and expected ranges provided only as guidelines.

ASSIGNED VALUES

Level 2		Lot No.: 1212091 Exp. Date: 2017-01	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	202	161 - 242

REFERENCES

Baselt, R.C. Analytical Procedures for Therapeutic Drug Monitoring and Emergency Toxicology. Littleton, MA, PSG Publishing, 1987.

IVD **For in vitro diagnostic use**

See package insert for proper use

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EC REP
CEpartner4U
Esdoornlaan 13
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P: +31 (0)6 516 536 26

RE-ORDER INFORMATION
Whole Blood Ethanol Control

Catalog No.	Catalog No.	Catalog No.
REF 93211	REF 93212	REF 93213
Level 1, 6 x 5 mL	Level 2, 6 x 5 mL	Level 3, 6 x 5 mL

CLINIQA®

33101_04 12/6/10

ACQ SCIENCE

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

Ethanolkontrollen im Vollblut

Anwendung
Die Probe ist als Richtigkeitskontrolle und 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: 402101060
Best.-Nr.: WH20-015 (10 x 1,5 ml)
WH20-030 (10 x 3,0 ml)
Version: 3 – 201303

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: 402101060
Order no.: WH20-015 (10 x 1.5 ml)
WH20-030 (10 x 3.0 ml)
Version: 3 - 201303

Messverfahren Method	Zielwert Target value	Konfidenzbereiche / Confidence ranges			Einheit Unit
		statistisch / statistical[1]	forensisch / forensic[2]	klinisch / clinical[3]	
GC	**2,002**	**1,949 – 2,055**	**1,902 – 2,102**	**1,822 – 2,182**	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] ≥ 1,0 g/L → Konfidenzbereich ± 5% von dem Zielwert
Für [EtOH] < 1,0 g/L → Konfidenzbereich ± 0,05 g/L von dem Zielwert

Literatur:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
DACH(23.04.2008) - Spezieller Leitfaden für die Blutalkoholbestimmung für forensische Zwecke – VA 0900-54 Version1

[3] Konfidenzbereich – Richtlinie der deutschen Bundesärztekammer

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

Literatur:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

[1] Confidence ranges – measured values

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

[2] Confidence ranges – German forensic directives

[EtOH] ≥ 1.0 g/l → ± 5% from the target value
[EtOH] < 1.0 g/l → ± 0.05 g/l from the target value

References:
Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
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

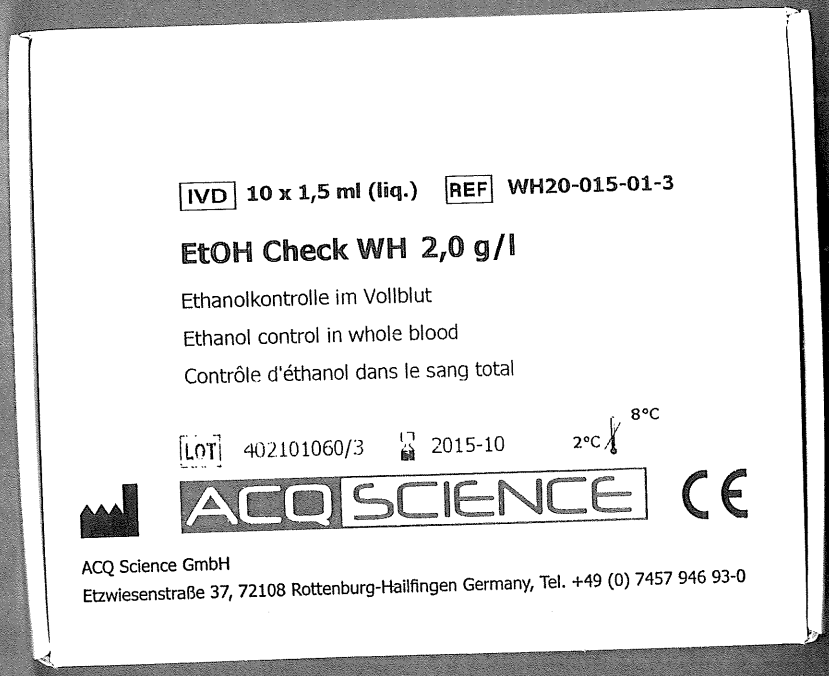
References:
Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (15.02.2008)

Hersteller / Manufacturer

ACQ Science GmbH
Etzwiesenstraße 37
72108 Rottenburg-Hailfingen
Germany

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

CE


IVD 10 x 1,5 ml (liq.) REF WH20-015-01-3
EtOH Check WH 2,0 g/l
Ethanolkontrolle im Vollblut
Ethanol control in whole blood
Contrôle d'éthanol dans le sang total
LOT 402101060/3 2015-10 2°C 8°C
ACQ SCIENCE CE
ACQ Science GmbH
Etzwiesenstraße 37, 72108 Rottenburg-Hailfingen Germany, Tel. +49 (0) 7457 946 93-0

Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

ISO GUIDE 34
ISO/IEC 17025
ISO 13485
ISO 9001
GMP/GLP

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-20

Ethyl Alcohol

Catalog Number: E-056
Solution Lot: FN09031301
Expiration Date: September 2018
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.

Component	Solution Chromatographic Purity	Certified Concentration
Ethanol	100%	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 172025 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

February 13, 2009
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	FN09031301	20.02	0.66%
Prior Lot	FN092710-01	19.89	0.90%
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

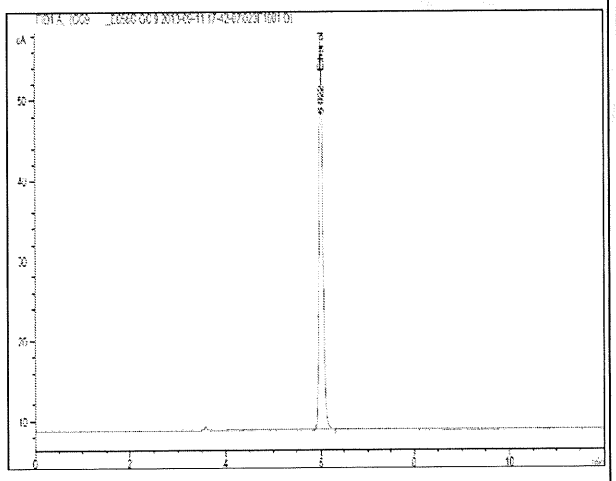
Analysis Method: GC/FID Headspace

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



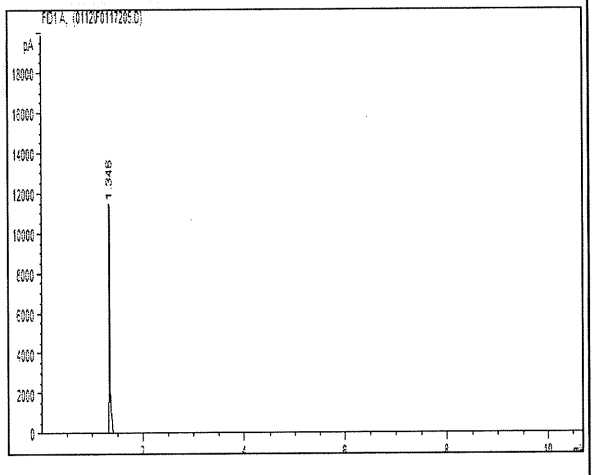
Neat Material Analysis

Purity by GC/FID Analysis: 100.0%

Water Content by Karl Fischer: 0.1%

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.



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

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-100

Ethyl Alcohol

Catalog Number: E-031
Solution Lot: FN050312-01
Expiration Date: May 2017
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.

Component	Solution Chromatographic Purity	Certified Concentration
Ethanol	100%	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 172025 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.
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- 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

Lara Sparks

Lara Sparks, Quality Assurance Director

May 31, 2012
Date

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2894 (mg/dL)	Results compared to Control (% Difference)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN050312-01	98.49	0.78%	0.75%
Prior Lot	FN111711-01	98.70	0.58%	1.45%
Acceptance Criteria		±2%	±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

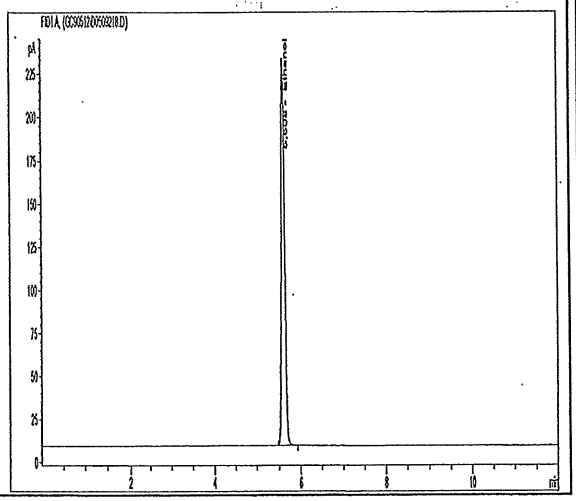
Analysis Method: GC/FID Headspace

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



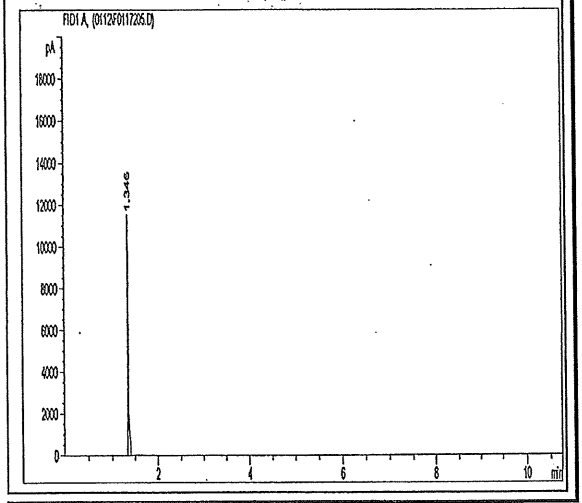
Neat Material Analysis

Purity by GC/FID Analysis: 100.0%

Water Content by Karl Fischer: 0.10%

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.



Cerilliant®
Analytical Reference Standards
a SIGMA-ALDRICH company

ISO GUIDE 34
ISO/IEC 17025
ISO 13485
ISO 9001
GMP/GLP

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-200

Ethyl Alcohol

Catalog Number: E-032
Solution Lot: FN032712-01
Expiration Date: March 2017
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.

Component	Solution Chromatographic Purity	Certified Concentration
Ethanol	100%	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).
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ACLASS ACCREDITED
REFERENCE MATERIAL PRODUCER

Lara Sparks, Quality Assurance Director

May 6, 2012
Date

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2895 (mg/dL)	Results compared to Control (% Difference)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN032712-01	200.3	0.14%	0.70%
Prior Lot	FN070209-01	199.0	0.76%	0.50%
Acceptance Criteria		±2%	±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.
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Solution Standard Assay Parameters

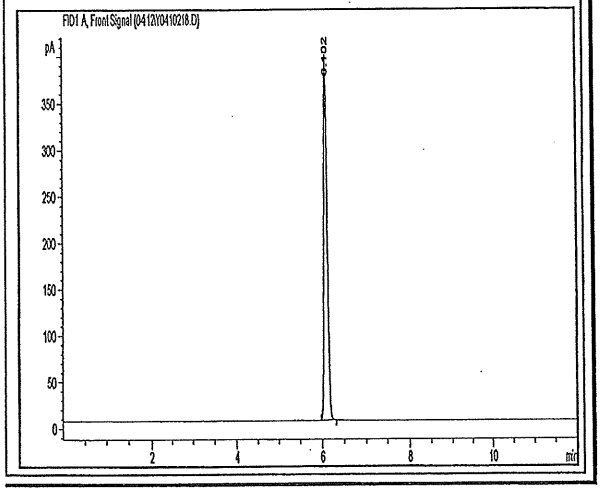
Analysis Method: GC/FID Headspace

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



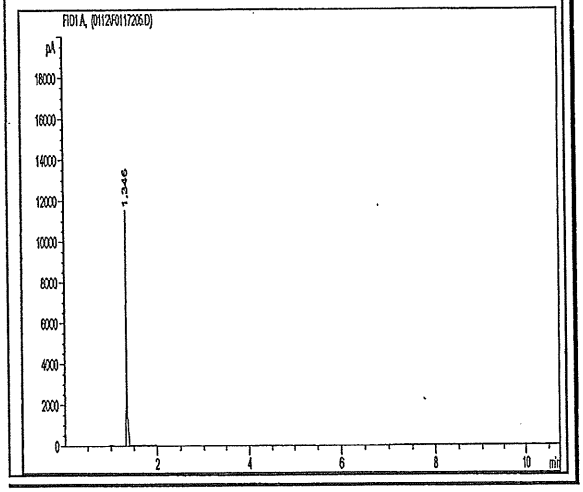
Neat Material Analysis

Purity by GC/FID Analysis: 100.0%

Water Content by Karl Fischer: 0.10%

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.



Cerilliant
Analytical Reference Standards
a SIGMA-ALDRICH company

ISO GUIDE 34
ISO/IEC 17025
ISO 13485
ISO 9001
GMP/GLP

Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-400

Ethyl Alcohol

Catalog Number: E-036
Solution Lot: FN012712-01
Expiration Date: January 2017
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.

Component	Solution Chromatographic Purity	Certified Concentration
Ethanol	100%	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 172025 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.

A2LA ACCREDITED
REFERENCE MATERIAL PRODUCER

Lara Sparks, Quality Assurance Director

February 20, 2012
Date

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2896 (mg/dL)	Results compared to Control (% Difference)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN012712-01	399.9	0.19%	0.72%
Prior Lot	FN040909-01	397.6	0.39%	1.09%
Acceptance Criteria		±2%	±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

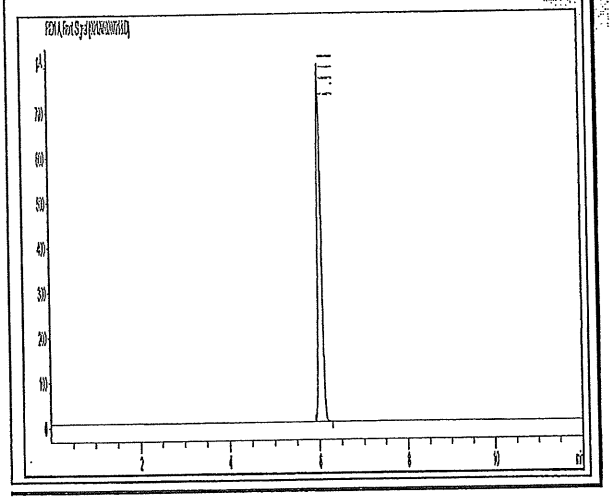
Analysis Method: GC/FID Headspace

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



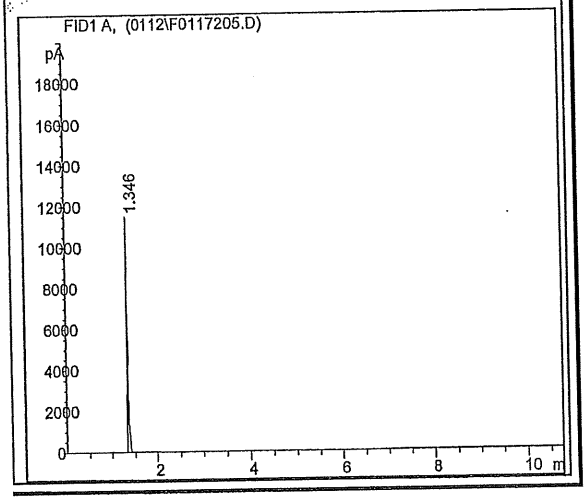
Neat Material Analysis

Purity by GC/FID Analysis: 100.0%

Water Content by Karl Fischer: 0.10%

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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Specifications and Certificate of Analysis

Lipomed Document QC-CA-ETH-40-1ML
Version: 001-13 Jan 2012

Supersedes: new

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: 30112011-B
Art. Nr.: ETH-40-1ML

Release date: 16 01 2012
Expiry date: **November 2016**

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 = 1.58 min R_t test = 1.58 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	40.00 ± 0.80 mg/dL	**39.29 ± 0.63 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.

Note: Gravimetric preparation of each reference solution is ensured by using balances calibrated with ilac-MRA traceable weights.
Lipomed disclaims any liability with respect to mistakes due to inadvertence (e.g. slips of the pen) readily identifiable for an expert or a practitioner.

QC - Officer: Deputy: Dr. L. Prévot

Date of signature: Arlesheim,

January 16, 2012

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

Ampoule to ampoule consistency:

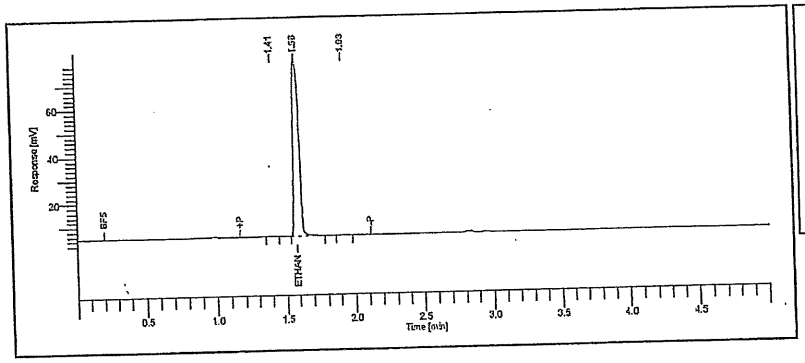
	Specification	Result
% RSD	< 2 %	1.6 %

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	30112011-B	39.29 ± 0.63 mg/dL
Previous Lot	N/A	N/A

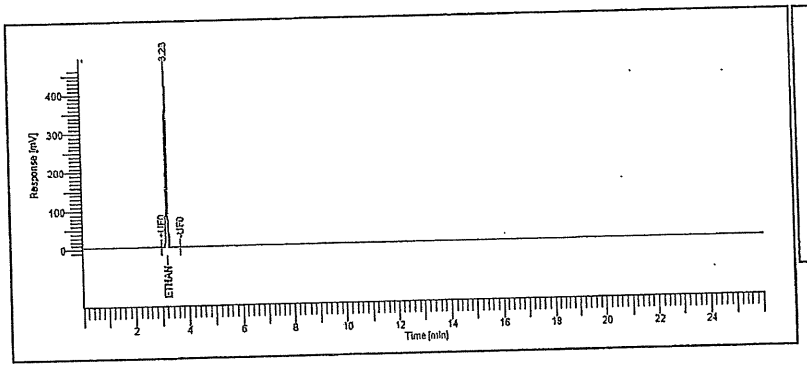
GC/FID Headspace Data: Calibration



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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Specifications and Certificate of Analysis

Lipomed Document QC-CA-ETH-80-1ML
Version: 001-22 Jun 2011

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: 14112011-A
Art. Nr.: ETH-80-1ML

Release date: 26 01 2012
Expiry date: **November 2016**

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 = 1.58 min R_t test = 1.58 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	80.00 ± 1.60 mg/dL	**79.92 ± 1.37 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.

Note: Gravimetric preparation of each reference solution is ensured by using balances calibrated with ilac-MRA traceable weights.
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QC - Officer: Deputy: Dr. L. Prévot

Date of signature: Arlesheim,

January 26, 2012

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

Ampoule to ampoule consistency:

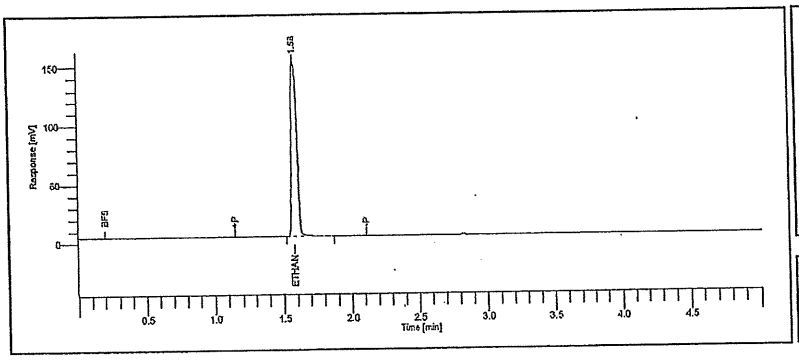
	Specification	Result
% RSD	< 2 %	1.72 %

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	14112011-A	79.92 ± 1.37 mg/dL
Previous Lot	21022011-A	80.13 ± 0.40 mg/dL

GC/FID Headspace Data: Calibration

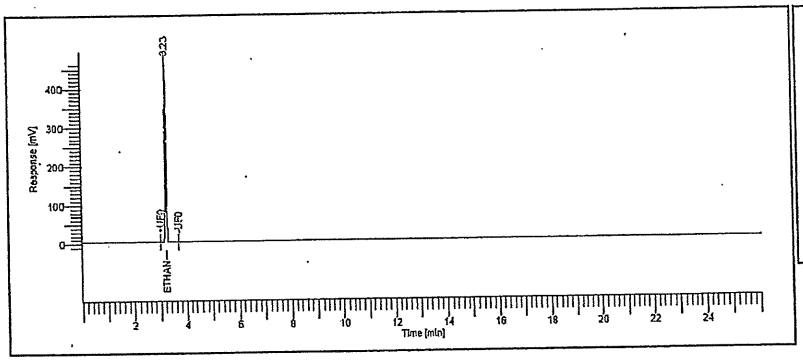


Analytical conditions:

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]	Area [%]
1	Ethanol	1.58	443327.0	100.000

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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Specifications and Certificate of Analysis

Lipomed Document QC-CA-ETH-150-1ML
Version: 001-22 Jun 2011 Supersedes: new

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: 11012012-C
Art. Nr.: ETH-150-1ML

Release date: 09 02 2012
Expiry date: **January 2017**

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)	150.00 ± 3.00 mg/dL	**150.04 ± 1.35 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.

Note: Gravimetric preparation of each reference solution is ensured by using balances calibrated with ilac-MRA traceable weights.
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QC - Officer: Deputy: Dr. L. Prévot

Date of signature: Arlesheim,

February 09, 2012

Prévot

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

Ampoule to ampoule consistency:

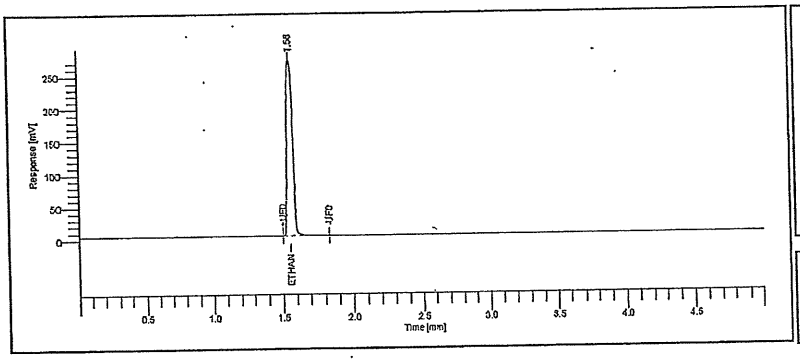
	Specification	Result
% RSD	< 2 %	0.90 %

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	11012012-C	150.04 ± 1.35 mg/dL
Previous Lot	22022011-A	151.49 ± 0.59 mg/dL

GC/FID Headspace Data: Calibration

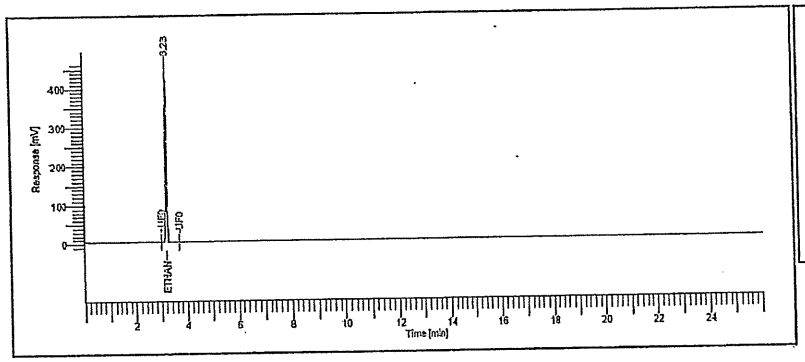


Analytical conditions:

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]	Area [%]
1	Ethanol	1.58	777173.3	100.000

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
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needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 25 min

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Specifications and Certificate of Analysis

Lipomed Document QC-CA-ETH-400-1ML
Version: 001-22 Jun 2011 Supersedes: new

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: 05012012-C
Art. Nr.: ETH-400-1ML

Release date: 27 01 2012
Expiry date: **January 2017**

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 = 1.57 min R_t test = 1.57 min
3. Concentration of calibrated ampoule (GC/FID Headspace)	400.00 ± 8.00 mg/dL	**400.73 ± 3.31 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.

Note: Gravimetric preparation of each reference solution is ensured by using balances calibrated with ilac-MRA traceable weights.
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QC - Officer: Deputy: Dr. L. Prévot

Date of signature: Arlesheim,

January 27, 2012

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

Ampoule to ampoule consistency:

	Specification	Result
% RSD	< 2 %	0.83 %

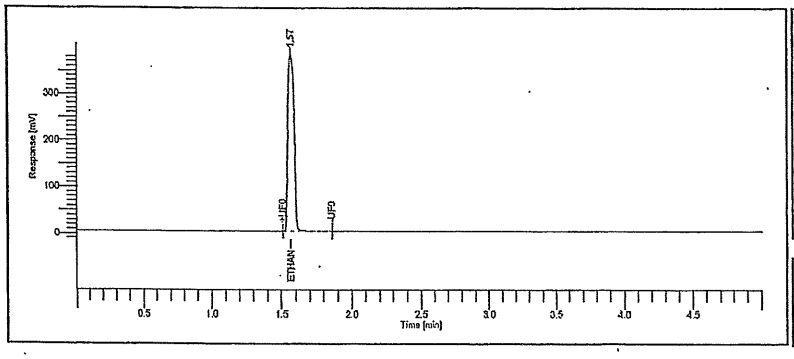
Homogeneity of the lot is confirmed by an analysis of 6 ampoules. These samples are representative of the batch from which they were taken.

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	05012012-C	400.73 ± 3.31 mg/dL
Previous Lot	09032011-G	402.89 ± 4.86 mg/dL

GC/FID Headspace Data: Calibration

Analytical conditions:

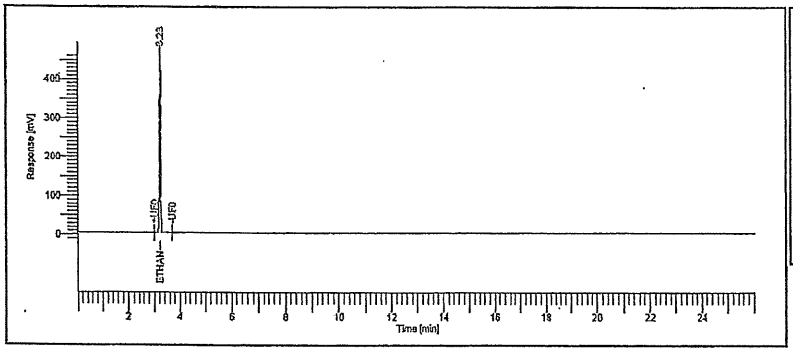


column:
Restek BAC 1, 30 m x 0.32 mm, 1.8 um
Injektor: 200 °C, split 20 ml/min
FID: 300 °C
Ofen:40 °C, 5 min isotherm
Helium 100 kPa (GC), 125 kPa (HS)
pressurization time: 2 min
injection time: 0.05 min
withdrawal time: 0.5 min
needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 15 min

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1	Ethanol	1.57	1122371.7	100.000

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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