



Whole Blood Ethanol Control Level 2

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.



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 Cliniqua, 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.



For in vitro diagnostic use



See package insert for proper use



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3951 DB Maarn, The Netherlands
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RE-ORDER INFORMATION Whole Blood Ethanol Control

Catalog No.



93211

Level 1, 6 x 5 mL

Catalog No.



93212

Level 2, 6 x 5 mL

Catalog No.



93213

Level 3, 6 x 5 mL



Certificate of Analysis
Certified Reference Standard - NIST Traceable
Ethanol-20
Ethyl Alcohol

ISO GUIDE 34
CERTIFICATE ARI353
ISO/IEC 17025
CERTIFICATE AT1352
ISO 9001:2008
CERTIFICATE 3854

Catalog Number: E-056
Solution Lot: FN092710-01
Expiration Date: October 2015
Diluent: Water
Volume per Ampoule: 1.2 mL
Storage: Refrigerate. Do not freeze.
Intended Use: For laboratory use 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.

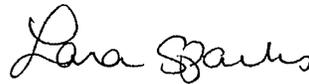
| Component | Solution Chromatographic Purity | Certified Concentration |
|--|---------------------------------|-------------------------|
| Ethanol | 100% | 20.00 ± 0.07 mg/dL |
| <ul style="list-style-type: none"> ▪ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 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.




 Lara Sparks, Quality Assurance Director

December 22, 2010
 Date

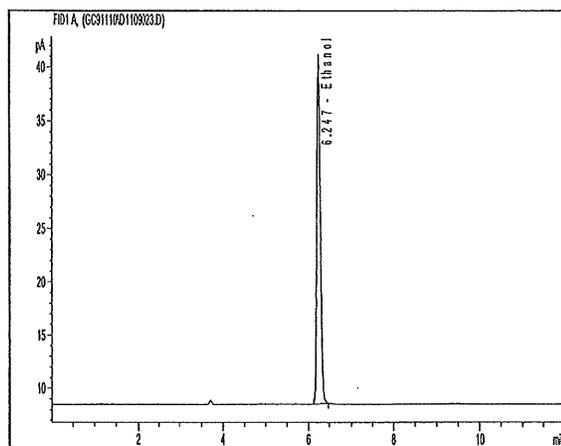
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

| Solution Standard | Lot Number | Results compared to NIST SRM Lot 2891 (mg/dL) | Results compared to Control (mg/dL) | Homogeneity (ampoule to ampoule consistency) %RSD |
|---------------------|-------------|---|-------------------------------------|---|
| New Lot | FN092710-01 | 19.88 | 0.6% | 0.7% |
| Prior Lot | FN030409-01 | 20.19 | 1.0% | 1.3% |
| 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.

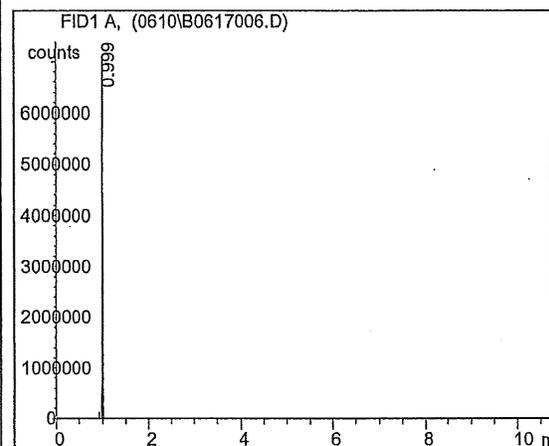
Solution Standard Assay Parameters

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: 0.03%
 Purity Factor: 99.97%

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.



Certificate of Analysis
Certified Reference Standard - NIST Traceable
Ethanol-100
Ethyl Alcohol

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

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 |
| <ul style="list-style-type: none"> Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 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:

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- 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.

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Lara Sparks
Lara Sparks, Quality Assurance Director

May 31, 2012
Date

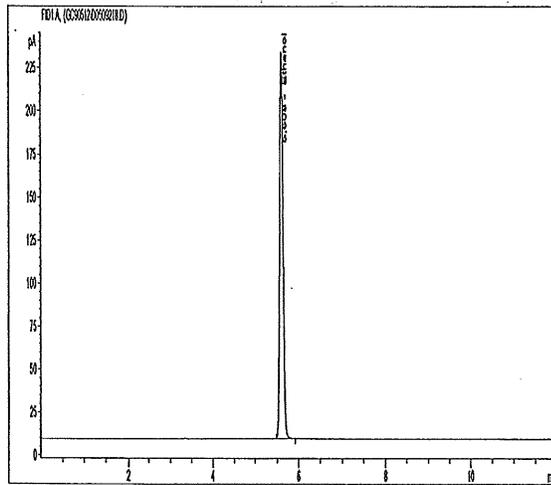
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

| 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.
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Solution Standard Assay Parameters

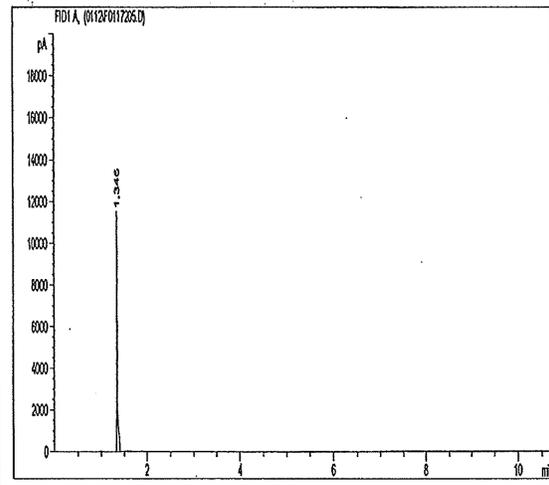
Analysis Method: GC/FID Headspace
 Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
 Temp Program: 40°C hold for 12 min
 Injector Temp: 200°C
 Detector Temp: 250°C



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.



Certificate of Analysis
Certified Reference Standard - NIST Traceable
Ethanol-200
Ethyl Alcohol

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

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 |
| <ul style="list-style-type: none"> ▪ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 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. | | |

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Lara Sparks

Lara Sparks, Quality Assurance Director

May 6, 2012

Date

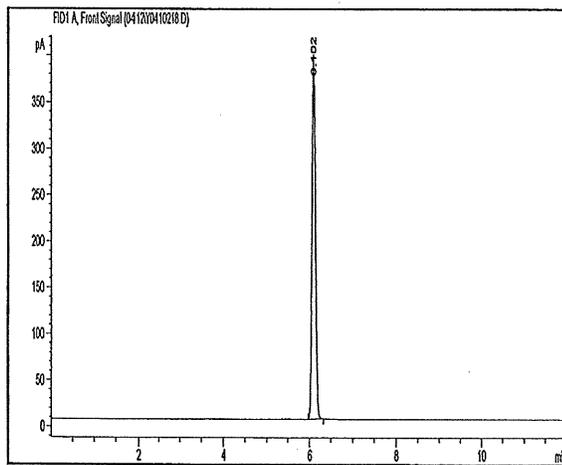
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

| 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.
- 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.
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Solution Standard Assay Parameters

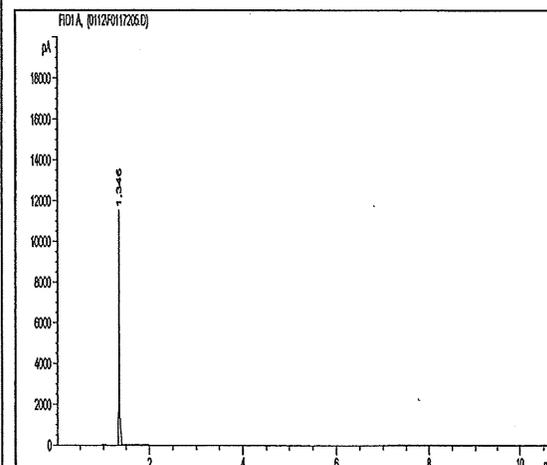
Analysis Method: GC/FID Headspace
 Column: DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
 Temp Program: 40°C hold for 12 min
 Injector Temp: 200°C
 Detector Temp: 250°C



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.



Certificate of Analysis
Certified Reference Standard - NIST Traceable
Ethanol-400
Ethyl Alcohol

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

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 |
| <ul style="list-style-type: none"> ▪ Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 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. | | |

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Lara Sparks
Lara Sparks, Quality Assurance Director

February 20, 2012
Date

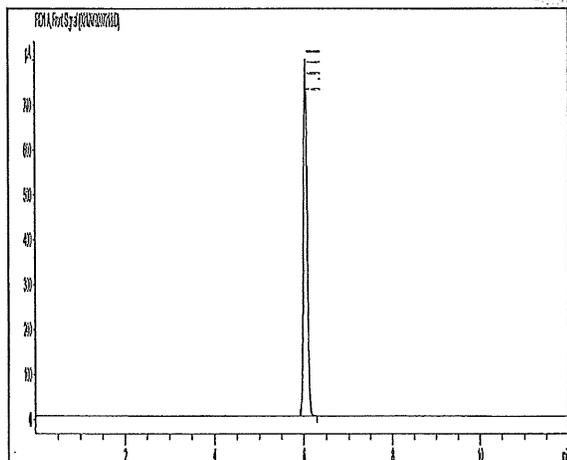
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

| 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.
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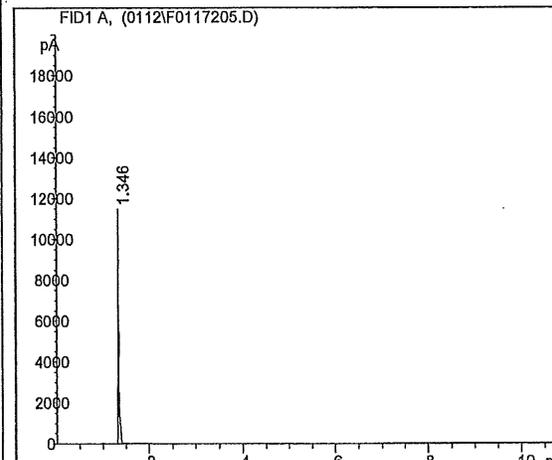
Solution Standard Assay Parameters

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.



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: C₂H₆O 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 IAC-MRA traceable weights.
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QC - Officer: Deputy: Dr. L. Prévot

Date of signature: Arlesheim,



January 16, 2012



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Ampoule to ampoule consistency:

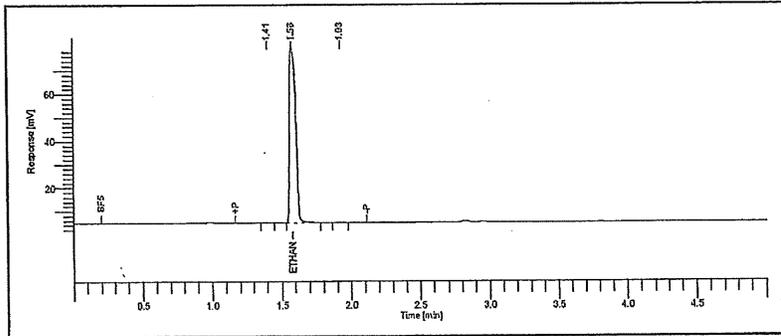
| | Specification | Result |
|-------|---------------|--------|
| % RSD | < 2 % | 1.6 % |

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 |

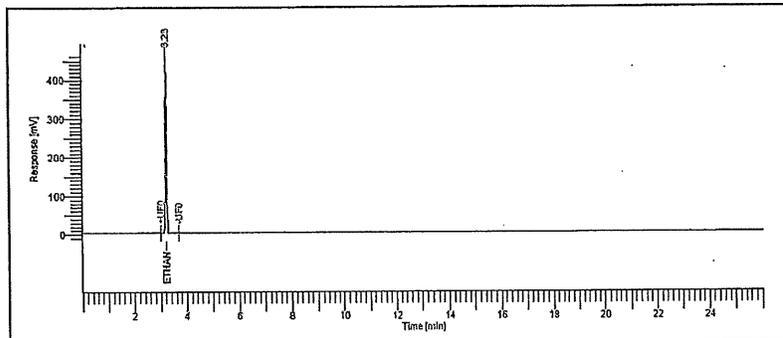
GC/FID Headspace Data: Calibration



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 ₂ H ₆ O | 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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Ampoule to ampoule consistency:

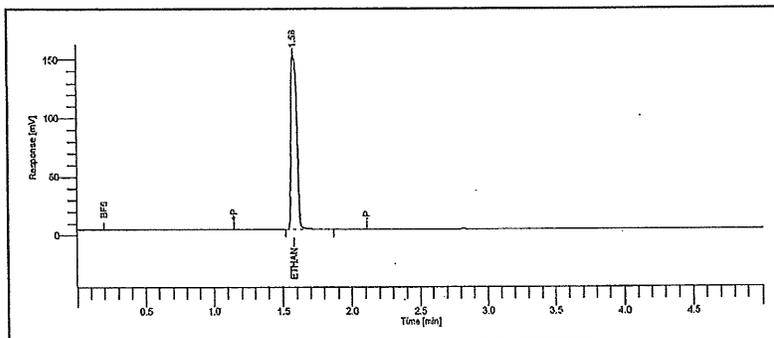
| | Specification | Result |
|-------|---------------|--------|
| % RSD | < 2 % | 1.72 % |

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

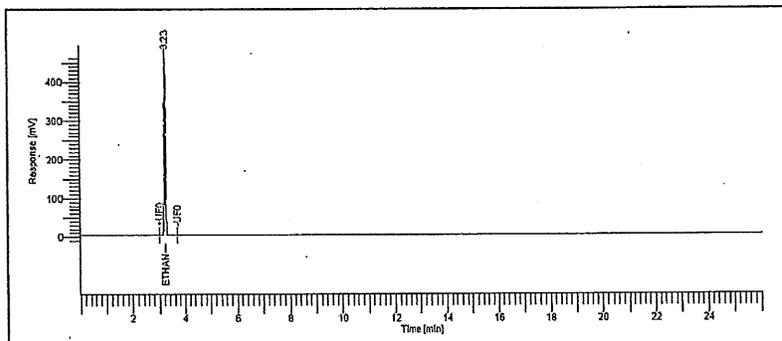


Analytical conditions:

column:
Restek BAC 1, 30 m x 0.32 mm, 1.8 µm
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
Thermostatierung: 60 °C, 15 min

| Peak # | Component Name | Time [min] | Area [µV*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 µm
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
Thermostatierung: 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: C₂H₆O 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



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Ampoule to ampoule consistency:

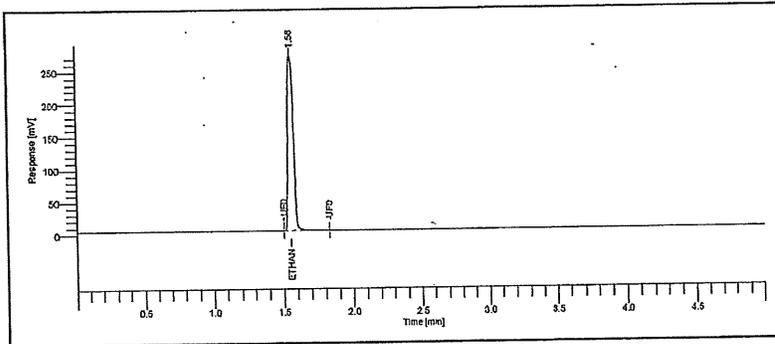
| | Specification | Result |
|-------|---------------|--------|
| % RSD | < 2 % | 0.90 % |

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

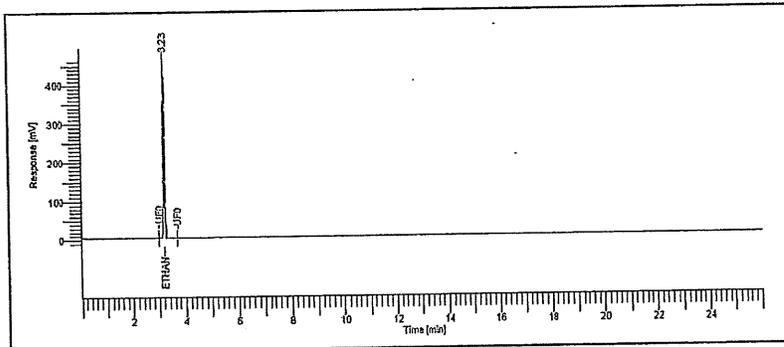


Analytical conditions:

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 [µV·sec] | Area [%] |
|--------|----------------|------------|---------------|----------|
| 1 | Ethanol | 1.56 | 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
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-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: C₂H₆O 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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Ampoule to ampoule consistency:

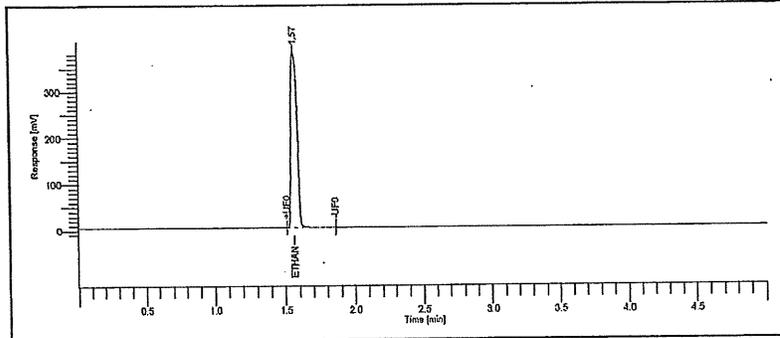
| | Specification | Result |
|-------|---------------|--------|
| % RSD | < 2 % | 0.83 % |

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

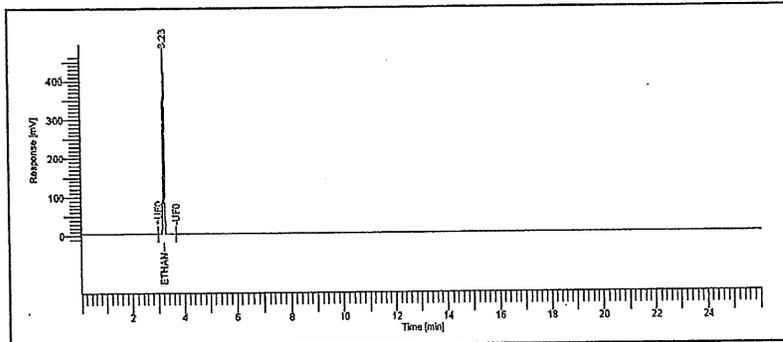


Analytical conditions:

column:
Reslek BAC 1, 30 m x 0.32 mm, 1.8 µm
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 [µV·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 µm
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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