GF 8445 Rec'd 3/17/15



E-036 FN012712-01 Revision 0 Page 1 of 2

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

stnanoi-400

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 purpose

Ethyl Alcohol

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

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.

Explation Date has been established inforgin real time stability studies and applies to the ampoule store of unperfect at the reconnicided 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%	$400.0 \pm 1.4 \text{ mg/dL}$
•		essed in terms of volume, is an expanded uncertainty in a constraint factor of $k=2$ and has been calculated by st	

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.

7455

Lara Starts

February 20, 2012

Lara Sparks, Quality Assurance Director

811 Paloma Drive, Suite A, Round Rock, TX 78665



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%
Accep	tance Criteria	±2%	±2%	≤2%

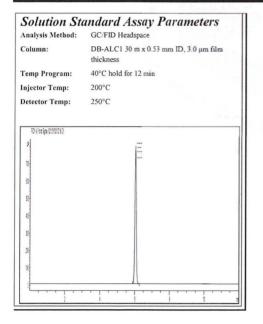
Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.

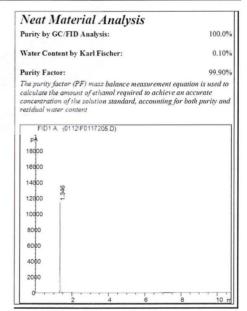
 The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.

 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.





811 Paloma Drive, Suite A, Round Rock, TX 78665



E-033 FN09061305 Revision 0 Page 1 of 2

Certificate of Analysis Certified Reference Standard - NIST Traceable Ethanol-300

Ethyl Alcohol

Catalog Number:	E-033
Solution Lot:	FN09061305
Expiration Date:	October 2018
Diluent:	Water
Volume per Ampoule:	1.2 mL
Storage:	Refrigerate. Do not freeze.
Intended User	For P &D analytical purpor

ISO GUIDE 34 ISO/IEC 17025 150 13485 150 9001 GMP/GLP

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% 300.0 ± 1.06 mg/d		300.0 ± 1.06 mg/dL
34 at the 95% confidence interval using applicable to ethanol reference standards dispensing process is sufficiently control	ed in terms of volume, is an expanded uncertainty in a a coverage factor of k=2 and has been calculated by st and incorporates uncertainty of the purity factor, mat led as to not be a significant contributor to uncertainty eal time stability studies and is, therefore, excluded.	atistical analysis of our production methods erial density and mass measurement. The

- 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.

145

January 10, 2014 Date

Darron Ellsworth, Quality Assurance Manager

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

GF 8445 Rec'd 3/3/15



Solution Standard	Lot Number	Results compared to NIST SRM Lot 2896 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN09061305	301.13	0.79%
Prior Lot	FN121510-01	301.64	0.73%
Accep	otance Criteria	±2%	≤2%

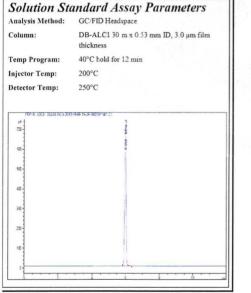
 Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.

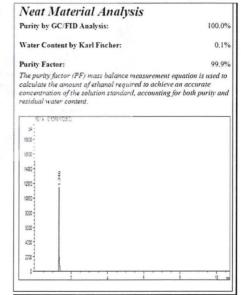
 The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.

 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.





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

Ê	Cerilliant Analytical Reference Standards
\checkmark	a SIGMA-ALDRICH company

E-032 FN12011401 Revision 01 Page 1 of 3

Cerilliant Quality

ISO GUIDE 34

ISO/IEC 17025

150 13485

ISO 15194

150 9001

GMP/GLP

GF 8445

Rec'd 3/3/15

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

 Catalog Number:
 E-032

 Solution Lot:
 FN12011401

 Expiration Date:
 December 2019

 Diluent:
 Water

 Volume per Ampoule:
 1.2 mL

 Storage:
 Refrigerate. Do not freeze.

 Intended Use:
 For R&D/ analytical purpo

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	>99.9%	$200.0\pm0.7~mg/dL$
34 at the 95% confidence interval using applicable to ethanol reference standard dispensing process is sufficiently control	ssed in terms of volume, is an expanded uncertainty in a a coverage factor of k=2 and has been calculated by st ls and incorporates uncertainty of the purity factor, mate olled as to not be a significant contributor to uncertainty real time stability studies and is, therefore, excluded.	atistical analysis of our production methods erial density and mass measurement. The
 When expressed in percentage terms, th is 0.35% at the 95% confidence interva 	ne relative standard uncertainty of the concentration is 0 1 (k=2).	.175% and the relative expanded uncertainty

- 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. Weight 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.



Darron Ellsworth, Quality Assurance Manager

January 23, 2015 Date

811 Paloma Drive. Suite A. Round Rock. TX 78665



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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	FN12011401	198.3	0.75%
Prior Lot	FN05211403	197.7	1.50%
Accep	otance Criteria	± 2%	≤ 2 %
standard uncerta concentration. The Control is i against a NIST Homogeneity is %RSD of samp homogeneity of The %RSD of th beginning and e All instruments qualified throug	ainty of the analysis is 1.675 ndependently prepared from SRM. ensured through rigorous pr les pulled from across the lot 'the New Lot. he Prior Lot represents syste nd of the sequence. %RSD used for certification of the 1 h an Installation Qualificatic	% and includes both uncertainty of the a different lot of neat ethanol to ensure roduction process controls statistically a t using a stratified random sampling pla an suitability on the date of analysis. The criteria ensures proper system performa- neat materials and verification of the so	lution concentration and homogeneity are fully ch is repeated annually. System suitability is
Solution Sta Analysis Method:	andard Assay Par GC/FID Headspace DB-ALC1 30 m x 0.53 mm I thickness	ameters Neat	Material Analysis y GC/FID Analysis: >99.9
Solution St Analysis Method: Column:	andard Assay Par GC/FID Headspace DB-ALC1 30 m x 0.53 mm 1	ameters Neat	Material Analysis y GC/FID Analysis: >99.9 ontent by Karl Fischer: 0.10
	GC/FID Headspace DB-ALC1 30 m x 0.53 mm I thickness	ID, 3.0 µm film Purity b Water C Purity F The puri	Material Analysis y GC/FID Analysis: >99.9 ontent by Karl Fischer: 0.10 actor: 99.90 y factor (PF) mass balance measurement equation is used to
Solution St i Analysis Method: Column: Temp Program:	GC/FID Headspace DB-ALC1 30 m x 0.53 mm 1 thickness 40°C hold for 12 min 200°C 250°C	ID, 3.0 µm film Purity b Water C Purity b Purity b Purity b The purity calculat concentur residual	Material Analysis y GC/FID Analysis: >99.9 ontent by Karl Fischer: 0.10

811 Paloma Drive. Suite A. Round Rock. TX 78665

	Cerilliant
•	SESMA-ALCENCHIONNY

E-032 FN12011401 Revision 01 Page 3 of 3

COA Revision History

Revision No.	Date	Reason for Revision
00	January 14, 2015	Initial version
01	January 23, 2015	Corrected Expiration Date format from Dec 2019 to December 2019.

811 Paloma Drive. Suite A. Round Rock. TX 78665

GF 8445 Rec'd 3/3/15



E-031 FN02021403 Revision 01 Page 1 of 3

Certiliant Quality

ISO GUIDE 34 ISO/IEC 17025

> 150 13485 150 15194

150 9001

GMP/GLP

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

Ethvl Alcohol

Catalog Number:	E-031
Solution Lot:	FN02021403
Expiration Date:	March 2019
Diluent:	Water
Volume per Ampoule:	1.2 mL
Storage:	Refrigerate. Do not freeze.
Intended Use:	For R&D/ analytical purposes only. Not su

lytical 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	>99.9%	$100.0 \pm 0.4 \text{ mg/dL}$
Uncertainty of the concentration, expr	essed in terms of volume, is an expanded uncertainty in	accordance with ISO 17025 and ISO Gui
	ng a coverage factor of k=2 and has been calculated by st	

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.

01+5

July 02, 2014 Date

811 Paloma Drive, Suite A, Round Rock, TX 78665

Darron Ellsworth, Quality Assurance Manager



F-031 FN02021403 Revision 01 Page 2 of 3

>99.9%

0.09%

99.91%

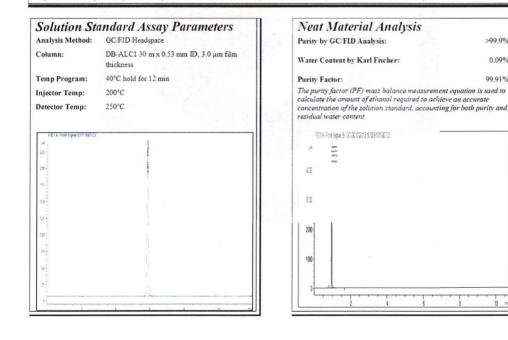
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2894 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN02021403	99.34	0.80%
Prior Lot	FN050312-01	99.13	1.08%
Accept	ance 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.



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E-031 FN02021403 Revision 01 Page 3 of 3

COA Revision History

Revision No.	Date	Reason for Revision
00	June 03, 2014	Initial Version
01	July 02, 2014	Removed "Results Compared to Control" data. Corrected Karl
		Fischer and Purity Factor data. Added Revision History.

811 Palomo Drive, Suite A, Round Rock, TX 78665

GF 8445 Rec'd 313/15



F-030 FN09051304 Revision 1 Page 1 of 3

Certificate of Analysis Certified Reference Standard - NIST Traceable Ethanol-80

Ethyl Alcohol

Catalog Number:	E-030
Solution Lot:	FN09051304
Expiration Date:	October 2018
Diluent:	Water
Volume per Ampoule:	1.2 mL
Storage:	Refrigerate. Do not freeze.
· · · · · · · · ·	D D0D: 1.1.1

Cerilliant Quality
ISO GUIDE 34
ISO/IEC 17025
150 13485
ISO 9001
GMP/GLP

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%	80.00 ± 0.28 mg/dL
Uncertainty of the concentration, expr	essed in terms of volume, is an expanded uncertainty in a	accordance with ISO 17025 and ISO Guide
	g a coverage factor of k=2 and has been calculated by st	

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.

CLAS.

811 Paloma Drive, Suite A, Round Rock, TX 78665

May 16, 2014 Date

Darron Ellsworth, Quality Assurance Manager



E-030 FN09051304 Revision 1 Page 2 of 3

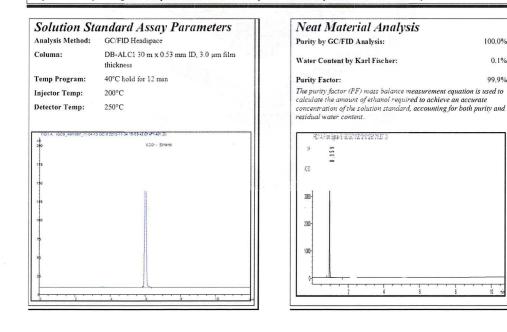
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2893 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN09051304	80.29	1.46%
Prior Lot	FN011712-02	80.09	0.58%
Accep	otance 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.



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



E-030 FN09051304 Revision 1 Page 3 of 3

COA Revision History

Revision No.	Date	Reason for Revision
00	February 07, 2014	Initial Version
01	May 16, 2014	Corrected Catalog and Lot numbers in header on page 2. Added
		Revision History.

811 Paloma Drive, Suite A, Round Rock, TX 78665

GF 8445 Rec'd 3/3/15



E-029 FN06231406 Revision 0 Page 1 of 2

Cerilliant Quality

ISO GUIDE 34

Certificate of Analysis Certified Reference Standard - NIST Traceable

	Ethanol-50	ISO/IEC 17025
	Ethyl Alcohol	ISO 13485
Catalog Number:	E-029	ISO 15194
Solution Lot:	FN06231406	150 0001
Expiration Date:	July 2019	ISO 9001
Diluent:	Water	GMP/GLP
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	>99.9%	50.00 ± 0.18 mg/dL
2	44 at the 95% confidence interval using a applicable to ethanol reference standards lispensing process is sufficiently controll	ed in terms of volume, is an expanded uncertainty in coverage factor of k=2 and has been calculated by st and incorporates uncertainty of the purity factor, mat ed as to not be a significant contributor to uncertainty altime stability studies and is therefore excluded	atistical analysis of our production methods erial density and mass measurement. The

- 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. Weight 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.

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Darron Ellsworth, Quality Assurance Manager

August 21, 2014 Date

811 Paloma Drive. Suite A. Round Rock. TX 78665



Solution Standard	Lot Number	Results compared to NIST SRM Lot 2892 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN06231406	49.56	0.83%
Prior Lot	FN010912-01	50.18	1.17%
Accep	otance Criteria	±2%	≤2%

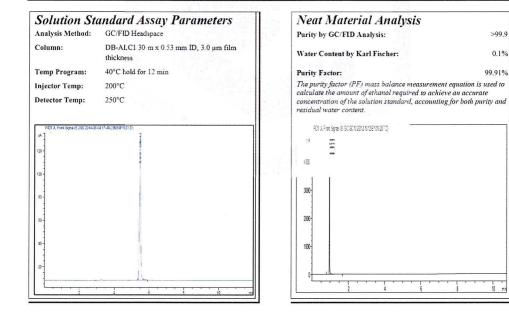
 Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 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.



811 Paloma Drive. Suite A. Round Rock. TX 78665

tes Rec'd 1/21/16



E-039 FN03211401 Revision 0 Page 1 of 2

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

Certificant Quelity ISO GUIDE 34 ISO/IEC 17025 ISO 13485 ISO 15194 ISO 9001 GMP/GLP

Catalog Number:	E-039
Solution Lot:	FN03211401
Expiration Date:	June 2019
Diluent:	Water
Volume per Ampoule:	5 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 5 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	>99.9%	$200.0 \pm 0.7 \text{ mg/dL}$

- 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.



REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

July 02, 2014 Date



E-039 FN03211401 Revision 0 Page 2 of 2

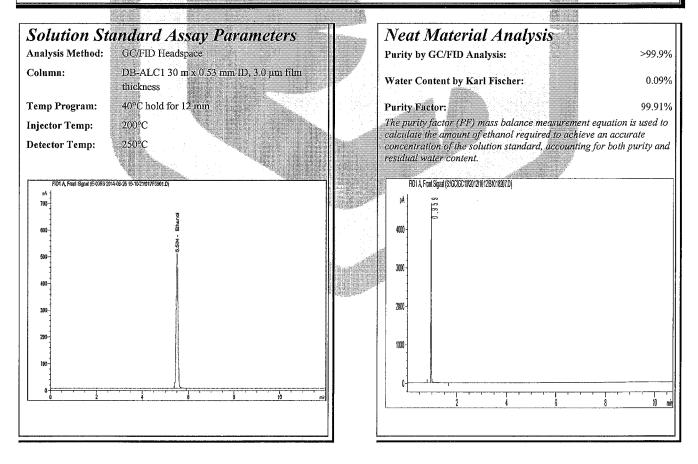
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2895 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN03211401	200.6	0.58%
Prior Lot	FN100511-01	198.8	0.51%
Accep	ptance Criteria	±2%	<u>≤2%</u>

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.



tos Recid 1/14/16



E-032 FN12011401 Revision 01 Page 1 of 3

	Certificate of Analysis	Cerilliant Quality
	Certified Reference Standard - NIST Traceable	ISO GUIDE 34
	Ethanol-200	ISO/IEC 17025
	Ethyl Alcohol	ISO 13485
Catalog Number:	E-032	ISO 15194
Solution Lot:	FN12011401	150 0001
Expiration Date:	December 2019	ISO 9001
Diluent:	Water	GMP/GLP
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	>99.9%	$200.0\pm0.7~mg/dL$
** ** **		1

- 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. Weight apes 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.



January 23, 2015 Date

ENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager



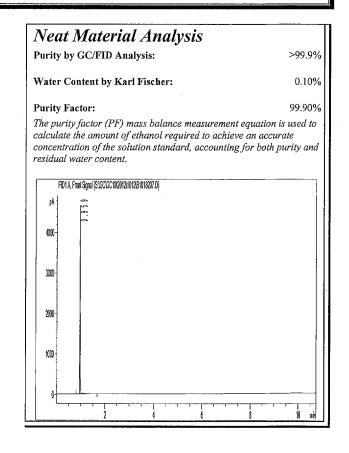
Solution Standard	Lot Number	Results compared to NIST SRM Lot 2895 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN12011401	198.3	0.75%
Prior Lot	FN05211403	197.7	1.50%
Acceptance Criteria		±2%	≤2%

• 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 DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film Column: thickness 40°C hold for 12 min **Temp Program:** 200°C Injector Temp: 250°C **Detector Temp:** FD1 A. Front Sional (E-032S 2015-01-06 16-05-14610F1901 D) 560 £00 37 20

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811 Paloma Drive. Suite A. Round Rock. TX 78665



E-032 FN12011401 Revision 01 Page 3 of 3

COA Revision History

Revision No.	Date	Reason for Revision	
00	January 14, 2015	Initial version	
01	January 23, 2015	Corrected Expiration Date format from Dec 2019 to December 2019.	

TOS REC'O 1/14/11.



F-033 FN06051501 Revision 00 Page 1 of 2

Cerilliant Quality
ISO GUIDE 34
ISO/IEC 17025
150 13485
150 15194
ISO 9001
GMP/GLP

Certificate of Analysis
Certified Reference Standard - NIST Traceable
Ethanol-300
Ethyl Alcohol

Catalog Number:	E-033
Solution Lot:	FN06051501
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 esta 	blished 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%	$300.0 \pm 1.1 \text{ mg/dL}$

- 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. Oualification 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. Weight appear 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.



Darron Ellsworth, Quality Assurance Manager

July 01, 2015



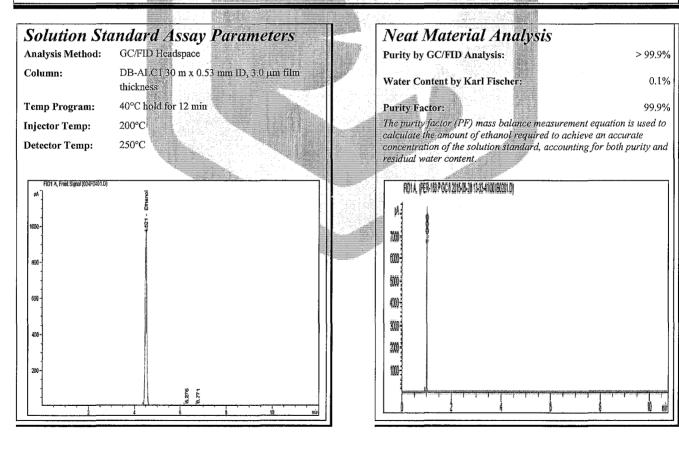
E-033 FN06051501 Revision 00 Page 2 of 2

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	FN06051501	296.4	0.6%
Prior Lot	FN09061305	297.4	0.6%
Accept	ance 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.



Rec'd 2/5/16



Certificate of Analysis Certified Reference Standard - NIST Traceable Ethanol-50

Ethyl Alcohol

Catalog Number:	E-029
Solution Lot:	FN06231406
Expiration Date:	July 2019
Diluent:	Water
Volume per Ampoule:	1.2 mL
Storage:	Refrigerate. Do not freeze.
Intended Use:	For R&D/ analytical purposes only.
-	

SIGMA-ALDFICH company

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.

Componen	t Solution Chromatographic Purity Certified Concentration
Ethanol	$>99.9\%$ $50.00 \pm 0.18 \text{ mg/dL}$
 Uncertainty of the conce 	ntration, 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 or 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.



Darron Ellsworth, Quality Assurance Manager

August 21, 2014

811 Paloma Drive, Suite A. Round Rock, TX 78665

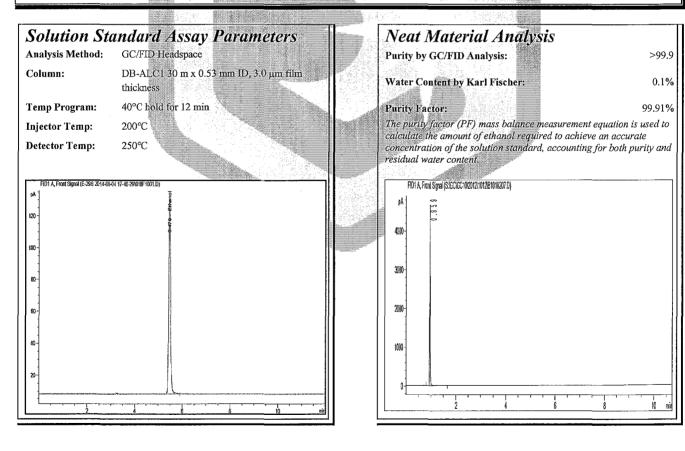




Solution Standard	Lot Number	Results compared to NIST SRM Lot 2892 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN06231406	49.56	0.83%
Prior Lot	FN010912-01	50.18	1.17%
Acce	eptance Criteria	±2%	<u>≤2%</u>

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.



Recid 2/16/16 /5



E-030 FN10281510 Revision 0 Page 1 of 2

Certificate of Analysis Certified Reference Standard - NIST Traceable Ethanol-80

Ethyl Alcohol

Catalog Number:	E-030	
Solution Lot:	FN10281510	
Expiration Date:	November 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 consumptio	n.
Expiration Date has been established by the state of t	licked through real time stability studies and applies to the appoule stored unonened at the recommende	d et

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%	80.00 ± 0.28 mg/dL	
and the second			

- 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.



Darron Ellsworth, Quality Assurance Manager

December 02, 2015 Date

Cerilliant Quality ISO GUIDE 34 ISO/IEC 17025 ISO 13485

> ISO 9001 GMP/GLP

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



Solution Standard	Lot Number	Results compared to NIST SRM Lot 2893 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN10281510	79.40	0.89%
Prior Lot	FN09051304	79.29	1.76%
Acc	eptance 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.



Recid 3/28/16

E-031 FN06181501 Revision 00 Page 1 of 2

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

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

GMP/GLP

 Eindlight Foo

 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%	$100.0 \pm 0.4 \text{ mg/dL}$
ACCHEDING.		

- 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.



Darron Ellsworth, Quality Assurance Manager

July 01, 2015 Date



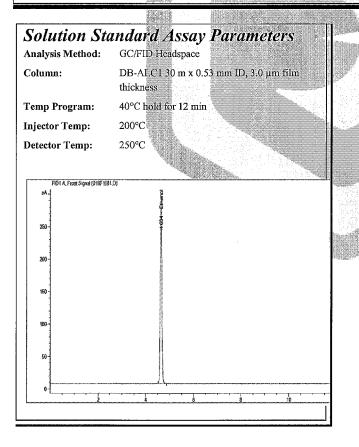
E-031 FN06181501 Revision 00 Page 2 of 2

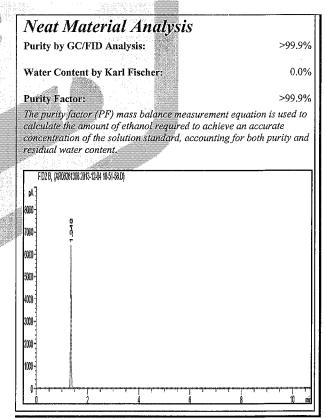
Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

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.





Rec'a 4/26/16 TCS

F-036 FN11191402 Revision 0 Page 1 of 2



Certificate of Analysis Cerilliant Quality Certified Reference Standard - NIST Traceable **ISO GUIDE 34** Ethanol-400 **ISO/IEC 17025** Ethyl Alcohol 150 13485 **Catalog Number:** F-036 ISO 15194 Solution Lot: FN11191402 **ISO 9001** February 2020 **Expiration Date: Diluent:** Water GMP/GLP Volume per Ampoule: 1.2 mL

Storage: Refrigerate. Do not freeze.

For R&D/ analytical purposes only. Not suitable for human or animal consumption. **Intended Use:**

 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%	$400.0 \pm 1.4 \text{ mg/dL}$

- 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.



REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

June 25, 2015 Date

811 Paloma Drive, Suite A. Round Rock, TX 78665



E-036 FN11191402 Revision 0 Page 2 of 2

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%	<u>≤2%</u>

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 Sta	undard Assay Parameters	Near	t Material Analysis	3
Analysis Method:	GC/FID Headspace	Purity l	by GC/FID Analysis:	100.0%
Column:	DB-ALCI 30 m x 0.53 mm ID, 3.0 µm film thickness	Water (Content by Karl Fischer:	0.0%
Temp Program:	40°C hold for 12 min	Purity I	Factor:	100.0%
Injector Temp:	200°C		ity factor (PF) mass balance mea	
Detector Temp:	250°C	concenti	te the amount of ethanol required ration of the solution standard, ac l water content.	
F611 & Post Signal (E-2005 2015-03	28 12-10-28:00F10(1-0)	FIT2B //	AR02261308 2013-12-04 18-51-58 D)	
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E-029 FN06231406 Revision 0 Page 1 of 2

	Certificate of Analysis	Cerilliant Quality
	Certified Reference Standard - NIST Traceable	ISO GUIDE 34
	Ethanol-50	ISO/IEC 17025
	Ethyl Alcohol	ISO 13485
Catalog Number:	E-029	ISO 15194
Solution Lot:	FN06231406	150 0001
Expiration Date:	July 2019	ISO 9001
Diluent:	Water	GMP/GLP
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	>99.9%	50.00 ± 0.18 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. Weight apes 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.



Darron Ellsworth, Quality Assurance Manager

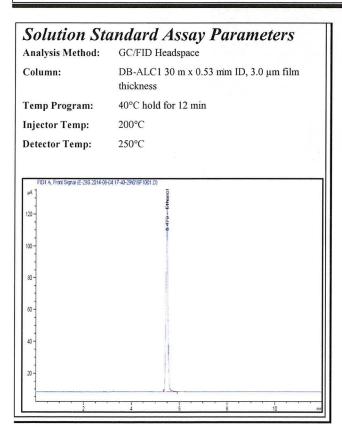
August 21, 2014

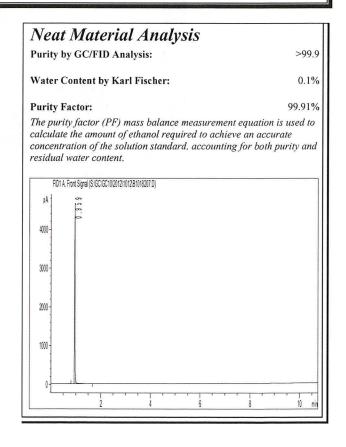


Solution Standard	Lot Number	Results compared to NIST SRM Lot 2892 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN06231406	49.56	0.83%
Prior Lot	FN010912-01	50.18	1.17%
Acc	eptance Criteria	±2%	<u>≤2%</u>

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.





Rec'd 5/8/17 AP



E-030 FN10281510 Revision 0 Page 1 of 2

Certificate of Analysis Certified Reference Standard - NIST Traceable Ethanol-80

Ethyl Alcohol

Catalog Number:	E-030
Solution Lot:	FN10281510
Expiration Date:	November 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 esta	ablished through real time stability studies and applies to the ampoule stored unopened at the recommended st

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%	$80.00\pm0.28~mg/dL$
		and the second

- 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.



Darron Ellsworth, Quality Assurance Manager

December 02, 2015 Date





E-030 FN10281510 Revision 0 Page 2 of 2

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

Solution Standard	Lot Number	Results compared to NIST SRM Lot 2893 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD
New Lot	FN10281510	79.40	0.89%
Prior Lot	FN09051304	79.29	1.76%
Acc	eptance Criteria	±2%	<u>≤2%</u>

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 Sta analysis Method:	andard Assay Parameters GC/FID Headspace
Column:	DB-ALC1 30 m x 0.53 mm ID, 3.0 μ m film thickness
emp Program:	40°C hold for 12 min
njector Temp:	200°C
etector Temp:	250°C
FID1 A, (_904_024F1201.D)	
6A -	Ethanoi
250-	
200-	
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Purity by GC/F	'ID Analysis:	> 99.9
Water Content	by Karl Fischer:	0.09
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calculate the am concentration of residual water c		hieve an accurate
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E-032 FN03301601 **Revision 00** Page 1 of 2



Storage:

	Certificate of Analysis	Cerilliant Quality
	Certified Reference Standard - NIST Traceable	ISO GUIDE 34
	Ethanol-200	ISO/IEC 17025
	Ethyl Alcohol	ISO 13485
Catalog Number:	E-032	ISO 15194
Solution Lot:	FN03301601	100 0001
Expiration Date:	April 2021	ISO 9001
Diluent:	Water	GMP/GLP
Volume per Ampoule:	1.2 mL	

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.

Refrigerate. Do not freeze.

Component	Solution C	hromatographic Purity	Certified Concentration
Ethanol		> 99.9%	$200.0\pm0.70~mg/dL$
 1000		Manager and Annual Contract	

- 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.

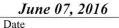
Traceability to SI through NIST:

- 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.



Darron Ellsworth, Ouality Assurance Manager



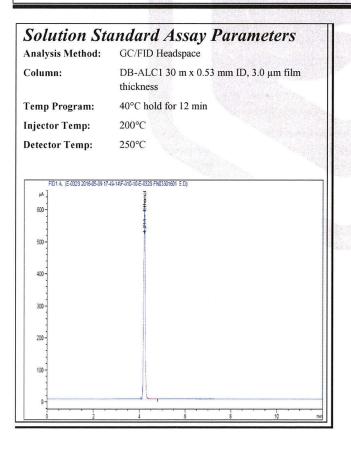
811 Paloma Drive, Suite A. Round Rock, TX 78665



Solution Standard	Lot Number	Results compared to NIST SRM Lot 2895 (mg/dL)	Homogeneity (ampoule to ampoule consistency) %RSD	
New Lot	FN03301601	198.8	0.79%	
Prior Lot	FN07201502	197.6	0.54%	
Acc	eptance Criteria	± 2%	<u>≤ 2%</u>	

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.



Neat Material		> 99.9
Purity by GC/FID Analys	sis:	> 99.9
Water Content by Karl F	ischer:	0.1
Purity Factor:		99.91
The purity factor (PF) mas. calculate the amount of eth concentration of the solutic residual water content.	anol required to achiev	e an accurate
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E-033 FN06051501 **Revision 00** Page 1 of 2

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ISO GUIDE 34 ISO/IEC 17025

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ISO 9001

GMP/GLP

Certificate of Analysis Certified Reference Standard - NIST Traceable Ethanol-300

Ethyl Alcohol

Catalog Number:	E-033	
Solution Lot:	FN06051501	
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 estal 	blished through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition	ı.

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%	$300.0 \pm 1.1 \text{ mg/dL}$	

- 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.



Darron Ellsworth, Quality Assurance Manager

July 01, 2015 Date



E-033 FN06051501 Revision 00 Page 2 of 2

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	FN06051501	296.4	0.6%
Prior Lot	FN09061305	297.4	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

Content by Karl Fischer:	0.19
Factor:	99.9%
rity factor (PF) mass balance measurement equation te the amount of ethanol required to achieve an accur tration of the solution standard, accounting for both p l water content.	rate
A, (PER-HSP (C & 2016-05-201333-4100100201.0)	
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E-036 FN11191402 Revision 0 Page 1 of 2

	Certificate of Analysis	Cerilliant Quality
	Certified Reference Standard - NIST Traceable	ISO GUIDE 34
	Ethanol-400	ISO/IEC 17025
	Ethyl Alcohol	150 13485
Catalog Number:	E-036	ISO 15194
Solution Lot:	FN11191402	100 0001
Expiration Date:	February 2020	ISO 9001
Diluent:	Water	GMP/GLP
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%	$400.0\pm1.4~mg/dL$

- 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.



Darron Ellsworth, Quality Assurance Manager

June 25, 2015

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



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%
Acc	eptance Criteria	± 2%	≤ 2 %o

Analytical Verification of Solution Standard Concentration and Batch Homogeneity:

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				
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Purity by GC/FID Analysis:					100.0%		
Water Co	ontent by l	Karl Fise	her:				0.0%
Purity Fa	ctor:						100.0%
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ISO/IEC 17025

ISO 13485

150 9001

GMP/GLP

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 esta 	blished 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%	$100.0 \pm 0.4 \text{ mg/dL}$

- 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.



Darron Ellsworth, Quality Assurance Manager

July 01, 2015



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%
Accept	ance 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.

Analysis Method:	GC/FID Headspace
Column:	DB-ALC1 30 m x 0.53 mm ID, 3.0 μ m film thickness
Temp Program:	40°C hold for 12 min
Injector Temp:	200°C
Detector Temp:	250°C
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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 meas calculate the amount of ethanol required t concentration of the solution standard, acc residual water content.	o achieve an accurate
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National Institute of Standards and Technology

Certificate of Analysis

Standard Reference Material[®] 2894

Ethanol-Water Solution (Nominal Mass Fraction 0.1 %)

This Standard Reference Material (SRM) is a solution of ethanol (ethyl alcohol): Chemical Abstracts Service [CAS] Registry Number 64-17-5) in water at a nominal concentration of 0.1 % by mass. SRM 2894 is intended primarily for use in the calibration of instruments and techniques used for the determination of ethanol in blood. A unit of SRM 2894 consists of five 2-mL ampoules, each containing approximately 1.2 mL of solution.

Certified Mass Fraction of Ethanol: The certified mass fraction value given below is based on results obtained from the gravimetric preparation of the solution and from the analytical results determined using gas chromatography and titrimetry. A NIST certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or accounted for by NIST [1].

Ethanol Certified Mass Fraction Value: 0.100 84 % \pm 0.000 83 %

The results are expressed as the certified value \pm the expanded uncertainty. Certified values are unweighted means of concentrations determined by gravimetric preparation and chromatographic and titrimetric measurements [2]. The uncertainty listed with each value is an expanded uncertainty about the mean, with coverage factor 2 (approximately 95 % confidence), calculated by combining a between-source variance incorporating inter-method bias with a pooled within-source variance following the ISO/NIST Guides [3]. The uncertainty includes both correction for estimated purity and allowance for differences among the concentrations determined by gravimetric preparation and chromatographic and titrimetric measurements.

Expiration of Certification: The certification of **SRM 2894** is valid, within the measurement uncertainty specified, until **30 April 2023**, provided the SRM is handled, stored in accordance with the instructions given in this certificate (see "Instructions for Handling, Storage, and Use"). However, the certification is nullified if the SRM is damaged, contaminated, or modified.

Maintenance of SRM Certification: NIST will monitor this SRM over the period of its certification. If substantive technical changes occur that affect the certification before the expiration of this certificate, NIST will notify the purchaser. Registration (see attached sheet) will facilitate notification.

The coordination of the technical measurements leading to the certification of this SRM was under the direction of M.M. Schantz and S.A. Wise of the NIST Chemical Sciences Division.

Consultation on the statistical design of the experimental work and evaluation of the data were provided by S.D. Leigh of the NIST Statistical Engineering Division.

Partial funding support for the preparation and certification of this Standard Reference Material was provided by the National Institute of Justice (NIJ) and managed through the NIST Office of Law Enforcement Standards (OLES).

Carlos A. Gonzales, Chief Chemical Sciences Division

Robert L Watters, Jr., Director Office of Reference Materials

Gaithersburg, MD 20899 Certificate Issue Date: 11 April 2013 Certificate Revision History on Last Page

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REFERENCES

- [1] May, W.; Parris, R.; Beck, C.; Fassett, J.; Greenberg, R.; Guenther, F.; Kramer, G.; Wise, S.; Gills, T.; Colbert, J.; Gettings, R.; MacDonald, B.; *Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements*; NIST Special Publication 260-136; U.S. Government Printing Office: Washington, DC (2000); available at http://www.nist.gov/srm/publications.cfm (accessed Apr 2013)
- [2] Levenson, M.S.; Banks, D.L.; Eberhardt, K.R.; Gill, L.M.; Guthrie, W.F.; Liu, H.K.; Vangel, M.G.; Yen, J.H.; Zhang, N.F.; An Approach to Combining Results from Multiple Methods Motivated by the ISO GUM; J. Res. Natl. Inst. Stand. Technol., Vol. 105, pp. 571-579 (2000).
- [3] JCGM 100:2008; Evaluation of Measurement Data Guide to the Expression of Uncertainty in Measurement (ISO GUM 1995 with Minor Corrections); Joint Committee for Guides in Metrology (2008); available at http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf (accessed Apr 2013); see also Taylor, B.N.; Kuyatt, C.E.; Guidelines for Evaluating and Expressing Uncertainty of NIST Measurement Results; NIST Technical Note 1297; U.S. Government Printing Office: Washington, DC (1994); available at http://www.nist.gov/pml/pubs/index.cfm (accessed Apr 2013).

Certificate Revision History: 11 April 2013 (Extended certification period; editorial changes); 26 March 2004 (Original certificate date)

Users of this SRM should ensure that the Certificate of Analysis in their possession is current. This can be accomplished by contacting the SRM Program: telephone (301) 975-2200; fax (301) 948-3730; e-mail srminfo@nist.gov; or via the Internet at http://www.nist.gov/srm.

National Institute of Standards and Technology

Certificate of Analysis

Standard Reference Material[®] 2895

Ethanol-Water Solution (Nominal Mass Fraction 0.2 %)

This Standard Reference Material (SRM) is a solution of ethanol (ethyl alcohol: Chemical Abstracts Service [CAS] Registry Number 64-17-5) in water at a nominal concentration of 0.2 % by mass. SRM 2895 is intended primarily for use in the calibration of instruments and techniques used for the determination of ethanol in blood. A unit of SRM 2895 consists of five 2-mL ampoules, each containing approximately 1.2 mL of solution.

Certified Mass Fraction of Ethanol: The certified mass fraction value given below is based on results obtained from the gravimetric preparation of the solution and from the analytical results determined using gas chromatography and titrimetry. A NIST certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or accounted for by NIST [1].

Ethanol Certified Mass Fraction Value: 0.1701 % \pm 0.0014 %

The results are expressed as the certified value \pm the expanded uncertainty. Certified values are unweighted means of concentrations determined by gravimetric preparation and chromatographic and titrimetric measurements [2]. The uncertainty listed with each value is an expanded uncertainty about the mean, with coverage factor 2 (approximately 95 % confidence), calculated by combining a between-source variance incorporating inter-method bias with a pooled within-source variance following the ISO/NIST Guides [3]. The uncertainty includes both correction for estimated purity and allowance for differences among the concentrations determined by gravimetric preparation and chromatographic and titrimetric measurements.

Expiration of Certification: The certification of this **SRM 2895** is valid, within the measurement uncertainty specified, until **30 April 2023**, provided the SRM is handled, and stored in accordance with the instructions given in this certificate (see "Instructions for Handling, Storage, and Use"). However, the certification is nullified if the SRM is damaged, contaminated, or modified.

Maintenance of SRM Certification: NIST will monitor this SRM over the period of its certification. If substantive technical changes occur that affect the certification before the expiration of this certificate, NIST will notify the purchaser. Registration (see attached sheet) will facilitate notification.

The coordination of the technical measurements leading to the certification of this SRM was under the direction of M.M. Schantz and S.A. Wise of the NIST Chemical Sciences Division.

Consultation on the statistical design of the experimental work and evaluation of the data were provided by S.D. Leigh of the NIST Statistical Engineering Division.

Partial funding support for the preparation and certification of this Standard Reference Material was provided by the National Institute of Justice (NIJ) and managed through the NIST Office of Law Enforcement Standards (OLES).

Carlos A Gonzalez, Chief Chemical Sciences Division

Robert L Watters, Jr., Director Office of Reference Materials

Gaithersburg, MD 20899 Certificate Issue Date: 11 April 2013 Certificate Revision History on Last Page

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- [1] May, W.; Parris, R.; Beck, C.; Fassett, J.; Greenberg, R.; Guenther, F.; Kramer, G.; Wise, S.; Gills, T.; Colbert, J.; Gettings, R.; MacDonald, B.; *Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements*; NIST Special Publication 260-136; U.S. Government Printing Office: Washington, DC (2000); available at http://www.nist.gov/srm/publications.cfm (accessed Apr 2013)
- [2] Levenson, M.S.; Banks, D.L.; Eberhardt, K.R.; Gill, L.M.; Guthrie, W.F.; Liu, H.K.; Vangel, M.G.; Yen, J.H.; Zhang, N.F.; An Approach to Combining Results from Multiple Methods Motivated by the ISO GUM; J. Res. Natl. Inst. Stand. Technol., Vol. 105, pp. 571-579 (2000).
- [3] JCGM 100:2008; Evaluation of Measurement Data Guide to the Expression of Uncertainty in Measurement (ISO GUM 1995 with Minor Corrections); Joint Committee for Guides in Metrology (2008); available at http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf (accessed Apr 2013); see also Taylor, B.N.; Kuyatt, C.E.; Guidelines for Evaluating and Expressing Uncertainty of NIST Measurement Results; NIST Technical Note 1297; U.S. Government Printing Office: Washington, DC (1994); available at http://www.nist.gov/pml/pubs/index.cfm (accessed Apr 2013).

Certificate Revision History: 11 April 2013 (Extended certification period; editorial changes); 26 March 2004 (Original certificate date)

Users of this SRM should ensure that the Certificate of Analysis in their possession is current. This can be accomplished by contacting the SRM Program: telephone (301) 975-2200; fax (301) 948-3730; e-mail srminfo@nist.gov; or via the Internet at http://www.nist.gov/srm.

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National Institute of Standards and Technology

Certificate of Analysis

Standard Reference Material[®] 2896

Ethanol-Water Solution (Nominal Mass Fraction 0.3 %)

This Standard Reference Material (SRM) is a solution of ethanol (ethyl alcohol: Chemical Abstracts Service [CAS] Registry Number 64-17-5) in water at a nominal mass fraction of 0.3 % and is intended primarily for use in the calibration of instruments and techniques used for the determination of ethanol. A unit of SRM 2896 consists of five 2 mL ampoules, each containing approximately 1.2 mL of solution.

Certified Mass Fraction of Ethanol: The certified value given below is based on results obtained from the gravimetric preparation of the solution and from the analytical results determined using gas chromatography and titrimetry. A NIST certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or taken into account [1].

Certified Mass Fraction of Ethanol: 0.2980 % \pm 0.0030 %

The result is expressed as the certified value \pm the expanded uncertainty. The certified value is an unweighted mean of concentrations determined by gravimetric preparation and chromatographic and titrimetric measurements [2]. The uncertainty listed is an expanded uncertainty about the mean, with coverage factor 2 (approximately 95 % confidence), calculated by combining a between-source variance incorporating inter-method bias with a pooled within-source variance following the GUM Guide [3]. The uncertainty includes both correction for estimated purity and allowance for differences among the concentrations determined by gravimetric preparation and chromatographic and titrimetric measurements.

Expiration of Certification: The certification of **SRM 2896** is valid, within the measurement uncertainty specified, until **30 April 2023**, provided the SRM is handled and stored in accordance with instructions given in this certificate (see "Instructions for Handling, Storage, and Use"). However, the certification is nullified if the SRM is damaged, contaminated, or otherwise modified.

Maintenance of SRM Certification: NIST will monitor this SRM over the period of its certification. If substantive technical changes occur that affect the certification before the expiration of this certificate, NIST will notify the purchaser. Registration (see attached sheet) will facilitate notification.

The coordination of the technical measurements leading to the certification of this SRM was under the direction of M.M. Schantz and S.A. Wise of the NIST Chemical Sciences Division.

Statistical consultation for this SRM was provided by S.D. Leigh of the NIST Statistical Engineering Division.

Partial funding support for the preparation and certification of this SRM was provided by the National Institute of Justice (NIJ) and managed through the NIST Office of Law Enforcement Standards (OLES).

Preparation of and analytical measurements on the SRM were performed by J.V. Goodpaster and M.M. Schantz of the NIST Chemical Sciences Division and M.P. Cronise and C.N. Fales of the NIST Office of Reference Materials. Additional analytical measurements were performed by M. Archer of the National Metrology Laboratory, Pretoria, South Africa.

Carlos A. Gonzalez, Chief Chemical Sciences Division

Robert L. Watters, Jr., Director Office of Reference Materials

Gaithersburg, MD 20899 Certificate Issue Date: 11 April 2013 Certificate Revision History on Last Page

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