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Certificate of Analysis

Certified Reference Standard - NIST Traceable

Ethanol-50

Ethyl alcohol

Catalog Number:	E-029
Solution Lot:	FN06171903
Expiration:	November 2024
Diluent:	Water
Volume per Ampule:	1.2 mL
Storage:	Refrigerate (Do Not Freeze)
Intended Use:	For R&D/ analytical purposes only. Not suitable for human or animal consumption.

- Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- For quantitative applications, the minimum sample size for intended use is 100 µL.

Component	Solution Purity	Certified Concentration
Ethanol	> 99.9%	50.00 ± 0.19 mg/dL

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.194% and the relative expanded uncertainty is 0.39% at the 95% confidence interval (k=2).
- The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.
- Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date. Warranty applies to ampoules stored unopened and stored under the recommended storage conditions. Warranty and expiry do not extend to solutions into which this product has been incorporated. Establishment of shelf life of all such products is the responsibility of the user.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

September 01, 2020
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
Sigma-Aldrich Production GmbH is a subsidiary of Merck KGaA, Darmstadt, Germany.

Traceability to SI through NIST:

- This standard has been prepared and certified under the ISO 17034 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

Solution Standard Concentration and Batch Homogeneity

Standard Solution	Lot Number	Comparison to NIST Lot SRM 2892 mg/dL	Homogeneity % RSD
New Lot	FN06171903	49.87	0.6
Previous Lot	FN05211804	50.19	0.8
Acceptance Criteria		± 2%	≤ 0.2

- Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.
- The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.
- Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.
- The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.
- All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters.

Analyte Certification - Mass Balance Purity Factor

The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.

Material Characterization Summary		
Analytical Test	**Method**	**Results**
Chromatographic Purity by GC/FID Analysis	SP10-0101	> 99.9%
Residual Water Analysis by Karl Fischer Coulometry	AM1346 [1]	0.05%
Mass Balance Purity Factor		99.94%

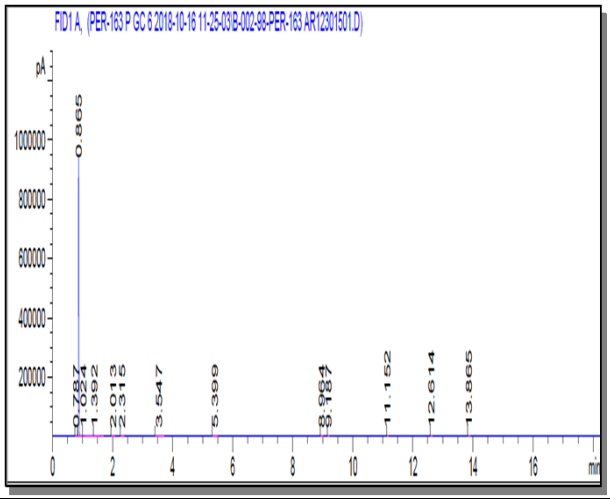
[1] Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- Mass Balance Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics)

Spectral and Physical Data

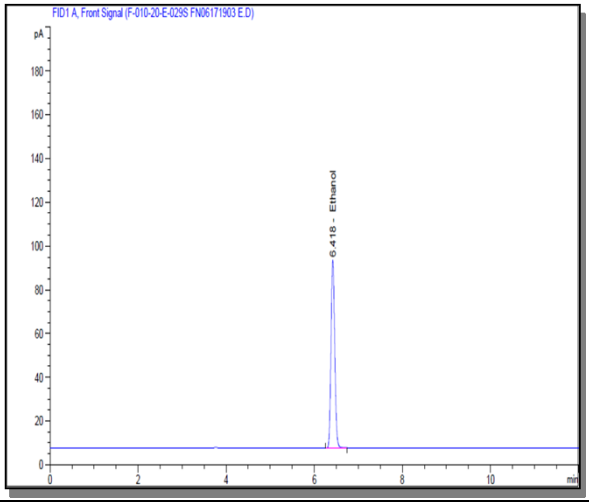
Neat Material

Analysis Method: GC/FID
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 35°C hold 5 min to 260°C at 20°C/min hold 2 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C



Standard Solution

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



COA Revision History

Revision No.	Date	Reason for Revision
00	April 06, 2020	Initial version.
01	September 01, 2020	Added the Relative Standard Uncertainty Statement on page 1.