lipomed
SERVICES TO HEALTH

Certificate of Analysis
Certified Reference Material

Lipomed Document QC-CA-ETH-400-1ML
Version: 003-01.Nov.2018 Supersedes: 002-24.Mar.2014

Product name: **400 mg/dL Aqueous Ethanol Standard Solution**
0.400 % by Mass (400 mg Ethanol / 1 dL Water) – 1 ml / ampoule
Ethyl alcohol

Lot No: 30012020-A
Art. No: ETH-400-1ML

Release date: October 16, 2020
Expiry date: **January 2025**

Bulk Product Information: Ethanol

Chemical formula:	C_2H_6O	Purity Ethanol GC/FID:	100 %
CAS Registry No:	64-17-5	Water content Karl Fischer:	0.08 %
Molwt:	46.07		

CERTIFIED CONCENTRATION **400.04 ± 0.49 mg/dL**

Uncertainty of the certified concentration is an expanded uncertainty in accordance with ISO/IEC 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k = 2 and has been calculated by analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The solution stability is established through real time stability studies and is, therefore, excluded from the uncertainty calculation.

TEST	SPECIFICATIONS	RESULTS
1. Appearance	Clear colorless solution	conforms
2. Identity (GC/FID analysis)	R_t corresponds to R_t of reference standard (± 0.1 min)	R_t standard = 2.6 min R_t test = 2.6 min
3. Extractable volume	> 1 ml	conforms
4. Water quality	Pharmaceutical water for injection	conforms

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Storage conditions: For maximum stability store air-tight below 30 °C in a dark location. Do not freeze.

Lipomed certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiry date when stored unopened as recommended. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

Issued by Dr. L. Prévot

Date sign: Arlesheim,

October 30, 2020

Lipomed AG
Fabrikmattenweg 4
4144 Arlesheim
Switzerland
Tel. +41 61 702 02 00
Fax +41 61 702 02 20

Lipomed GmbH
Hegenheimer Str. 2
79576 Weil am Rhein
Germany
+49 7621 1693 473
+49 7621 1693 474

Lipomed Inc.
150 Cambridgepark Drive, Suite 705
Cambridge, MA 02140
U.S.A.
+1 (617) 577 7222
+1 (617) 577 1776

www.lipomed.com
lipomed@lipomed.com

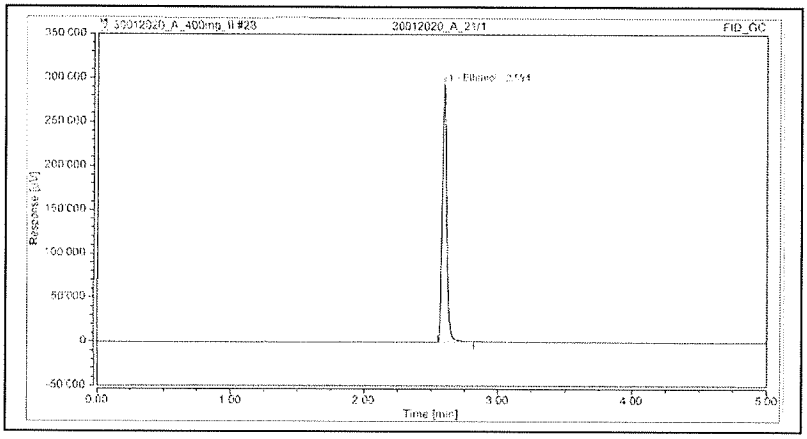
Concentration Verification / Lot to Lot Consistency (GC/FID analysis):

Standard solution	Lot Number	Concentration (± 2%) 392.00 – 408.00 mg/dL (Compared to NIST SRM 2896 / 2897a)	Ampoule to ampoule consistency (≤ 3.0%)
Actual Lot	30012020-A	398.90 mg/dL	0.7 %
Previous Lot	N/A	N/A	N/A

Homogeneity of the lot is confirmed by a duplicate analysis of 21 ampoules. These samples are representative of the batch from which they were taken.

The verified concentration of the ampoules is calculated from the distribution of 21 GC/FID analyses calibrated with 2 different freshly prepared ethanol solutions (duplicate injections of each solution) and compared with NIST SRM 2896 and 2897a with a 95% level of confidence. During the preparation, the content has been corrected to account for the purity of ethanol and residual water.

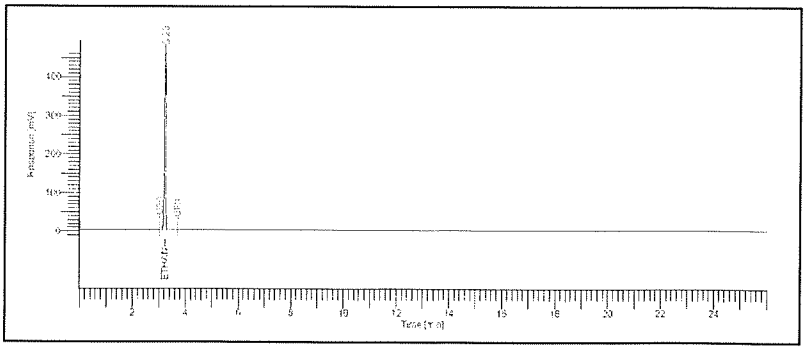
GC/FID Data: Calibration



Analytical conditions:

Column:
Rtx-624Sil-MS (30m x 0.32 mm * 1.8 um)
Injektionstechnik: Split ratio 50.0
Makeup flow: 24.0 mL/min (N_2)
H_2 flow: 32.0 mL/min
Air flow: 200.0 mL/min
Injector temp.: 240°C
Detector temp: 270°C
Säulenofen : 40°C / während 5min (isotherm)
Injektionsvolumen: 1.0µl

GC/FID Data: Ethanol purity



Analytical conditions:

column:
BAC 1, 30 m x 0.32 mm, 1.8 um
Injektor: 200 °C, split 20 ml/min
FID: 300 °C
Ofen:40 °C, 5 min isotherm
Helium 100 kPa (GC), 125 kPa (HS)
range 1, attenuation -6
pressurization time: 2 min
injection time: 0.05 min
withdrawal time: 0.5 min
needle: 75 °C
transferline: 150 °C
Thermostatisierung: 60 °C, 25 min

Lipomed AG
Fabrikmattenweg 4
4144 Arlesheim
Switzerland
Tel. +41 61 702 02 03
Fax +41 61 702 02 20

Lipomed GmbH
Hegenheimer Str. 2
79576 Weil am Rhein
Germany
+49 7621 1693 473
+49 7621 1693 474

Lipomed Inc.
150 Cambridgepark Drive, Suite 705
Cambridge, MA 02140
U.S.A.
+1 (617) 577 7222
+1 (617) 577 1776

www.lipomed.com
lipomed@lipomed.com

GENERAL INFORMATION

Quality Documentation:

This certificate is designed in accordance with ISO Guide 31 (Reference Materials – Contents of Certificates and Labels) and ISO Guide 35 (Reference Materials – General and Statistical Principles for Certification).

Quality Standards for Arlesheim production site:

ISO 9001 Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199

ISO/IEC 17025 General requirements for the competence of Testing Analytical Reference Standards. ANAB Certificate number: AT-1760

ISO 17034 General requirements for the competence of Reference Material Producer. ANAB Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by regularly performed analytical control tests/retests.

Intended Use:

The product covered by this certificate is designed for calibration or for use in quality control procedures for the specified chemical compound listed on the first page. This product can be used for quantification and/or identification. All solutions should be thoroughly mixed prior to use. If dilution is required, use only diluent compatible with the substance and solvent in this preparation.

Expiration/Retest Date:

Expiration/retest date of the unopened ampoule stored at the recommended storage conditions is the last day of the month.

A retest will be performed 6 months prior to the stated retest date. Upon successful retesting, a new retest date or expiration date is set for the product. The certificate of analysis is then updated and made available on our website. For our products, the extension of the shelf life is capped to 10 years after release as the maximum period.

Gravimetric Preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly with certified and traceable weights. For each balance, a minimum weighing value has been assigned.

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: HPLC, GC/FID, LC/MS, IR, UV, NMR, Karl Fischer, melting point, and optical rotation if applicable
- Purity of isomeric compounds is reported as the sum of the isomers
- Purity values are rounded to the last decimal place given
- The salt form, purity, residual water, and residual solvents are already taken into account for the given content value.

Uncertainty Statistics:

The uncertainties are determined in accordance with ISO 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. The certified uncertainty value (including characterization uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) is combined using the following formula:

$$U(y) = \sqrt{U^2_{characterization} + U^2_{homogeneity} + U^2_{storage\ stability} + U^2_{shipping\ stability}}$$

The filling volume is the minimum sample size for which the uncertainty is valid. The ampoules are over-filled to ensure that the minimum filling volume can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of 12 ampoules. 4 ampoules are taken at start, middle and end of the filling process. The analyzed concentration at each position is the average value obtained from duplicate analysis of 4 ampoules.

Stability:

The manufacturer guarantees the stability of this product throughout its intended shelf life, when handled and stored accordingly to the given storage conditions.

Legal and Safety Notice:

This product is for routine laboratory analysis and research purposes only. Due to the hazardous nature, only trained personnel should handle this product. The General Terms and Conditions of Lipomed apply.

Lipomed AG
Fabrikmattenweg 4
4144 Arlesheim
Switzerland
Tel. +41 61 702 02 00
Fax +41 61 702 02 20

Lipomed GmbH
Hegenheimer Str. 2
79576 Weil am Rhein
Germany
+49 7621 1693 473
+49 7621 1693 474

Lipomed Inc.
150 Cambridgepark Drive, Suite 705
Cambridge, MA 02140
U.S.A.
+1 (617) 577 7222
+1 (617) 577 1776

www.lipomed.com
lipomed@lipomed.com