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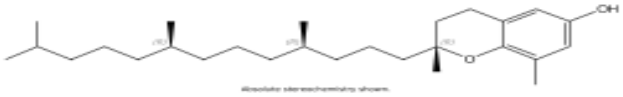
Certificate of Analysis - Analytical Standard

δ-Tocopherol

Product no.: 47784
Lot no.: LRAD2017
Description of CRM: Liquid
Expiry date: March 2025
Storage: FREEZER
Certificate version: LRAD2017.01 (*Note: Certificates may be updated due to the availability of new data. Check our website at: www.sigma-aldrich.com for the most current version.)*
Chemical formula: $C_{27}H_{46}O_2$
Molecular mass: 402.65
CAS No. 119-13-1



Analyte	Purity (mass balance / as is basis)
δ-Tocopherol	**93.1 % (mass balance / as is basis)**

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. When applicable, additional traceability to Primary Standards is established through comparative assay determinations. See "Details on metrological traceability" on page 2.

Measurement method: Where applicable, the certified value is based on a purity determination by mass balance. See section "Certification process details".

Intended use: Intended for Laboratory Use only. Not for drug, household or other uses

Minimum sample size: 100 mg

Health and safety information: All chemical reference materials should be considered potentially hazardous and should be used only by qualified laboratory personnel. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Certificate issue date: 23-March-2022

[Andy Ommen - Quality Control]

[Shawn Stetler - Quality Assurance]

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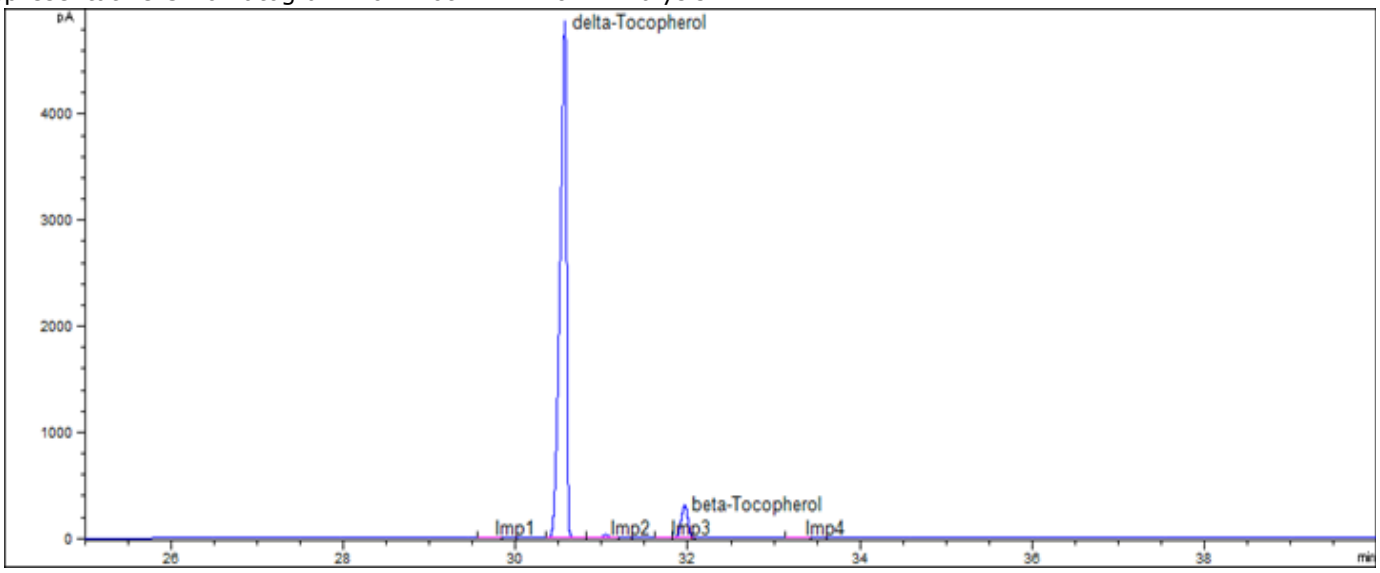
Sigma-Aldrich RTC is a subsidiary of Merck KGaA, Darmstadt, Germany.

Instructions for handling and correct use: The internal pressure of the container may be slightly different from the atmospheric pressure at the user`s location. Open slowly and carefully to avoid dispersion of the material. All values reported on the CoA are for the contents of the unopened standard and apply to the initial use of the standard. Any unused portions remaining after the container has been opened should be carefully stored in accordance with prudent laboratory procedures. Many variables are outside of the control of MilliporeSigma. Therefore, MilliporeSigma makes no warranties concerning the continued suitability of previously opened CRMs. Decisions concerning the proper use of previously opened CRMs are the responsibility of the user.
Expiration is at end of month given on certificate and label.

Packaging: 100 MG IN AMBER AMPULE

Representative Chromatogram from Lot: LRAD2017 Analysis

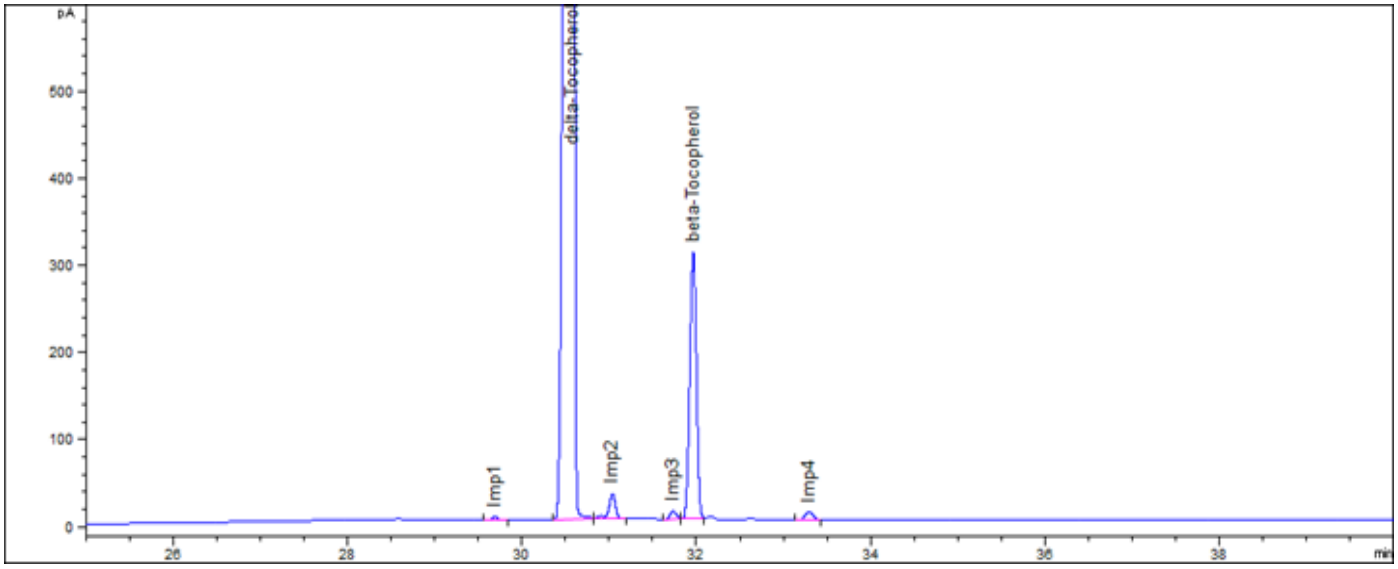


CHROMATOGRAPHIC IMPURITY ANALYSIS

METHOD: GC (In House)

Column: SPB-5, 30 m × 0.53 mm I.D., 1.5 µm film thickness
Carrier Gas: H_2 Flow Rate: 4.5 mL/min
Inlet Temperature: Track Oven Mode Injection Volume: 0.2 µL
Injection Mode: Cool on Column
Temperature Program: 40 °C (Hold 1 min) @ 10 °C/min to 300 °C (Hold 18 min)
Detector: FID Temperature: 300 °C

Representative Chromatogram from Lot: LRAD2017 Impurities Analysis



Impurities Detected:

Impurity 1:	0.064 %
Impurity 2:	0.509 %
Impurity 3:	0.171 %
b-tocopherol:	5.901 %
Impurity 4:	0.207 %
Total Impurities:	**6.852** %

WATER DETERMINATION

Method: Karl Fischer Titration (ref.: Current Compendial Monographs)
Mean of three measurements, Water Content = **<0.1 %**

PURITY BY MASS BALANCE

93.1 % mass balance / as is basis

Homogeneity assessment:

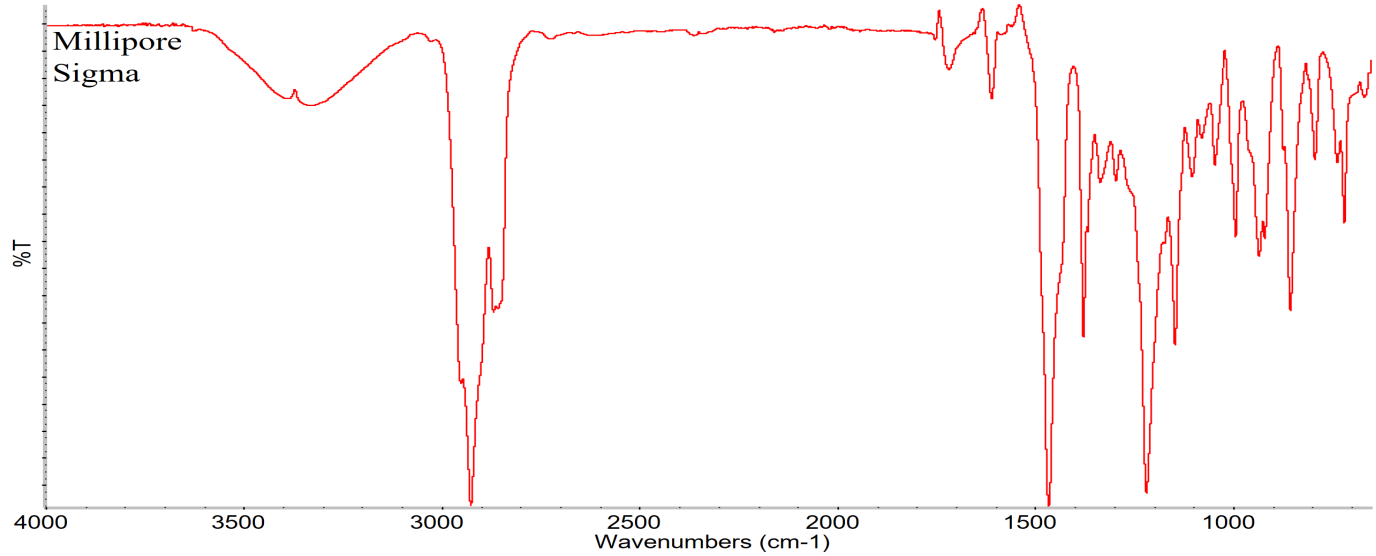
Homogeneity was assessed in accordance with ISO Guide 35. Completed units were sampled using a random stratified sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA. Heterogeneity was not detected under the conditions of the ANOVA.
Analytical method: GC
Sample size: 100 mg

Stability assessment:

Significance of the stability assessment will be demonstrated if the analytical result of the study and the range of values represented by the Expanded Uncertainty do not overlap the result of the original assay and the range of its values represented by the Expanded Uncertainty. The method employed will usually be the same method used to characterize the assay value in the initial evaluation.
Long Term Stability Evaluation - An assessment, or re-test, versus a Compendial Reference Standard may be scheduled, within the 3 year anniversary date of a release of a Secondary Standard. The re-test interval will be determined on a case-by-case basis. Short Term Stability Study - It is useful to assess stability under reasonably anticipated, short term transport conditions by simulating exposure of the product to humidity and temperature stress. This type of study is conducted under controlled conditions of elevated temperature and humidity.

Identification Test:

INFRARED SPECTROPHOTOMETRY (Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)



MilliporeSigma Lot: LRAD2017

Certificate of analysis revision history:

Certificate version	Date	Reason for version
LRAD2017.01	23 MAR 2022	Original release date

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