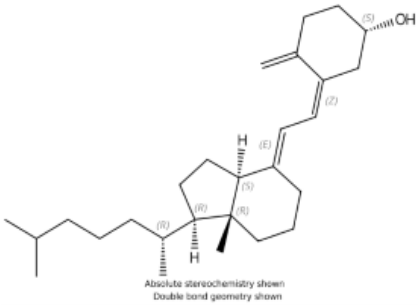
Certificate of Analysis - Analytical Standard

CHOLECALCIFEROL

Product no.: 47763
Lot no.: **LRAE1392**
Description of CRM: White powder
Expiry date: June 2027
Storage: REFRIGERATE (2 °C to 8 °C)
Certificate version: LRAE1392.01 *(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: $C_{27}H_{44}O$
Molecular mass: 384.6
CAS No. 67-97-0



Analyte	Purity (certification method / basis)
CHOLECALCIFEROL	**99.7 % (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: 20 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: 04 JUN 2025

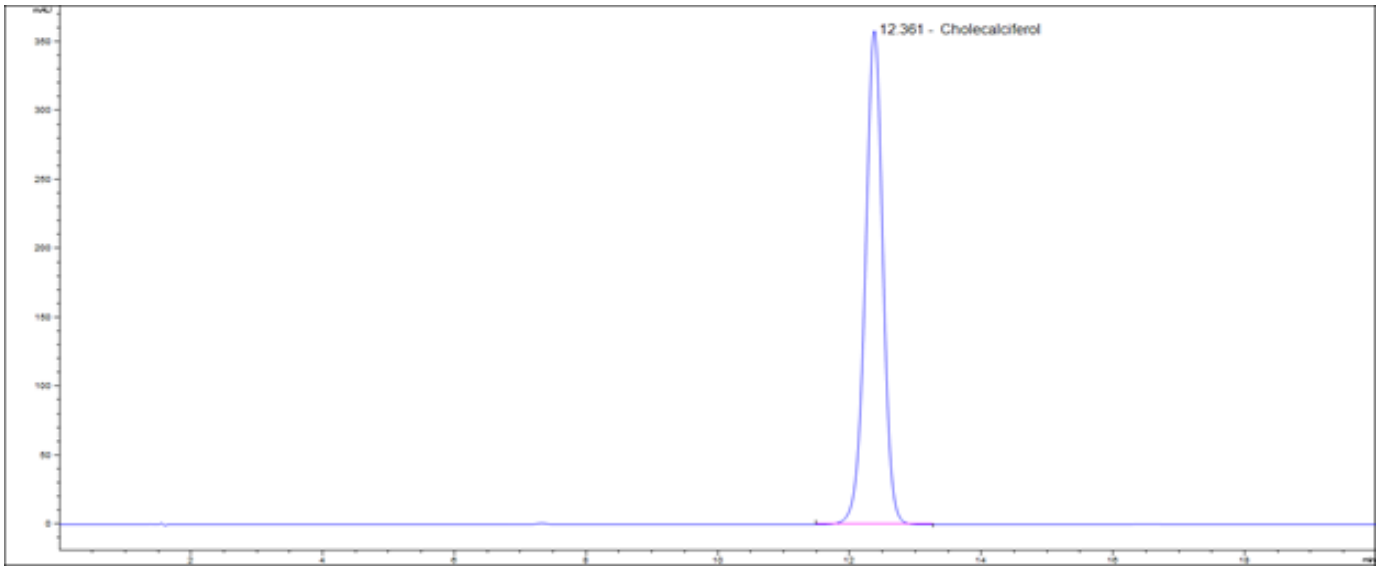
[Andy Ommen - QC Authority]

[Christopher Rucinski - QA Authority]

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: 100MG IN AMBER VIAL

Representative Chromatogram from MilliporeSigma Lot:LRAE1392 Analysis



MASS BALANCE ANALYSIS

Certification process details: The certified purity is determined by mass balance and calculated as

$$\%\ Purity = (\mathbf{100} - \mathbf{ROI} - \mathbf{LOD} - \mathbf{H_2O} - \mathbf{RS}) * (\frac{\mathbf{100} - \boldsymbol{TCI}}{\mathbf{100}})$$

- TCI = Total Chromatographic Impurities
- LOD = Loss on Drying
- H_2O = Water content determined by Karl Fischer analysis
- ROI = Residue on Ignition
- RS = Residual Solvents

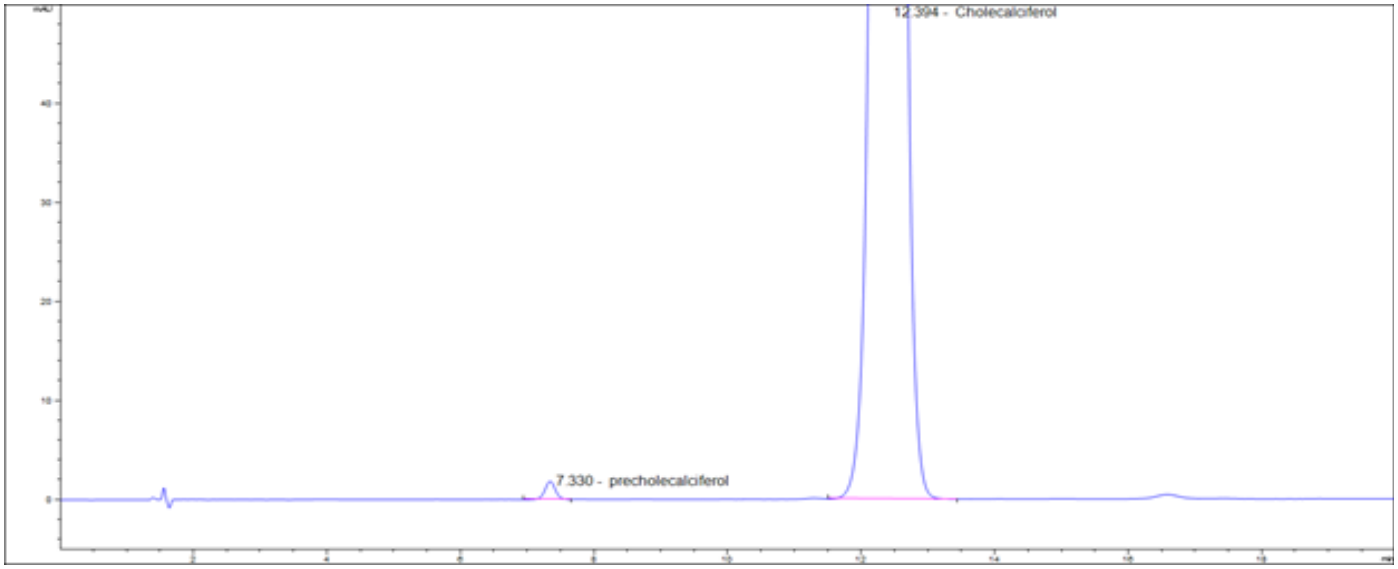
Methods for impurity determination may be added or deleted as required.

CHROMATOGRAPHIC IMPURITY ANALYSIS

METHOD: HPLC (In house)

Column: Kromasil Silica 4.6 x 250 mm, 5 µm particle size
Mobile Phase: Hexane:1-Butanol (994:6)
Flow Rate: 2.0 mL/min
Column Temperature: 30 °C
Injection Volume: 10 µL
Detector: DAD
Wavelength: 265 nm

Representative Chromatogram from Lot: LRAE1392 Impurities Analysis



Impurities Detected:

Precalciferol:	0.153 %
Total Impurities:	**0.153** %

RESIDUAL SOLVENTS

Method: GC-MS Headspace (ref.: Adapted from Residual Solvents USP <467>)
Column: SPB-624, 30 m x 0.25 mm x 1.4 µm
Carrier gas: He
Flow: 1.0 mL/min
Split Ratio: 5:1
Injection/Temperature: 1 mL/180 °C
Temperature Program: 40 °C for 5 min, 8 °C/min to 200 °C, hold 5 min

Solvents Detected: **None**

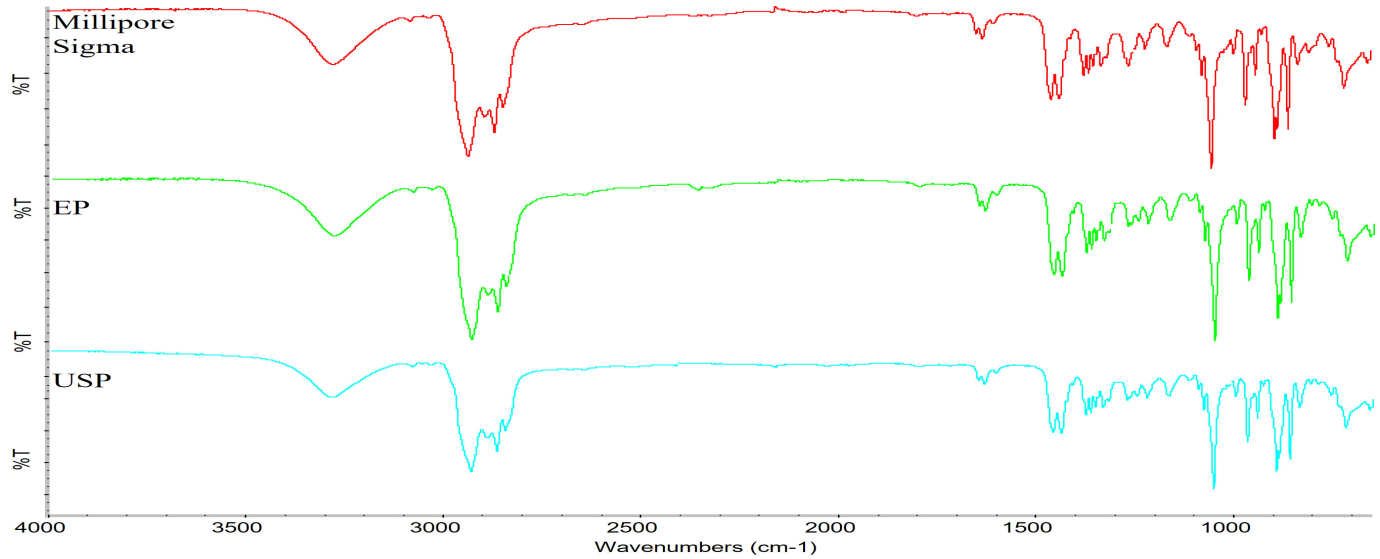
WATER DETERMINATION

Method: Karl Fischer (ref.: Current Compendial Monographs)
Mean of three measurements, Water Content = **0.153 %**

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: HPLC Sample size: 20 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: LRAE1392

Certificate of analysis revision history:

Certificate version	Date	Reason for version
LRAE1392.01	04 JUN 2025	Original release date

Disclaimer: The purchaser is required to determine the suitability of this product for any particular application. Sigma-Aldrich RTC makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Sigma-Aldrich RTC. We do not guarantee that the product can be used for any particular application.

The vibrant M, Supelco, TraceCERT and Sigma-Aldrich are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources. © 2018 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved.

The life science business of Merck KGaA, Darmstadt, Germany
operates as MilliporeSigma in the US and Canada.