

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Aug-2022
 Document Type: Dietary Supplement Monographs
 DocId: GUID-11D014AC-AEC7-45F2-878C-AE7A7AC2048B_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M10396_02_01
 DOI Ref: zlh48

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Add the following:

▲Palm Oil Tocotrienols and Tocopherols

DEFINITION Palm Oil Tocotrienols and Tocopherols consists chiefly of a mixture of α -, β -, γ -, and δ -tocotrienols and α -tocopherol derived from the oil from the mesocarp of fruits of *Elaeis guineensis* Jacq. (Family *Arecaceae*). β -, γ -, and δ -tocopherols may be present in minor amounts. It contains NLT 90% and NMT 110% of the labeled amount of the total tocotrienols (α -, β -, γ -, and δ -tocotrienols) and NLT 90% and NMT 110% of the labeled amount of α -tocopherol, all calculated on the anhydrous basis. The combined total tocotrienols and α -tocopherol contain NLT 75% of total tocotrienols and NLT 20% of α -tocopherol, calculated on the anhydrous basis. It also consists of phytosterols and squalene, which are naturally present in Palm Oil. It may contain added edible vegetable oils.

IDENTIFICATION

• **A.** The chromatogram of the *Sample solution* obtained from the test for *Content of Total Tocotrienols and α -Tocopherol* exhibits five main peaks. The retention times of these peaks match those of the peaks due to α -tocopherol, α -tocotrienol, β -tocotrienol, γ -tocotrienol, and δ -tocotrienol in the *System suitability solution*, with α -tocopherol, α -tocotrienol, and γ -tocotrienol are the most abundant, followed by δ -tocotrienol, and β -tocotrienol. Additional minor peaks corresponding to α -tocomonoenol and other tocopherol isomers may be present. The ratio of total tocotrienols (*T3*) to α -tocopherol (*T*) is approximately 3.0 (distinction from rice bran oil tocotrienols, in which the ratio is approximately 1).

COMPOSITION

• CONTENT OF TOCOTRIENOLS AND α -TOCOPHEROL

[NOTE—Use low-actinic glassware.]

Mobile phase: Hexane, ethyl acetate, glacial acetic acid, and 2,2-dimethoxypropane (500: 8.0: 4.0: 0.1)

System suitability solution: 1.0 mg/mL of [USP Palm Oil Tocotrienols and Tocopherols RS](#) in hexane

Standard solution: 0.1 mg/mL of [USP Alpha Tocopherol RS](#) in hexane

Sample solution: Prepare in hexane with the amount of α -tocopherol equivalent to $\pm 50\%$ of that in the *Standard solution*. Dilute if necessary with the same solvent. [NOTE—Multiple *Sample solutions* may be needed to get the concentration of the analytes within $\pm 50\%$ of those in the *Standard solution*.]

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 292 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L3](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 μ L

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for the approximate relative retention times in the *System suitability solution*.]

Suitability requirements

Resolution: NLT 1.5 between α -tocopherol and α -tocomonoenol; NLT 3.0 between α -tocomonoenol and α -tocotrienol, *System suitability solution*

Tailing factor: NMT 1.5 for α -tocopherol, *Standard solution*

Relative standard deviation: NMT 2.0% for α -tocopherol, *Standard solution*

Chromatogram similarity: The chromatogram from the *System suitability solution* is similar to the reference chromatogram provided with the lot of [USP Palm Oil Tocotrienols and Tocopherols RS](#) being used.

Table 1

Name	Approximate Relative Retention Time ^a	Relative Response Factor ^b
α-Tocopherol	0.85	1.00
α-Tocomonoenol	0.89	—
α-Tocotrienol	1.00	0.986
β-Tocotrienol	1.54	0.956
γ-Tocotrienol	1.79	0.956
δ-Tocotrienol	2.80	0.922

^a Chromatographic similarity should be used to confirm peak retention time.

^b The relative response factors (*F*) were calculated based on the molecular weight of the different tocotrienols isomers relative to the molecular weight of α-tocopherol.

Analysis

Samples: Standard solution and Sample solution

Identify the peaks due to α-tocotrienol, β-tocotrienol, γ-tocotrienol, and δ-tocotrienol in the *Sample solution* by comparing with those in the *System suitability solution*.

Separately calculate the percentages of the labeled amounts of α-tocotrienol, β-tocotrienol, γ-tocotrienol, and δ-tocotrienol in the portion of Palm Oil Tocotrienols and Tocopherols taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times (1/F) \times 100$$

r_U = peak area of α-tocotrienol, β-tocotrienol, γ-tocotrienol, or δ-tocotrienol from the *Sample solution*

r_S = peak area of α-tocopherol from the *Standard solution*

C_S = concentration of α-tocopherol in the *Standard solution* (mg/mL)

V = total volume used to prepare the *Sample solution* (mL)

W = weight of Palm Oil Tocotrienols and Tocopherols taken to prepare the *Sample solution* (mg)

F = relative response factor for the relevant analyte (see [Table 1](#))

Calculate the percentage of total tocotrienols (*T3*) as the sum of the percentages of α-tocotrienol, β-tocotrienol, γ-tocotrienol, and δ-tocotrienol in the portion of Palm Oil Tocotrienols and Tocopherols taken.

Calculate the percentage of the labeled amount of total tocotrienols:

$$\text{Result} = (T3/L) \times 100$$

$T3$ = content of total tocotrienols as previously determined (%)

L = label claim of total tocotrienols (%)

Identify the peak due to α-tocopherol in the *Sample solution* by comparing with that in the *Standard solution*.

Calculate the percentage of α-tocopherol (*T*) in the portion of Palm Oil Tocotrienols and Tocopherols taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times 100$$

r_U = peak area of α-tocopherol from the *Sample solution*

r_S = peak area of α-tocopherol from the *Standard solution*

C_S = concentration of α-tocopherol in the *Standard solution* (mg/mL)