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Tomato Extract Containing Lycopene

DEFINITION

Change to read:

Tomato Extract Containing Lycopene is an ethyl acetate extract of the natural tomato lipids. It is produced from the pulp of ripe fruits of *Lycopersicon esculentum* Mill. (Family Solanaceae), after removing the ▲▲ (USP 1-May-2021) water-soluble fraction. It contains NLT 95.0% and NMT 105.0% of the labeled amount of lycopene ($C_{40}H_{56}$). It also contains NLT 4.7% and NMT 12.0% of lycopene, NLT 0.8% of the combined amount of phytofluene ($C_{40}H_{62}$) and phytoene ($C_{40}H_{64}$), NLT 0.2% of beta carotene ($C_{40}H_{56}$), and NLT 1.0% of tocopherols ($C_{28}H_{48}O_2$), ▲all▲ (USP 1-May-2021) on the anhydrous basis. Tocopherols may be added as antioxidants.

IDENTIFICATION

• A. PRESENCE OF LYCOPENE, PHYTOFLUENE, AND PHYTOENE

Analysis: Proceed as directed in *Procedure 2: Content of Other Carotenoids and Tocopherols*.

Acceptance criteria: The retention times of the lycopene, phytofluene, and phytoene peaks of the *Sample solution* correspond to those of the *Standard solution*.

• B. RATIO OF ALL-*E*-LYCOPENE AND 5Z-LYCOPENE

Butylated hydroxytoluene stock solution: Prepare as directed in *Procedure 1: Content of Lycopene*.

Mobile phase: 0.05% [diisopropylethylamine](#) in [n-hexane](#). Sonicate for 3–4 min.

Sample solution: Prepare as directed in *Procedure 1: Content of Lycopene*, except dilute with [n-hexane](#) (5:100).

Chromatographic system

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

Mode: LC

Detector: UV-Vis 472 nm

Column: Two 4.0-mm × 25-cm columns in a series; 5-μm packing [L3](#) (300-Å pore size)

Column temperature: 22°

Flow rate: 0.5 mL/min

Injection volume: 10 μL

Analysis

Sample: *Sample solution*

[NOTE—The peak for all-*E*-lycopene elutes in 30–45 min.]

[NOTE—The relative retention times for all-*E*-lycopene and 5Z-lycopene are 1.00 and in the range of 1.04–1.10, respectively.]

Measure the areas of the two major peaks, and calculate their area ratio:

$$\text{Result} = r_{U1}/r_{U2}$$

r_{U1} = peak area of 5Z-lycopene

r_{U2} = peak area of all-*E*-lycopene

Acceptance criteria: NMT 0.10

COMPOSITION

Change to read:

• PROCEDURE 1: CONTENT OF LYCOPENE

Butylated hydroxytoluene stock solution: 5 mg/mL of butylated hydroxytoluene in [methylene chloride](#). [NOTE—This solution can be stored protected from light for up to 3 months.]

Mobile phase: [Acetonitrile](#), [methylene chloride](#), [n-hexane](#), and [methanol](#) (850:25:25:100). Add 0.05% of diisopropylethylamine, mix, and sonicate for 3–4 min.

Diluent: [Acetonitrile](#), [methylene chloride](#), [n-hexane](#), [butylated hydroxytoluene](#), and [methanol](#) (600: 150: 100: 0.5: 150). Add 0.05% of diisopropylethylamine, mix, and sonicate for 3–4 min.

Standard solution: ▲ Accurately weigh a ▲ (USP 1-May-2021) quantity of [USP Tomato Extract Containing Lycopene RS](#), equivalent to about 6 mg of lycopene, ▲ and transfer ▲ (USP 1-May-2021) to a 100-mL volumetric flask. Dissolve in 1 mL of *Butylated hydroxytoluene stock solution* and 9 mL of [methylene chloride](#) using a sonicator. Dilute with *Diluent* to volume to obtain a solution with a known concentration of about 0.06 mg/mL of lycopene.

Sample stock solution: Warm Tomato Extract Containing Lycopene to 50° in a water bath and mix well with a glass rod or a spatula.

▲ Transfer ▲ (USP 1-May-2021) 1–1.2 g of the sample, ▲ accurately weighed, into a 100 mL volumetric flask, and dissolve ▲ (USP 1-May-2021) in 10 mL of *Butylated hydroxytoluene stock solution* and 30 mL of [methylene chloride](#). Sonicate for 1 min to dissolve the sample completely. Cool to room temperature, and dilute with [methylene chloride](#) ▲ to volume. ▲ (USP 1-May-2021)

Sample solution: Dilute the *Sample stock solution* with *Diluent* (1 in 10).

Chromatographic system

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

Mode: LC

Detector: UV-Vis 472 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Column temperature: 39° ▲ (USP 1-May-2021)

Flow rate: 0.7 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for lycopene is about 6 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for the lycopene peak area

▲ **Chromatogram similarity:** The chromatogram of the *Sample solution* is similar to the reference chromatogram provided with the lot of [USP Tomato Extract Containing Lycopene RS](#) being used. ▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution*, ▲ *Sample stock solution*, ▲ (USP 1-May-2021) and *Sample solution*

▲ Inject the *Sample solution* and the *Standard solution*, and register the chromatograms. Using the chromatogram of the *Standard solution* and the reference chromatogram provided with the lot of [USP Tomato Extract Containing Lycopene RS](#) being used, identify the retention times of the relevant peaks in the chromatographic system. ▲ (USP 1-May-2021)

Calculate the percentage of lycopene in the portion of Tomato Extract Containing Lycopene taken:

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

r_U = peak area of lycopene from the *Sample solution*

r_S = peak area of lycopene from the *Standard solution*

C_S = concentration of lycopene in the *Standard solution* (mg/mL)

V = volume of the *Sample stock solution* (mL)

W = weight of Tomato Extract Containing Lycopene taken to prepare the *Sample stock solution* (mg)

D = dilution factor used to prepare the *Sample solution* from the *Sample stock solution*

Acceptance criteria: 95.0%–105.0% of the labeled amount of lycopene; 4.7%–12.0% of lycopene

Change to read:

• PROCEDURE 2: CONTENT OF OTHER CAROTENOIDS AND TOCOPHEROLS (PHYTOFLUENE, PHYTOENE, BETA CAROTENE, AND TOCOPHEROLS)

Butylated hydroxytoluene stock solution, Diluent, Standard solution, ▲ Sample stock solution, ▲ (USP 1-May-2021) and Sample

solution: Prepare as directed in *Procedure 1: Content of Lycopene*.

Mobile phase: [Acetonitrile](#), [methylene chloride](#), [n-hexane](#), and [methanol](#) (19:1:1:19). Add 0.05% of [diisopropylethylamine](#), mix, and sonicate for 3–4 min.

Chromatographic system

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

Mode: LC

Detector: UV-Vis

For lycopene: 472 nm

For beta carotene: 450 nm

For phytofluene: 350 nm

For phytoene and tocopherol: 288 nm