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Lycopene Preparation

DEFINITION

Lycopene Preparation is a combination of Lycopene with one or more inert substances and suitable antioxidants. It may be in a solid or oily liquid form. It contains NLT 95.0% and NMT 120.0% of the labeled amount of lycopene ($C_{40}H_{56}$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-MAY-2020)

Analytical wavelength: 300–700 nm

Sample solution: Prepare as directed for the *Sample solution* in the test for *Content of Lycopene*.

Acceptance criteria: Meets the requirements. The absorbance ratio A_{476}/A_{508} is 1.10–1.14 in [cyclohexane](#). The absorbance ratio A_{472}/A_{504} is 1.09–1.13 in [isopropyl alcohol](#).

COMPOSITION

• CONTENT OF LYCOPENE

Procedure for oily preparations

Sample stock solution: Transfer a weighed quantity of oily Preparation containing 25 mg of lycopene to a 100-mL volumetric flask. Add 25 mg of [butylated hydroxytoluene](#) and 60 mL of [methylene chloride](#), and sonicate to dissolve. Dilute with [methylene chloride](#) to volume.

Sample solution: 2.0 mL of the *Sample stock solution* diluted with [cyclohexane](#) to 200.0 mL

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 476 nm

Blank: [Cyclohexane](#)

Analysis

Sample: *Sample solution*

Calculate the percentage of the labeled amount of lycopene ($C_{40}H_{56}$) in the portion of Preparation taken:

$$\text{Result} = [A_U / (a \times C_U)] \times 100$$

A_U = absorbance of the *Sample solution*

a = absorptivity of the pure lycopene in cyclohexane, 331 ($\text{mL} \cdot \text{mg}^{-1} \cdot \text{cm}^{-1}$)

C_U = nominal concentration of lycopene in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–120.0% on the anhydrous basis

Procedure for solid preparations

Sample stock solution: Transfer a weighed quantity of solid Preparation, equivalent to approximately 5 mg of lycopene, into a 200-mL volumetric flask. Add about 60 units of [bacterial alkaline protease preparation](#), or another suitable enzyme, and about 25 mg of [butylated hydroxytoluene](#). Add 2.5 mL of [ammonium hydroxide](#) diluted in [water](#) (2 in 100), and mix. Place in an ultrasonic bath at 50° for 10 min, rotate the flask occasionally to avoid having the material stick to the glass surface, and continue until the material is dispersed with no lumps. Add 5 mL of [tetrahydrofuran](#) and 40 mL of [dehydrated alcohol](#), and mix. Place in an ultrasonic bath for about 1 min. Cool to room temperature, and dilute with [tert-butyl methyl ether](#) to volume. Shake vigorously, then allow to stand until the solid has settled.

Sample solution: 2.0 mL of the *Sample stock solution* diluted with [isopropyl alcohol](#) to 25.0 mL

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 472 nm

Blank: [Isopropyl alcohol](#)

Analysis

Sample: *Sample solution*

Calculate the percentage of the labeled amount of lycopene ($C_{40}H_{56}$) in the portion of Preparation taken:

$$\text{Result} = [A_U / (a \times C_U)] \times 100$$

A_U = absorbance of the *Sample solution*

a = absorptivity of the pure lycopene in isopropyl alcohol, $320 \text{ (mL} \cdot \text{mg}^{-1} \cdot \text{cm}^{-1})$

C_U = nominal concentration of lycopene in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–120.0% on the anhydrous basis

Change to read:

• **CONTENT OF ALL-*E*-LYCOPENE, 5Z-LYCOPENE, AND RELATED COMPOUNDS**

Mobile phase: [tert-Butyl methyl ether](#), [methanol](#), and [tetrahydrofuran](#) (784:665:74)

Standard solution: Transfer a weighed quantity of [▲USP Lycopene Preparation RS](#),▲ (USP 1-May-2019) equivalent to approximately 5 mg of lycopene, into a 250-mL volumetric flask. Add about 60 units of [bacterial alkaline protease preparation](#), or another suitable enzyme, and about 25 mg of [butylated hydroxytoluene](#). Add 2.5 mL of [ammonium hydroxide](#) diluted in [water](#) (2 in 100), and mix. Place in an ultrasonic bath at 50° for 10 min, rotate the flask occasionally to avoid having the material stick to the glass surface, and continue until the material is dispersed with no lumps. Add 5 mL of tetrahydrofuran and 40 mL of [dehydrated alcohol](#), and mix. Place in an ultrasonic bath for about 1 min. Cool to room temperature, and dilute with [tert-butyl methyl ether](#) to volume. Shake vigorously, then allow the precipitate to settle. Filter the supernatant.

Sample solution for oily preparations: Transfer a quantity of oily Preparation, equivalent to 15 mg of lycopene, to a 25-mL volumetric flask, and dissolve in [tetrahydrofuran](#) containing 50 mg/L of [butylated hydroxytoluene](#). Dilute with the same solvent to volume. Pipet 2 mL of this solution into a 50-mL volumetric flask, and add 8 mL of [tetrahydrofuran](#). Dilute with [tert-butyl methyl ether](#) to volume.

Sample solution for solid preparations: Transfer a weighed quantity of solid Preparation, equivalent to approximately 5 mg of lycopene, into a 250-mL volumetric flask. Add about 60 units of [bacterial alkaline protease preparation](#), or another suitable enzyme, and about 25 mg of [butylated hydroxytoluene](#). Add 2.5 mL of [ammonium hydroxide](#) diluted in [water](#) (2 in 100), and mix. Place in an ultrasonic bath at 50° for 10 min, rotate the flask occasionally to avoid having the material stick to the glass surface, and continue until the material is dispersed with no lumps. Add 5 mL of [tetrahydrofuran](#) and 40 mL of [dehydrated alcohol](#), and mix. Place in an ultrasonic bath for about 1 min. Cool to room temperature, and dilute with [tert-butyl methyl ether](#) to volume. Shake vigorously, then allow the precipitate to settle. Filter the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 472 nm

Column: 4.6-mm × 25-cm, 5-μm packing L62; second column connected in series, 4.6-mm × 25-cm, 3-μm packing L62. [NOTE—New columns may require conditioning.]

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for all-*E*-lycopene and 5Z-lycopene are 1.0 and about 1.07, respectively.]

Suitability requirements

Resolution: NLT 1.0 between all-*E*-lycopene and 5Z-lycopene

Tailing factor: 0.8–2.0 for all-*E*-lycopene

Relative standard deviation: NMT 2.0% for all-*E*-lycopene

Analysis

Sample: Relevant *Sample solution*

Calculate the percentage of all-*E*-lycopene in the portion of Preparation taken:

$$\text{Result} = (r_E / r_T) \times 100$$

r_E = peak response of the all-*E*-lycopene isomer

r_T = sum of all the peak responses

Acceptance criteria: NLT 65.0% of all-*E*-lycopene

Calculate the percentage of the 5Z-lycopene isomer in the portion of Preparation taken:

$$\text{Result} = (r_{5Z} / r_T) \times 100$$

r_{5Z} = peak response for the 5Z-lycopene isomer

r_T = sum of all the peak responses