

Lycopene Preparation

» 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 not less than 95.0 percent and not more than 120.0 percent of the labeled amount of lycopene (C₄₀H₅₆), calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers under inert gas. Store the oil preparations in a cool place and the solid preparations at controlled room temperature.

Labeling—Label it to state the name and content of added antioxidants and inert substances. Label it to indicate whether the article is prepared with lycopene from natural sources or with synthetic lycopene. If prepared with lycopene from natural sources, label it to indicate the natural source, including its Latin binomial.

USP Reference standards—USP Lycopene RS.

Identification, Ultraviolet-Visible Absorption (197U)—

FOR OILY PREPARATIONS—

Spectral range: 300 to 700 nm.

Solution—Prepare as directed below for the *Test solution* in *Content of lycopene (test for oily preparations)*.

Ratio: A₄₇₆ / A₅₀₈ between 1.10 and 1.14 in cyclohexane.

FOR SOLID PREPARATIONS—

Spectral range: 300 to 700 nm.

Solution—Prepare as directed below for the *Test solution* in *Content of lycopene (test for solid preparations)*.

Ratio: A₄₇₂ / A₅₀₄ between 1.09 and 1.13 in isopropyl alcohol.

Water, Method I (921): not more than 8.0%.

Change to read:

Content of all-*E*-lycopene, 5*Z*-lycopene, and related compounds—

Mobile phase, Standard solution, and Chromatographic system—Proceed as directed for *Content of all-*E*-lycopene, 5*Z*-lycopene, and related compounds* under *Lycopene*.

Test solution for oil preparations—Transfer a quantity of oil Preparation, equivalent to about 15 mg of lycopene, to a 25-mL volumetric flask, and dissolve in tetrahydrofuran containing 50 mg of butylated hydroxytoluene per L. Dilute with the same solvent to volume. Pipet 2 mL into a 50-mL volumetric flask, and add 8 mL of tetrahydrofuran. Dilute with *tert*-butyl methyl ether to volume. Use this solution for injection.

Test solution for solid preparations—*Transfer an accurately 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 dilute ammonium hydroxide (2 in 100) in water, mix, place in an ultrasonic bath at 50° for 10 minutes, 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, 40 mL of dehydrated alcohol, mix, and place in the ultrasonic bath for about 1 minute. Cool to room temperature, and dilute with *tert*-butyl methyl ether to volume. Shake vigorously. Allow the precipitate to settle, and filter the supernatant. • (RB 1-Mar-2009)

Procedure—Proceed as directed for *Content of all-*E*-lycopene, 5*Z*-lycopene, and related compounds* under *Lycopene*. Calculate the

percentage of related compounds in the portion of Lycopene Preparation taken by the formula:

$$r_s / r_T$$

in which r_s is the sum of the responses of all peaks except the peak for all-*E*-lycopene and the peak for 5*Z*-lycopene, and r_T is the total detected area in the chromatogram: not more than 14.0% of other related compounds calculated as lycopene is found. Calculate the percentage of the 5*Z*-lycopene isomer in the portion of Lycopene Preparation taken by the formula:

$$r_{5Z} / r_T$$

in which r_{5Z} is the peak response for the 5*Z*-lycopene isomer, and the other terms are as described above: not more than 23.0% of the 5*Z*-lycopene isomer is found. Calculate the percentage of all-*E*-lycopene in the portion of Lycopene Preparation taken by the formula:

$$r_E / r_T$$

in which r_E is the peak response of the all-*E*-lycopene isomer, and the other terms are as described above: not less than 65.0% of all-*E*-lycopene is found.

Change to read:

Content of lycopene—

TEST FOR OILY PREPARATIONS—

Test stock solution—Transfer an accurately weighed quantity of Lycopene Preparation containing about 25 mg of lycopene to a 100-mL volumetric flask, and add about 25 mg of butylated hydroxytoluene and about 60 mL of methylene chloride. Sonicate to dissolve, and dilute with methylene chloride to volume.

Test solution—Transfer 2.0 mL of the *Test stock solution* to a 200-mL volumetric flask, and dilute with cyclohexane to volume.

Procedure—Determine the absorbance of the *Test solution* at the wavelength of maximum absorbance at about 476 nm, using cyclohexane as the blank. Calculate the percentage of lycopene in the portion of Lycopene Preparation taken by the formula:

$$1000A/331W$$

in which A is the absorbance of the *Test solution*; W is the weight, in g, of the portion of Lycopene Preparation taken to prepare the *Test stock solution*; and 331 is the absorptivity of the pure lycopene in cyclohexane.

TEST FOR SOLID PREPARATIONS—

Test stock solution—*Transfer an accurately 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 dilute ammonium hydroxide (2 in 100) in water, mix, place in an ultrasonic bath at 50° for 10 minutes, 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, 40 mL of dehydrated alcohol, mix, and place in the ultrasonic bath for about 1 minute. Cool to room temperature, and dilute with *tert*-butyl methyl ether to volume. Shake vigorously. Add 100 mL of diethyl ether, and shake vigorously. Dilute with diethyl ether to volume, shake vigorously, and allow to stand until the solid has settled. • (RB 1-Mar-2009)

Test solution—Transfer 2.0 mL of the supernatant from the *Test stock solution* to a 25-mL volumetric flask, and dilute with isopropyl alcohol to volume.

Procedure—Determine the absorbance of the *Test solution* at the wavelength of maximum absorbance at about 472 nm, using isopro-

pyl alcohol as the blank. Calculate the percentage of lycopene in the portion of Lycopene Preparation taken by the formula:

$$250A/320W$$

in which *A* is the absorbance of the *Test solution*; *W* is the weight, in g, of the portion of Lycopene Preparation taken to prepare the

Test stock solution; and 320 is the absorptivity of the pure lycopene in isopropyl alcohol.