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Lutein Capsules

DEFINITION

Lutein Capsules contain NLT 95.0% and NMT 130.0% of the labeled amount of lutein ($C_{40}H_{56}O_2$). It may contain NMT 9% of zeaxanthin of the total carotenoid content.

IDENTIFICATION

Change to read:

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

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

Wavelength range: 300–700 nm

Ratio: A_{446}/A_{474} , 1.09–1.14

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Content of Lutein and Zeaxanthin*.

COMPOSITION

• CONTENT OF TOTAL CAROTENOIDS

Diluent: Hexanes, acetone, toluene, and dehydrated alcohol (10:7:7:6)

Sample stock solution: Weigh NLT 10 Capsules in a tared weighing bottle. With a sharp blade or by other appropriate means, carefully open the Capsules, without loss of the shell material, and transfer as much as possible of the combined Capsule contents to a suitable container. Remove any adhering substance from the emptied Capsules and shell remains by washing with several small portions of *n*-hexane. Discard the washings, and allow the empty Capsules and shell remains to dry in a current of dry air until the odor of *n*-hexane is no longer perceptible. Weigh the empty Capsules and shell remains in the original tared weighing bottle, and calculate the average net weight per Capsule by difference. Dissolve an accurately weighed portion of the combined Capsule contents in *Diluent* by stirring with a magnetic bar for 30 min, and dilute with *Diluent* to a designated volume to obtain a solution with a nominal concentration of 0.2 mg/mL of lutein.

Sample solution: Dilute a portion of the *Sample stock solution* with dehydrated alcohol to prepare a solution with a nominal concentration of 2.0 µg/mL of lutein.

Instrumental conditions

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

Analytical wavelength: 446 nm

Cell path: 1 cm

Blank: Dehydrated alcohol

Analysis

Sample: *Sample solution*

Calculate the content of total carotenoids as lutein ($C_{40}H_{56}O_2$), (*T*), in mg/Capsule, in the Capsules taken:

$$\text{Result} = [(A \times D \times V)/(F \times W)] \times A_w$$

A = absorbance of the *Sample solution*

D = dilution to obtain the *Sample solution* from *Sample stock solution*

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

F = absorptivity of the lutein in alcohol, 255.0 (mL/mg · cm)

W = weight of capsule contents to prepare the *Sample stock solution* (mg)

A_w = average weight of capsule contents (mg/Capsule)

• CONTENT OF LUTEIN AND ZEAXANTHIN

Mobile phase: Hexane and ethyl acetate (3:1)

Standard solution: 150 µg/mL of [USP Lutein RS](#) in *Mobile phase*

Sample solution: Transfer 1 mL of the *Sample stock solution* from the test for *Content of Total Carotenoids*, and evaporate under a stream of nitrogen to dryness. Add 1 mL of *Mobile phase*, and sonicate to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV-Vis at 446 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for lutein and zeaxanthin are about 1.0 and 1.05, respectively.]

Suitability requirements

Resolution: NLT 1.0 between lutein and zeaxanthin

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Sample: *Sample solution*

Calculate the percentage of the labeled amount of lutein in the Capsules taken:

$$\text{Result} = [(r_U/r_T) \times T] \times (100/L)$$

r_U = peak response of lutein

r_T = sum of the responses of all the peaks

T = content of total carotenoids as determined in the test for *Content of Total Carotenoids* (mg/Capsule)

L = labeled amount of lutein (mg/Capsule)

Calculate the percentage of zeaxanthin relative to the total carotenoid content in the Capsules taken:

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

r_Z = peak response of zeaxanthin

r_T = sum of the responses of all the peaks

Acceptance criteria: 95.0%–130.0% of the labeled amount of lutein; NMT 9.0% of zeaxanthin in the total carotenoid content

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS \(2040\)](#): Meet the requirements for *Disintegration*
- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **LABELING:** Label it to indicate the amount of lutein and the amount of zeaxanthin per Capsule.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Lutein RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
LUTEIN CAPSULES	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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