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Curcuminoids Capsules

DEFINITION

Curcuminoids Capsules are prepared from Curcuminoids and contain NLT 90.0% and NMT 110.0% of the labeled amount of curcuminoids, calculated as the sum of curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin.

IDENTIFICATION

Delete the following:

▲ • A. [THIN-LAYER CHROMATOGRAPHY](#)▲ (USP 1-MAY-2023)

Add the following:

▲ • A. [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#)

Standard solution: 1 mg/mL of [USP Curcuminoids RS](#) in [methanol](#)

Sample solution: Weigh and finely powder the contents of NLT 10 Capsules. Suspend a portion equivalent to about 5 mg of curcuminoids in 5 mL of [methanol](#), sonicate briefly, and pass through a PVDF filter of 0.45-µm pore size.

Chromatographic system

(See standard parameters as defined in [HPTLC for Articles of Botanical Origin \(203\)](#), [Table 1](#).)

Application volume: 2 µL each of the *Standard solution* and the *Sample solution*, both as 8-mm bands

Developing solvent system: [Toluene](#) and glacial acetic acid (4:1)

Derivatization reagent: 85 mL of ice-cold [methanol](#) combined with 10 mL of glacial acetic acid, 5 mL of [sulfuric acid](#), and 0.5 mL of [p-anisaldehyde](#)

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber and dry in air. Treat with *Derivatization reagent*, heat at 100° for 3 min, and examine under long-wave UV light and under white light.

System suitability

Under long-wave UV light: In the lower half of the derivatized chromatogram of the *Standard solution*, three bands in increasing R_f are observed: an orange band due to bisdesmethoxycurcumin, an orange band due to desmethoxycurcumin, and a red band due to curcumin.

Under white light: The two lower bands are orange, while the topmost band is reddish pink.

Acceptance criteria

Under long-wave UV light: The derivatized chromatogram of the *Sample solution* exhibits two orange bands and one red band, similar in position and color to those in the *Standard solution*.

Under white light: Under white light, two orange bands and a darker red band correspond in increasing R_f to the bands due to bisdesmethoxycurcumin, desmethoxycurcumin, and curcumin in the *Standard solution*.▲ (USP 1-May-2023)

Change to read:

• B. ▲HPLC

Analysis: Proceed as directed in the test for *Content of Curcuminoids*.

Acceptance criteria:▲ (USP 1-May-2023) The retention times of the peaks for curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin of the *Sample solution* correspond to those of ▲*Standard solution A*.▲ (USP 1-May-2023)

STRENGTH

Change to read:

• CONTENT OF CURCUMINOIDS

Mobile phase: [Tetrahydrofuran](#) and 1 mg/mL of [citric acid](#) in [water](#) (4:6)

▲ (USP 1-May-2023)

Standard solution A: 40 µg/mL of [USP Curcuminoids RS](#) in *Mobile phase*

Standard solution B: 40 µg/mL of [USP Curcumin RS](#), 10 µg/mL of [USP Desmethoxycurcumin RS](#), and 2 µg/mL of [USP Bisdsmethoxycurcumin RS](#) (USP 1-May-2023) in *Mobile phase*. ▲Sonicate if necessary for complete dissolution. Pass through a filter with 0.45-µm pore size before injection. ▲ (USP 1-May-2023)

Sample stock solution: Weigh and finely powder the contents of NLT 20 Capsules. Transfer an accurately weighed portion equivalent to about 20 mg of curcuminoids to a 50-mL volumetric flask. Add about 30 mL of acetone, sonicate for 30 min, dilute with acetone to volume, mix, and centrifuge.

Sample solution: Dilute a portion of the *Sample stock solution* (1 in 10) with *Mobile phase*, and mix. ▲Pass through a filter with 0.45-µm pore size before injection. ▲ (USP 1-May-2023)

Chromatographic system

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

Mode: LC

Detector: ▲ (USP 1-May-2023) Vis 420 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution A* ▲ and *Standard solution B* ▲ (USP 1-May-2023)

Suitability requirements

Chromatogram similarity: The chromatogram from *Standard solution A* is similar to the reference chromatogram provided with the lot of [USP Curcuminoids RS](#) being used.

Resolution: NLT 2.0 between the curcumin and desmethoxycurcumin peaks and the desmethoxycurcumin and bisdesmethoxycurcumin peaks, ▲*Standard solution A* ▲ (USP 1-May-2023)

Tailing factor: NMT 1.5 for the bisdesmethoxycurcumin, desmethoxycurcumin, and curcumin peaks, ▲*Standard solution A* ▲ (USP 1-May-2023)

Relative standard deviation: NMT 2.0% for desmethoxycurcumin peak in repeated injections, ▲*Standard solution B* ▲ (USP 1-May-2023)

Analysis

Samples: ▲ (USP 1-May-2023) *Standard solution B* ▲ (USP 1-May-2023) and *Sample solution*

Separately calculate the quantity, in mg, of curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin in each Capsule:

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

r_U = peak area for curcumin, desmethoxycurcumin, or bisdesmethoxycurcumin from the *Sample solution*

r_S = peak area for curcumin, desmethoxycurcumin, or bisdesmethoxycurcumin from ▲*Standard solution B* ▲ (USP 1-May-2023)

C_S = concentration of the ▲relevant Reference Standard in *Standard solution B* ▲ (USP 1-May-2023) (mg/mL)

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

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

W_F = average fill weight of Capsules (mg)

W_U = weight of content of Capsules taken to prepare the *Sample stock solution* (mg)

Calculate the percentage of the labeled amount of curcuminoids in the Capsule:

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

ΣQ = sum of the quantities of curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin in the Capsule (mg)

L = labeled amount of curcuminoids (mg/Capsule)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read: