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Ginger Capsules

DEFINITION

Ginger Capsules are prepared from Powdered Ginger and contain NLT 90.0% and NMT 110.0% of the labeled amount of gingerols, gingerdiones, and shogaols, and NLT 90.0% of the labeled amount of volatile oil.

IDENTIFICATION

• A.

Analysis: Pulverize an amount of the contents of Capsules equivalent to 5 g of ginger. To an amount equivalent to 1 g of ginger add 5 mL of dilute acetic acid, prepared by diluting 1 part of glacial acetic acid with 1 part of water, and shake for 15 min. Filter, and add a few drops of ammonium oxalate TS to the filtrate.

Acceptance criteria: NMT a slight turbidity is produced.

• B.

Sample (see [Articles of Botanical Origin \(561\)](#), [Alcohol-Soluble Extractives, Method 2](#)): Collect the filtrate in a 100-mL volumetric flask, and dilute with alcohol to volume. Evaporate 50 mL of the filtrate at a temperature not exceeding 90°. Use 50 mg of the residue for the test.

Analysis: Dissolve the *Sample* in 25 mL of water, and extract with two 15-mL portions of ether. Combine the ether extracts, and evaporate in a porcelain dish. To the residue add 5 mL of sulfuric acid solution (7.5 in 10.0) and 5 mg of vanillin. Allow to stand for 15 min, and add an equal volume of water.

Acceptance criteria: The solution turns azure blue.

• C. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST](#)

Standard solution A: Proceed as directed for the *Sample solution*, except to use 0.2 g of [USP Powdered Ginger RS](#).

Standard solution B: Use the *System suitability solution*, prepared as directed in the test for *Content of Gingerols, Gingerdiones, and Shogaols*.

Sample solution: Pulverize an amount of the contents of Capsules equivalent to 5 g of ginger. Transfer an amount equivalent to 0.2 g of ginger to a test tube, add 5 mL of methanol, shake for 30 min, and centrifuge. Apply the supernatant to the plate.

Adsorbent: 0.50-mm layer of chromatographic silica gel mixture

Application volume: 20 µL for *Standard solution A* and the *Sample solution*; 40 µL for *Standard solution B*

Developing solvent system: Ether and hexanes (7:3)

Spray reagent: 10% sulfuric acid in alcohol

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Proceed as directed in the chapter. Examine the plate under UV light at 254 nm. Spray the plate with *Spray reagent*, heat at 100°–105° for 10 min, and examine under daylight.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a spot due to gingerols that occurs at an R_f value of 0.2, and a spot of shogaols may occur at an R_f value of 0.4, corresponding to those shown in the chromatogram of *Standard solution B*. [NOTE—The chromatograms of *Standard solution A* and the *Sample solution* may exhibit other spots in the upper region and at the origin of the plate.]

STRENGTH

• CONTENT OF GINGEROLS, GINGERDIONES, AND SHOGAOLS

Solution A: Acetonitrile, dilute phosphoric acid (1 in 1000), and methanol (55:44:1)

Solution B: Acetonitrile

Mobile phase: Use *Solution A* for NLT seven times the retention time of capsaicin.

Column washing: After each chromatographic run, wash the column, using [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
2	0	100
12	0	100
14	100	0
29	100	0

Standard solution: 0.1 mg/mL of [USP Capsaicin RS](#) in methanol

System suitability solution: Reconstitute the content of 1 vial of [USP Ginger Constituent Mixture RS](#) in 1 mL of the *Standard solution*.

Sample solution: Mix and finely powder the contents of NLT 20 Capsules, and transfer an amount equivalent to 2.0 g of powdered ginger to a glass-stoppered conical flask. Add 50 mL of alcohol, insert a stopper into the flask, and macerate for 24 h, shaking frequently during the first 8 h, and then allowing to stand for 16 h. Filter, and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection size: 25 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—The relative retention times for 6-gingerol, capsaicin, and 6-shogaol are about 0.8, 1.0, and 1.9, respectively, *System suitability solution*.]

Suitability requirements

Resolution: NLT 3.0 between the 6-gingerol and capsaicin peaks and NLT 10.0 between the capsaicin and 6-shogaol peaks, *System suitability solution*

Tailing factors: NMT 2.0 for the 6-gingerol, capsaicin, and 6-shogaol peaks, *System suitability solution*

Relative standard deviation: NMT 2.5% for the capsaicin peak for replicate injections, *Standard solution*

Analysis

Samples: *Standard solution*, *Sample solution*, and *System suitability solution*

Calculate the sum of the peak responses due to gingerols and gingerdiones occurring at about the following retention times relative to 1.0 for capsaicin: 0.8 for 6-gingerol, 1.5 for 8-gingerol A, 2.2 for 8-gingerol B, 2.5 for 6-gingerdiol, 2.6 for 6-gingerdione, 3.4 for 10-gingerol, and 5.2 for 8-gingerdione.

Calculate the sum of the peak responses due to shogaols, occurring at about the following retention times, relative to 1.0 for capsaicin: 1.9 for 6-shogaol, 4.2 for 8-shogaol, and 5.8 for 10-shogaol.

Calculate the percentage of the labeled amount of gingerols, gingerdiones, and shogaols in the portion of Capsules taken:

$$\text{Result} = (r_T/r_S) \times C_S \times (V/W_U) \times (A_{WC}/L) \times 100$$

r_T = sum of the peak responses for gingerols, gingerdiones, and shogaols from the *Sample solution*

r_S = peak response of capsaicin from the *Standard solution*

C_S = concentration of [USP Capsaicin RS](#) in the *Standard solution* (mg/mL)

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

W_U = weight of the portion of Capsules taken (mg)

A_{WC} = average weight of the Capsule content (mg)

L = labeled amount of gingerols, gingerdiones, and shogaols (mg/Capsule)