

Ginger

Ginger is the dried rhizome of *Zingiber officinale* Roscoe (Fam. Zingiberaceae), scraped, partially scraped, or unscraped. It is known in commerce as unbleached ginger.

Packaging and storage— Preserve in well-closed containers, protected from light and moisture, and store in a cool area.

Labeling— The label states the Latin binominal and, following the official name, the part of the plant contained in the article.

USP Reference standards [<11>](#)

Botanic characteristics—

Macroscopic— Ginger occurs in horizontal, laterally flattened, sympodially branching pieces. Whole rhizomes are 5 to 15 cm long, 1.5 to 6 cm wide, and up to 2 cm thick, sometimes split longitudinally; pale yellowish buff or light brown externally, longitudinally striated, somewhat fibrous; branches flattish, obovate, short, about 2 cm long, each ending with a depressed stem scar; fracture, short with projecting fibers, or sometimes resinous; internally yellowish brown, showing a yellow endodermis separating the narrow cortex from the wide stele, and numerous yellowish points, secretion cells and numerous bigger greyish points, vascular bundles, scattered on the whole surface. The unscraped rhizome shows in addition an outer layer of dark brown cork. Morphological characteristics of different varieties and forms of Ginger from different geographical areas are listed in Table 1 of the general information chapter [Supplemental Information for Articles of Botanical Origin <2030>](#).

Histology— The scraped rhizome in transverse section shows a cortex composed of multiple layers of parenchyma cells rich in simple, large, flattened, ovoid or sack-shaped starch granules, 5 to 15 μm wide and 30 to 60 μm long having an eccentric hilum, some showing faint transverse striations. The cortex also shows numerous oleoresin cells with a yellow or yellowish-brown content and scattered collateral vascular bundles; a single layer of endodermal cells free from starch; a wide central stele composed of parenchyma cells rich in starch and oleoresin cells similar to those of the cortex, and containing scattered collateral vascular bundles, some enclosed in a sheath of septate nonlignified fibers with wide lumen. In addition to the above, the unscraped rhizome shows an outer zone of dark brown cork cells.

Identification—

A: Pulverize about 5 g of Ginger. To about 1 g of the pulverized 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 minutes. Filter, and add a few drops of [ammonium oxalate TS](#) to the filtrate: not more than a slight turbidity is produced.

B: Dissolve about 50 mg of the residue obtained in the test for Alcohol-soluble extractives in 25 mL of water, and extract this solution with two 15-mL portions of ether. Combine the ether extracts, and evaporate in a porcelain dish. To the residue so obtained, add 5 mL of sulfuric acid solution (7.5 in 10.0) and about 5 mg of vanillin. Allow to stand for 15 minutes, and add an equal volume of water: the solution turns azure blue.

C: [Thin-Layer Chromatographic Identification Test<201>](#)—

Adsorbent: 0.50-mm layer of chromatographic silica gel mixture.

Test solution— Pulverize about 5 g of Ginger. Transfer about 0.2 g of pulverized sample to a test tube, add 5 mL of methanol, shake for 30 minutes, and centrifuge. Apply the supernatant to the plate.

Standard solution 1— Proceed as directed for the Test solution, except to use 0.2 g of [USP Powdered Ginger RS](#).

Standard solution 2— Use the System suitability solution, prepared as directed in the test for Content of gingerols and gingerdiones.

Application volume: 20 µL for the Test solution and Standard solution 1; 40 µL for Standard solution 2.

Developing solvent system: a mixture of ether and hexanes (7:3).

Spray reagent— Prepare a solution of 10% sulfuric acid in alcohol.

Procedure— Proceed as directed in the chapter. Examine the plate under UV light at 254 nm.

Spray the plate with Spray reagent, heat between 100 °C and 105 °C for 10 minutes, and examine under daylight. The chromatogram of the Test solution exhibits a spot due to gingerols occurs at an R_F value of about 0.2 and a spot of shogaols may occur at an R_F value of about 0.4, corresponding to those shown in the chromatogram from Standard solution 2. [note—The

chromatograms of the Test solution and Standard solution 1 may exhibit other spots in the upper region and at the origin of the plate.]

Microbial enumeration <2021>— The total bacterial count does not exceed 10⁵ cfu per g. The total combined molds and yeasts count does not exceed 10³ cfu per g, the bile-tolerant Gram-negative bacteria count does not exceed 10³ cfu per g, and it meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

Total ash <561>: not more than 8.0%.

Acid-insoluble ash <561>: not more than 2.0%.

Water-soluble ash <561>: not less than 1.9%.

Water, [Method Ia <921>](#): not more than 10%.

Alcohol-soluble extractives, [Method 2 <561>](#)— Collect the filtrate in a 100-mL volumetric flask, dilute with alcohol to volume, and mix. Evaporate 50 mL of the filtrate at a temperature not exceeding 90 °C: not less than 4.5% residue is found. Save the residue for use in Identification test B and the remaining volume of the filtrate for the tests for Limit of shogaols and Content of gingerols and gingerdiones.

Water-soluble extractives, [Method 2 <561>](#): not less than 10.0%.

Foreign organic matter <561>: not more than 1.0%.

Volatile oil content <561>: not less than 1.8 mL per 100 g.

Pesticide residues <561>: meets the requirements.

Content of starch, [Method 1 <561>](#): not less than 42%, [Method Ia](#) of the General Procedures being used.

Limit of shogaols— From the chromatograms obtained in the test for [Content of gingerols and gingerdiones](#), 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 shogaols by the formula:

$$10(C / W)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Capsaicin RS](#) in the Standard preparation, prepared as directed in the test for Content of gingerols and gingerdiones; W is the weight, in g, of Ginger used in the test for Alcohol-soluble extractives; r_U is the sum of the peak responses due to

shogaols as calculated above; and rS is the peak response due to capsaicin obtained from the Standard preparation: not more than 0.18% of shogaols is found.

Content of gingerols and gingerdiones—

Solution A— Prepare a filtered and degassed mixture of acetonitrile, dilute phosphoric acid (1 in 1000), and methanol (55:44:1).

Solution B— Use filtered and degassed acetonitrile.

Mobile phase— Use variable mixtures of Solution A and Solution B as directed for

Chromatographic system. Make adjustments if necessary .

Standard preparation— Dissolve an accurately weighed quantity of [USP Capsaicin RS](#) in methanol to obtain a solution having a known concentration of about 0.1 mg per mL.

Test preparation— Use the filtrate retained from the test for Alcohol-soluble extractives.

System suitability solution— Reconstitute the content of 1 vial of [USP Ginger Constituent](#)

[Mixture RS](#) in 1 mL of the Standard preparation.

Chromatographic system— The liquid chromatograph is equipped with a 282-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. The chromatograph is programmed as follows.

| Time | Solution A (%) | Solution B (%) | Elution |
|--|----------------|----------------|-----------------|
| Not less than seven times the retention of capsaicin | 100 | 0 | isocratic |
| 2 minutes | 0 | 100 | linear gradient |
| 10 minutes | 0 | 100 | isocratic |
| 2 minutes | 100 | 0 | linear gradient |
| 15 minutes | 100 | 0 | isocratic |

Chromatograph the System suitability solution, and record the peak responses as directed for Procedure: the relative retention times are about 0.8 for 6-gingerol, 1.0 for capsaicin, and 1.9 for 6-shogaol; the resolution, R, between the 6-gingerol and the capsaicin peaks is not less than 3.0 and between the capsaicin and 6-shogaol peaks is not less than 10.0; and the tailing factors for the 6-gingerol, the capsaicin, and the 6-shogaol peaks are not more than 2.0. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative standard deviation for replicate injections is not more than 2.5%.

Procedure— Separately inject equal volumes (about 25 μL) of the Standard preparation, the System suitability solution, and the Test preparation into the chromatograph, and proceed as directed for Chromatographic system. Record the chromatograms, and measure all of the peak responses. 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 percentage of gingerols and gingerdiones by the formula:

$$10(C / W)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Capsaicin RS](#) in the Standard preparation; W is the weight, in g, of Ginger used in the test for Alcohol-soluble extractives; r_U is the sum of the peak responses due to gingerols and gingerdiones as calculated above; and r_S is the capsaicin peak response obtained from the Standard preparation: :not less than 0.8% is found.