

filtrate, add exactly 10 mL of the internal standard solution, and add water to make exactly 100 mL.

Containers and storage Containers—Tight containers.

Capsules

カプセル

Capsules are made of gelatin or a suitable material, and their shape is a pair of cylinders with one end closed which can be overlapped on each other.

Method of preparation Dissolve Gelatin or the like in water by warming, add Glycerin or D-Sorbitol, emulsifier, preservatives, coloring substances and so forth, if necessary, to make a thick gluey solution, and form into capsules while warm.

Capsules may be coated with a lubricant, if necessary.

Description Capsules are odorless and elastic.

Purity Odor, solubility, and acidity or alkalinity—Place, without overlapping of the parts, 1 piece (1 pair) of Capsules in a 100-mL conical flask, add 50 mL of water, and shake often, keeping the temperature at $37 \pm 2^\circ\text{C}$. Perform this test 5 times: they all dissolve within 10 minutes. All these solutions are odorless, and neutral or slightly acidic.

Containers and storage Containers—Well-closed containers.

Cardamon

Cardamomi Fructus

ショウズク

Cardamon is the fruit of *Elettaria cardamomum* Maton (*Zingiberaceae*). The capsules are removed from the seeds before use.

Description Nearly ellipsoidal, 1–2 cm in length, 0.5–1 cm in diameter; externally, light yellow with three blunt ridges and many longitudinal lines; 0.1–0.2-cm beak at one end; pericarp thin, light and fibrous; interior longitudinally divided into three loculi by thin membranes, each loculus containing 3 to 7 seeds joining by aril; seed irregularly angular ovoid, 0.3–0.4 cm in length, dark brown to blackish brown; the dorsal side convex, the ventral side longitudinally grooved; external surface coarsely tuberculated. Seed has a characteristic aroma, and pungent, slightly bitter taste; pericarp, odorless and tasteless.

Total ash Not more than 6.0% (seed).

Acid-insoluble ash Not more than 4.0% (seed).

Essential oil content Perform the test with 30.0 g of the pulverized seeds of Cardamon as directed in the Essential oil content under the Crude Drugs: the volume of essential oil is not less than 1.0 mL.

Carmellose

Carboxymethylcellulose

CMC

カルメロース

Carmellose is a polycarboxymethylether of cellulose.

Description Carmellose occurs as a white powder. It is odorless and tasteless.

It is practically insoluble in ethanol (95) and in diethyl ether.

It swells with water to form suspension.

It becomes viscid in sodium hydroxide TS.

The pH of a suspension, obtained by shaking 1 g of Carmellose with 100 mL of water, is between 3.5 and 5.0.

It is hygroscopic.

Identification (1) Shake well 0.1 g of Carmellose with 10 mL of water, add 2 mL of sodium hydroxide TS, shake, and allow to stand for 10 minutes. Use this solution as the sample solution. To 1 mL of the sample solution add water to make 5 mL. To 1 drop of this solution add 0.5 mL of concentrated disodium chlomotropate TS, and heat in a water bath for 10 minutes: a red-purple color develops.

(2) Shake 5 mL of the sample solution obtained in (1) with 10 mL of acetone: a white, flocculent precipitate is produced.

(3) Shake 5 mL of the sample solution obtained in (1) with 1 mL of iron (III) chloride TS: a brown, flocculent precipitate is produced.

Purity (1) Chloride—Shake well 0.8 g of Carmellose with 50 mL of water, dissolve in 10 mL of sodium hydroxide TS, and add water to make 100 mL. Heat 20 mL of this solution with 10 mL of dilute nitric acid on a water bath until a flocculent precipitate is produced, cool, centrifuge, and take out the supernatant liquid. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant liquid and the washings, and add water to make 100 mL. Take 25 mL of this solution, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.360%).

(2) Sulfate—Shake well 0.40 g of Carmellose with 25 mL of water, dissolve in 5 mL of sodium hydroxide TS, and add 20 mL of water. Heat this solution with 2.5 mL of hydrochloric acid in a water bath until a flocculent precipitate is produced. Cool, centrifuge, and take out the supernatant liquid. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant liquid and the washings, and add water to make 100 mL. Filter this solution, discard 5 mL of the first filtrate, take 25 mL of the subsequent filtrate, and add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 1.5 mL of 0.005 mol/L sulfuric acid VS (not more than 0.720%).

(3) Silicate—Weigh accurately about 1 g of Carmellose, ignite in a platinum dish, add 20 mL of dilute hydrochloric