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 ± 2°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

acid, cover with a watch glass, and boil gently for 30 minutes. Remove the watch glass, and evaporate on a water bath to dryness with the aid of a current of air. Continue heating further for 1 hour, add 10 mL of hot water, stir well, and filter through a filter paper for quantitative analysis. Wash the residue with hot water, dry the residue together with the filter paper when no turbidity is produced on the addition of silver nitrate TS to the last washing, and ignite to constant mass: the amount of residue is not more than 0.5%.

(4) Heavy metals—Proceed with 1.0 g of Carmellose according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(5) Arsenic—Take 1.0 g of Carmellose, prepare the test solution according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 8.0% (1 g, 105°C, 4 hours).

Residue on ignition Not more than 1.5% (after drying, 1 g).

Containers and storage Containers—Tight containers.

Carmellose Calcium

Carboxymethylcellulose Calcium
CMC Calcium

カルメロースカルシウム

Carmellose Calcium is the calcium salt of a polycarboxymethylether of cellulose.

Description Carmellose Calcium occurs as a white to yellowish white powder. It is odorless.

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

It swells with water to form a suspension.

The pH of a suspension, obtained by shaking 1 g of Carmellose Calcium with 100 mL of water, is between 4.5 and 6.0.

It is hygroscopic.

Identification **(1)** Shake thoroughly 0.1 g of Carmellose Calcium with 10 mL of water, followed by 2 mL of sodium hydroxide TS, allow to stand for 10 minutes, and 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.

(4) Ignite 1 g of Carmellose Calcium to ash, dissolve the residue in 10 mL of water and 5 mL of acetic acid (31), and filter, if necessary. Boil the filtrate, cool, and neutralize with ammonia TS: the solution responds to the Qualitative Tests (2), (3), and (4) for calcium salt.

Purity **(1)** Alkali—Shake thoroughly 1.0 g of Carmellose Calcium with 50 mL of water, freshly boiled and cooled, and add 2 drops of phenolphthalein TS: no red color develops.

(2) Chloride—Shake thoroughly 0.8 g of Carmellose Calcium with 50 mL of water, dissolve in 10 mL of sodium hydroxide TS, add water to make 100 mL, and use this solution as the sample solution. Heat 20 mL of the sample solution with 10 mL of dilute nitric acid on a water bath until a flocculent precipitate is produced. After cooling, centrifuge, and take out the supernatant liquid. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant 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%).

(3) Sulfate—Heat 10 mL of the sample solution obtained in (2) with 1 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 and the washings, and add water to make 100 mL. Take 25 mL of this solution, 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 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.960%).

(4) Silicate—Weigh accurately about 1 g of Carmellose Calcium, ignite in a platinum dish, add 20 mL of dilute hydrochloric acid, cover with a watch glass, and boil gently for 30 minutes. Remove the watch glass, and evaporate on a water bath to dryness, with the aid of a current of air. Continue heating for further 1 hour, add 10 mL of hot water, stir well, and filter through filter paper for quantitative analysis. Wash the residue with hot water, dry the residue together with the filter paper when no turbidity is produced on the addition of silver nitrate TS to the last washing, and then ignite to constant mass: the residue is not more than 0.5%.

(5) Heavy metals—Proceed with 1.0 g of Carmellose Calcium according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(6) Arsenic—Heat cautiously 2.0 g of Carmellose Calcium with 10 mL of sulfuric acid and 10 mL of nitric acid in a decomposition flask. Continue the heating with occasional addition of 2 mL of nitric acid until the liquid becomes colorless or light yellow. After cooling, add 15 mL of ammonium oxalate TS, heat until a white smoke evolves, cool, mix with 30 mL of water, and filter. Wash the residue with water, combine the washings with the filtrate, and add water to make 50 mL. Perform the test with 5 mL of this solution as the test solution using Appratus B: the stain is not deeper than the following standard stain.

Standard stain: Proceed in the same manner without Carmellose Calcium, transfer 5 mL of the obtained solution to a generator bottle, add 2 mL of Standard Arsenic Solution, and proceed as directed for the test with the test solution (not more than 10 ppm).

(7) Starch—Heat 0.10 g of Carmellose Calcium with 10 mL of water, cool, and add 2 drops of iodine TS: no blue color develops.