Identification (1) To 1.0 g of pulverized Gardenia Fruit, previously dried in a desiccator (silica gel) for 24 hours, add 100 mL of hot water, warm the mixture between 60°C and 70°C for 30 minutes with frequent shaking, and filter after cooling. To 1.0 mL of the filtrate add water to make 10 mL: the color of the resulting solution is yellow and is not lighter than that of the following control solution.

Control solution: Dissolve 2.0 mg of potassium dichromate in water to make exactly 10 mL.

(2) To 1.0 g of pulverized Gardenia Fruit add 20 mL of methanol, warm for 3 minutes on a water bath, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of geniposide for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and methanol (3:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 10 minutes: one spot among the spots from the sample solution and a dark purple spot from the standard solution show the same color tone and the same *Rf* value.

Total ash Not more than 6.0%.

Powdered Gardenia Fruit

Gardeniae Fructus Pulveratus

サンシシ末

Powdered Gardenia Fruit is the powder of Gardenia Fruit.

Description Powdered Gardenia Fruit occurs as a yellow-brown powder, and has a slight odor and a bitter taste.

Under a microscope, Powdered Gardenia Fruit reveals fragments of yellow-brown epidermis consisting of polygonal epidermal cells in surface view; unicellular hairs, spiral and ring vessels, stone cells often containing crystals of calcium oxalate; fragments of thin-walled parechyma containing yellow pigments, oil drops and rosette aggregates of calcium oxalate (the above elements from fruit receptacle and pericarp); fragments of large and thick-walled epidermis of seed coat, containing a red-brown substance; fragments of endosperm filled with aleuron grains (the above elements from seed).

Identification (1) To 1.0 g of Powdered Gardenia Fruit, previously dried in a desiccator (silica gel) for 24 hours, add 100 mL of hot water, warm the mixture between 60°C and 70°C for 30 minutes with frequent shaking, and filter after cooling. To 1.0 mL of the filtrate add water to make 10 mL: the color of the resulting solution is yellow and is not lighter than that of the following control solution.

Control solution: Dissolve 2.0 mg of potassium dichromate in water to make exactly 10 mL.

(2) To 1.0 g of Powdered Gardenia Fruit add 20 mL of methanol, warm for 3 minutes on a water bath, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of geniposide for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and methanol (3:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 10 minutes: one spot among the spots from the sample solution and a dark purple spot from the standard solution show the same in color tone and *Rf* value.

Total ash Not more than 6.0%.

Gas Gangrene Antitoxin, Equine

ガスえそウマ抗毒素

Gas Gangrene Antitoxin, Equine, is a liquid for injection containing *Clostridium perfringens* (*C. welchii*) Type A antitoxin, *Clostridium septicum* (*Vibrion septique*) antitoxin and *Clostridium oedematiens* (*C. novyi*) antitoxin in immunoglobulin of horse origin.

It may contain also *Clostridium histolyticum* antitoxin.

It conforms to the requirements of Gas Gangrene Antitoxin, Equine, in the Minimum Requirements for Biological Products.

Description Gas Gangrene Antitoxin, Equine, is a colorless to light yellow-brown, clear liquid or a slightly whitish turbid liquid.

Gelatin

ゼラチン

Gelatin is a product prepared from aqueous extract of raw collagen by heating. The raw collagen is obtained by acid or alkali treatment of the bone, skin, ligament or tendon of animals.

Description Gelatin occurs as colorless or white to light yellow-brown sheets, shreds, granules or powder. It is odorless and tasteless.

Gelatin is very soluble in hot water, and practically insoluble in ethanol (95) and in diethyl ether.

Gelatin does not dissolve in water, but slowly swells and softens when immersed in it, gradually absorbing water 5 to 10 times its own mass.

Gelatin derived from an acid-treated collagen exhibits an isoelectric point between pH 7.0 and 9.0, and Gelatin derived from an alkali-treated collagen exhibits an isoelectric point between pH 4.5 and 5.0.

Identification (1) To 5 mL of a solution of Gelatin (1 in 100) add chromium (VI) oxide TS or 2,4,6-trinitrophenol TS dropwise: a precipitate is formed.

(2) To 5 mL of a solution of Gelatin (1 in 5000) add tannic acid TS dropwise: the solution becomes turbid.

Purity (1) Foreign odor and water-insoluble substances—Dissolve 1.0 g of Gelatin in 40 mL of water by heating: the solution has no disagreeable odor. It is clear, or only slightly opalescent. The solution has no more color than Matching Fluid A.

(2) Sulfite—Take 20.0 g of Gelatin in a round-bottomed flask, dissolve in 150 mL of hot water, and add 3 to 5 drops of silicone resin, 5 mL of phosphoric acid and 1 g of sodium hydrogen carbonate. Attach a condenser, immediately distil the solution, immersing the end of the condenser into a receiver containing 50 mL of iodine TS, and continue the distillation until 50 mL of distillate is obtained. Acidify the distillate with 2 to 3 drops of hydrochloric acid, add 2 mL of barium chloride TS, and heat on a water bath until the color of iodine TS is discharged. Collect the precipitates, wash with water, and ignite: the mass of the residue is not more than 4.5 mg, but the mass of the residue obtained from Gelatin for use in the preparation of capsules and tablets is not more than 75 mg. Perform a blank determination, and make any necessary correction.

(3) Heavy metals—Proceed with 0.5 g of Gelatin according to Method 2, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 50 ppm).

(4) Arsenic—Take 15.0 g of Gelatin in a flask, add 60 mL of diluted hydrochloric acid (1 in 5), and heat until solution is effected. Add 15 mL of bromine TS, heat until the excess of bromine is expelled, neutralize with ammonia TS, add 1.5 g of disodium hydrogenphosphate 12-water, and allow to cool. To this solution add 30 mL of magnesia TS, allow to stand for 1 hour, and collect the precipitates. Wash the precipitates with five 10-mL portions of diluted ammonia TS (1 in 4), and dissolve in diluted hydrochloric acid (1 in 4) to make exactly 50 mL. Perform the test with 5 mL of this solution using Apparatus B: the solution has no more color than the following standard stain.

Standard stain: Proceed with 15 mL of Standard Arsenic Solution, instead of Gelatin, in the same manner (not more than 1 ppm).

(5) Mercury—Place 2.0 g of Gelatin in a decomposition flask, add 20 mL of diluted sulfuric acid (1 in 2) and 100 mL of a solution of potassium permanganate (3 in 50), heat gently under a reflux condenser, and boil for 2 hours. If the solution becomes clear during boiling, reduce the temperature of the solution to about 60°C, add further 5 mL of a solution of potassium permanganate (3 in 50), boil again, and repeat the above-mentioned procedure until the precipitate of manganese dioxide remains for about 20 minutes. Cool, add a solution of hydroxylammonium chloride (1 in 5) until the precipitate of manganese dioxide disappears, add water to make exactly 150 mL, and use the solution as the sample solution. Perform the test as directed under the Atomic Absorption Spectrophotometry (Cold vapor type) using the sample solution. Place the sample solution in a sample water bottle of the atomic absorption spectrophotometer, add 10 mL of tin (II) chloride-sulfuric acid TS, connect the bottle immediately to the atomic absorption spectrophotometer, and circulate air. Determine the absorbance A_T of the sample solution at 253.7 nm when the indication of the recorder has risen rapidly and become constant. On the other hand, place 2.0 mL of Standard Mercury Solution in a decomposition flask, add 20 mL of diluted sulfuric acid (1 in 2) and and 100 mL of a solution of potassium permanganate (3 in 50), and proceed in the same manner as for the sample solution. Determine the absorbance A_S of the standard solution: A_T is not more than A_S (not more than 0.1 ppm).

Loss on drying Not more than 15.0%. Take about 1 g of Gelatin, accurately weighed, in a tared 200-mL beaker containing 10 g of sea sand (No. 1) previously dried at 110°C for 3 hours. Add 20 mL of water, allow to stand for 30 minutes with occasional shaking, evaporate to dryness on a water bath with occasional shaking, and dry the residue at 110°C for 3 hours.

Residue on ignition Not more than 2.0% (0.5 g).

Containers and storage Containers—Tight containers.

Purified Gelatin

精製ゼラチン

Purified Gelatin is a product prepared from aqueous extract of raw collagen by heating. The raw collagen is obtained by acid or alkali treatment of the bone, skin, ligament, or tendon of animals.

Description Purified Gelatin occurs as colorless to light yellow sheets, shreds, pellets or powder. It is odorless and tasteless.

It is very soluble in hot water, and practically insoluble in ethanol (95) and in diethyl ether.

Purified Gelatin does not dissolve in water. It slowly swells and softens when immersed in water, and absorbs water 5 to 10 times its own mass.

Purified Gelatin derived from an acid-treated collagen has an isoelectric point at pH 7.0 to 9.0, and Purified Gelatin derived from an alkali-treated collagen has an isoelectric point at pH 4.5 to 5.0.

Identification (1) To 5 mL of a solution of Purified Gelatin (1 in 100) add chromium (VI) oxide TS or 2,4,6-trinitrophenol TS dropwise: a precipitate is formed.

(2) To 5 mL of a solution of Purified Gelatin (1 in 5000) add tannic acid TS dropwise: the solution becomes turbid.

Purity (1) Foreign odor and water-insoluble substances—Dissolve 1.0 g of Purified Gelatin in 40 mL of water by heating: the solution is clear, colorless and free from any disagreeable odor when the layer of the solution is 20 mm in depth.

(2) Sulfite—Take 20.0 g of Purified Gelatin in a round-bottomed flask, dissolve in 150 mL of hot water, and add 3 to 5 drops of silicone resin, 5 mL of phosphoric acid and 1 g of sodium hydrogen carbonate. Attach a condenser, immediately distil the solution, immersing the end of the condenser into a receiver containing 50 mL of iodine TS, and continue the distillation until 50 mL of distillate is obtained. Acidify the distillate by dropwise addition of hydrochloric acid, add 2 mL of barium chloride TS, and heat on a water bath until the color of iodine TS is discharged. Collect the precipitates, wash with water, and ignite: the mass of the residue is not more than 1.5 mg. Perform a blank determination, and make any necessary correction.