(2) Dissolve 0.15 g of β-Galactosidase (Penicillium) in 100 mL of water, filter if necessary, and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 278 nm and 282 nm.

Purity (1) Odor—β-Galactosidase (Penicillium) has no any rancid odor.

(2) Heavy metals—Proceed with 1.0 g of β-Galactosidase (Penicillium) 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).

(3) Arsenic—Prepare the test solution with 1.0 g of β-Galactosidase (Penicillium) according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Nitrogen—Weigh accurately about 0.1 g of β-Galactosidase (Penicillium), and perform the test as directed under the Nitrogen Determination: not more than 3 mg of nitrogen (N: 14.007) is found for each labeled 1000 Units.

(5) Protein contaminants—Dissolve 0.15 g of β-Galactosidase (Penicillium) in 4 mL of water, and use this solution as the sample solution. Perform the test with 15 μL of the sample solution as directed under the Liquid Chromatography according to the following conditions, and determine each peak area by the automatic integration method: the total area of the peaks other than the peak having retention time of about 19 minutes is not more than 75% of the total area of all peaks, and the areas of peaks other than the peaks having retention times of about 3, 16 and 19 minutes are not more than 15% of the total area of all peaks.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 280 nm).

Column: A stainless steel column about 7.5 mm in inside diameter and about 75 mm in length, packed with strongly acidic ion-exchange resin for liquid chromatography of sulfopropyl group-binding hydrophilic polymer (10 μm in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase: A solution obtained by dissolving 2.83 g of sodium acetate in 1000 mL of water, and adjusting to pH 4.5 with acetic acid (100) (mobile phase A), and a solution obtained by dissolving 29.2 g of sodium chloride in 1000 mL of mobile phase A (mobile phase B).

Flow system: Adjust a linear concentration gradient from the mobile phase A to the mobile phase B immediately after injection of the sample so that the retention times of non-retaining protein and the enzyme protein are about 3 minutes and 19 minutes, respectively, when the flow runs 0.8 mL per minute, and then continue the running of the mobile phase B.

Selection of column: Dissolve 15 mg of β-lactoglobulin in 4.5 mL of water, add 0.5 mL of a solution of cytosine (1 in 5000), and use this solution as the column-selecting solution. Proceed with 15 μL of the column-selecting solution under the above operating conditions, and calculate the resolution. Use a column giving elution of cytosine and β-lactoglobulin in this order with the resolution between these peaks being not less than 4.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of β-lactoglobulin from 15 μL of the column-selecting solution is between 5 cm and 14 cm.

Time span of measurement: About 1.4 times as long as the retention time of β-lactoglobulin.

Loss on drying Not more than 5.0% (0.5 g, in vacuum, phosphorus (V) oxide, 4 hours).

Residue on ignition Not more than 2.0% (1 g).

Assay (i) Substrate solution—Dissolve 0.603 g of 2-nitrophenyl-β-D-galactopyranoside in disodium hydrogenphosphate-citric acid buffer solution, pH 4.5 to make 100 mL.

(ii) Procedure—Weigh accurately about 0.15 g of β-Galactosidase (Penicillium), dissolve in water with thorough shaking to make exactly 100 mL, and allow to stand at room temperature for an hour. Pipet 2 mL of this solution, add disodium hydrogenphosphate-citric acid buffer solution, pH 4.5 to make exactly 100 mL, and use this solution as the sample solution. Transfer exactly 0.5 mL of the sample solution to a test tube, stand at 30 ± 0.1°C for 10 minutes, add exactly 0.5 mL of the substrate solution previously kept at 30 ± 0.1°C, then mix immediately, and stand at 30 ± 0.1°C for exactly 10 minutes. Then add exactly 1 mL of sodium carbonate TS, mix immediately to stop the reaction. To this solution add exactly 8 mL of water, mix, and use as the colored sample solution. Separately, pipet 0.5 mL of disodium hydrogenphosphate-citric acid buffer solution, pH 4.5, then proceed in the same manner as the sample solution, and use the solution so obtained as the colored blank solution. Perform the test with the colored sample solution and the colored blank solution as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank, and determine the absorbances, A_T and A_B, at 420 nm.

$$\text{Units per g of } \beta\text{-Galactosidase (Penicillium)} = \frac{A_T - A_B}{0.459} \times \frac{1}{10} \times \frac{1}{W}$$

0.459: Absorbance of 1 μmol/10 mL of *o*-nitrophenol

W: Amount (g) of the sample in 0.5 mL of the sample solution.

Unit: One unit indicates an amount of the enzyme which decomposes 1 μmol of 2-nitrophenyl-β-D-galactopyranoside in 1 minute under the above conditions.

Containers and storage Containers—Tight containers.

Gardenia Fruit

Gardeniae Fructus

サンシシ

Gardenia Fruit is the fruit of *Gardenia jasminoides* Ellis (*Rubiaceae*).

Description Nearly long ovoid to ovoid fruit, 1 - 5 cm in length, 1 - 1.5 cm in width; usually having 6, rarely 5 or 7, markedly raised ridges; calyx or its scar at one end, and sometimes peduncle at the other end; inner surface of pericarp yellow-brown, smooth and lustrous; internally divided into two loculi, containing a mass of seeds in yellow-red to dark red placenta; seed nearly circular, flat, about 0.5 cm in major axis, blackish brown or yellow-red. Odor, slight; taste, bitter.

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.