of starch TS). Perform a blank determination.

Each mL of 0.05 mol/L iodine VS = 1.5013 mg of CH_2O

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Formalin Water

ホルマリン水

Formalin Water contains not less than 0.9 w/v% and not more than 1.1 w/v% of formaldehyde (CH_2O: 30.03).

Method of preparation

Formalin	30 mL
Water or Purified Water	a sufficient quantity
To make	1000 mL

Prepare by mixing the above ingredients.

Description Formalin Water is a clear, colorless liquid. It has a slight odor of formaldehyde.
It is almost neutral.

Assay Transfer 20 mL of Formalin Water, measured exactly, to a 100-mL volumetric flask containing 2.5 mL of 1 mol/L sodium hydroxide VS, and add water to make 100 mL. Pipet 10 mL of this solution, and proceed as directed in the Assay under Formalin.

Each mL of 0.05 mol/L iodine VS = 1.5013 mg of CH_2O

Containers and storage Containers—Tight containers.

Forsythia Fruit

Forsythiae Fructus

レンギョウ

Forsythia Fruit is the fruit of *Forsythia suspensa* Vahl or *Forsythia viridissima* Lindley (*Oleaceae*).

Description Ovoid to long ovoid capsule, 1.5 - 2.5 cm in length, 0.5 - 1 cm in width, with acute apex, and sometimes with a peduncle at the base; externally light gray to dark brown, scattered with light gray and small ridged dots, and with two longitudinal furrows; a capsule dehiscing along the longitudinal furrows has the apexes bent backward; the inner surface of dehisced pericarp is yellow-brown in color, with a longitudinal partition-wall in the middle; seeds, slender and oblong, 0.5 - 0.7 cm in length, and usually with a wing. Odor, slight; tasteless.

Identification (1) To 0.2 g of pulverized Forsythia Fruit add 2 mL of acetic anhydride, shake well, allow to stand for 2 minutes, and filter. To 1 mL of the filtrate add gently 0.5 mL of sulfuric acid to form two layers: a red-purple color develops at the zone of contact.

(2) To 1 g of pulverized Forsythia Fruit add 10 mL of methanol, warm on a water bath for 2 minutes, and filter. To 5 mL of the filtrate add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow to stand: a light red to yellow-red color develops.

Purity (1) Branchlet—The amount of branchlets contained in Forsythia Fruit does not exceed 5.0%.

(2) Foreign matter—The amount of foreign matter other than branchlets contained in Forsythia Fruit does not exceed 1.0%.

Total ash Not more than 5.0%.

Extract content Dilute ethanol-soluble extract: not less than 10.0%.

Gambir

Gambir

アセンヤク

Gambir is the dried aqueous extract prepared from the leaves and young twigs of *Uncaria gambir* Roxburgh (*Rubiaceae*).

Description Brown to dark brown, brittle mass; inside light brown. Odor, slight; taste, extremely astringent and bitter.

Identification (1) To 0.2 g of pulverized Gambir add 10 mL of water, warm in a water bath for 5 minutes with occasional shaking, and filter. Cool the filtrate, and add 2 to 3 drops of gelatin TS: a white turbidity or precipitate is produced.

(2) Shake 0.1 g of pulverized Gambir with 20 mL of dilute ethanol for 2 minutes, and filter. Mix 1 mL of the filtrate with 9 mL of dilute ethanol, and to the solution add 1 mL of vanillin-hydrochloric acid TS: a light red to red-brown color develops.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.5%.

Extract content Dilute ethanol-soluble extract: not less than 70.0%.

Powdered Gambir

Gambir Pulveratum

アセンヤク末

Powdered Gambir is the powder of Gambir.

Description Powdered Gambir occurs as a red-brown to dark brown powder. It has a slight odor, and an extremely astringent and bitter taste.

Under a microscope, Powdered Gambir, immersed in olive oil or liquid paraffin, consists of needle crystalline masses or yellow-brown to red-brown angular fragments, and reveals epidermal tissue and thick-walled hairs.

Identification (1) To 0.2 g of Powdered Gambir add 10

mL of water, warm in a water bath for 5 minutes with occasional shaking, and filter. Cool the filtrate, and add 2 to 3 drops of gelatin TS: a white turbidity or precipitate is produced.

(2) Shake 0.1 g of Powdered Gambir with 20 mL of dilute ethanol for 2 minutes, and filter. Mix 1 mL of the filtrate with 9 mL of dilute ethanol, and to the solution add 1 mL of vanillin-hydrochloric acid TS: a light red to red-brown color develops.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.5%.

Extract content Dilute ethanol-soluble extract: not less than 70.0%.

β-Galactosidase (Aspergillus)

Aspergillus Galactosidase

β-ガラクトシダーゼ(アスペルギルス)

[*9031-11-2*]

β-Galactosidase (Aspergillus) contains an enzyme produced by *Aspergillus oryzae*. It is an enzyme drug having lactose decomposition activity, and contains 8000 to 12000 units per g. Usually, it is diluted with a mixture of maltose and dextrin, maltose and D-mannitol, or maltose, dextrin and D-mannitol.

Description β-Galactosidase (Aspergillus) occurs as a white to light yellow powder.

It is slightly soluble in water with a turbidity, and practically insoluble in ethanol (95) and in diethyl ether.

Identification (1) Dissolve 0.025 g of β-Galactosidase (Aspergillus) in 100 mL of water, then to 1 mL of this solution add 9 mL of lactose substrate TS, and stand at 30°C for 10 minutes. To 1 mL of this solution add 6 mL of glucose detection TS, and stand at 30°C for 10 minutes: a red to red-purple color develops.

(2) Dissolve 0.1 g of β-Galactosidase (Asperigillus) in 100 mL of water, and filter the solution if necessary. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

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

(2) Heavy metals—Proceed with 1.0 g of β-Galactosidase (Aspergillus) 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 (Aspergillus) according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 9.0% (0.5 g, in vacuum, 80°C, 4 hours).

Residue on ignition Not more than 3.0% (0.5 g).

Nitrogen content Weigh accurately about 0.07 g of β-Galactosidase (Aspergillus), and perform the test as directed under the Nitrogen Determination: the amount of nitrogen (N: 14.007) is between 0.5% and 5.0%, calculated on the dried basis.

Assay (i) Substrate solution: Dissolve 0.172 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 0.025 g of β-Galactosidase (Aspergillus), dissolve in water to make exactly 100 mL, then pipet 2 mL of this solution, add water to make exactly 50 mL, and use this solution as the sample solution. Take exactly 3.5 mL of the substrate solution, stand at 30 ± 0.1°C for 5 minutes, add exactly 0.5 mL of the sample solution, immediately mix, and stand at 30 ± 0.1°C for exactly 10 minutes, then add exactly 1 mL of sodium carbonate TS and mix immediately. Determine the absorbance, A_1, of this solution at 420 nm using water as the control. Separately, take exactly 3.5 mL of the substrate solution, add exactly 1 mL of sodium carbonate TS and mix, then add exactly 0.5 mL of the sample solution and mix. Determine the absorbance, A_2, of this solution in the same manner as above.

$$\text{Units per g of β-Galactosidase (Aspergillus)} = \frac{A_1 - A_2}{0.917} \times \frac{1}{0.5} \times \frac{1}{10} \times \frac{1}{W}$$

0.917: Absorbance of 1 μmol/ 5 mL of *o*-nitrophenol

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

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.

Storage—In a cold place.

β-Galactosidase (Penicillium)

β-ガラクトシダーゼ(ペニシリウム)

[*9031-11-2*]

β-Galactosidase (Penicillium) contains an enzyme, having lactose decomposition activity, produced by *Penicillium multicolor*. It contains not less than 8500 units and not more than 11,500 units in each g. Usually, it is diluted with D-mannitol.

Description β-Galactosidase (Penicillium) occurs as a white to pale yellowish white, crystalline powder or powder.

It is soluble in water with a turbidity, and practically insoluble in ethanol (95).

It is hygroscopic.

Identification (1) Dissolve 0.05 g of β-Galactosidase (Penicillium) in 100 mL of water, then to 0.2 mL of this solution add 0.2 mL of lactose substrate TS, and allow to stand at 30°C for 10 minutes. To this solution add 3 mL of glucose detection TS, and allow to stand at 30°C for 10 minutes: a red to red-purple color develops.