

Identification To 0.5 g of Powdered Fennel add 10 mL of hexane, allow to stand for 5 minutes with occasional shaking, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under the Thin-layer Chromatography. Spot 5 μ L of the sample solution on a plate prepared with silica gel with fluorescent indicator for thin-layer chromatography. Then develop the plate with a mixture of hexane and ethyl acetate (20:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a main spot with dark purple color appears at the *R_f* value of about 0.4.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 1.5%.

Essential oil content Perform the test with 50.0 g of Powdered Fennel as directed in Essential oil content under Crude Drugs: the volume of essential oil is not less than 0.45 mL.

Containers and storage Containers—Tight containers.

Fennel Oil

Oleum Foeniculi

ウイキョウ油

Fennel Oil is the essential oil distilled with steam from the fruit of *Foeniculum vulgare* Miller (*Umbeliferae*) or of *Illicium verum* Hooker fil. (*Illiciaceae*).

Description Fennel Oil is a colorless to pale yellow liquid. It has a characteristic, aromatic odor and a sweet taste with a slight, bitter aftertaste.

It is miscible with ethanol (95) and with diethyl ether.

It is practically insoluble in water.

When cold, white crystals or crystalline masses may often separate from the oil.

Identification Dissolve 0.30 g of Fennel Oil in 20 mL of hexane, pipet 1 mL of this solution, add hexane to make exactly 10 mL, and use this solution as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 5 μ L of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (20:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a main spot with a dark purple color appears at the *R_f* value of about 0.4.

Refractive index n_D^{20} : 1.528 – 1.560

Specific gravity d_{20}^{20} : 0.955 – 0.995

Purity (1) Clarity of solution—To 1.0 mL of Fennel Oil add 3 mL of ethanol (95): the solution is clear. To this solution add 7 mL of ethanol (95): the solution remains clear.

(2) Heavy metals—Proceed with 1.0 mL of Fennel Oil according to Method 2, and perform the test. Prepare the control solution with 4.0 mL of Standard Lead Solution (not more than 40 ppm).

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

Foeniculated Ammonia Spirit

アンモニア・ウイキョウ精

Method of preparation

Ammonia Water	170 mL
Fennel Oil	30 mL
Ethanol	a sufficient quantity
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	To make 1000 mL

Prepare as directed under Medicated Spirits, with the above ingredients. A sufficient quantity of ammonia solution (28) and Purified Water may be used in place of Ammonia Water.

Description Foeniculated Ammonia Spirit is a clear, pale yellow to yellow liquid, having a characteristic odor. It has a slightly sweet, pungent taste.

Specific gravity d_{20}^{20} : about 0.85

Alcohol number Not less than 7.8 (Method 2).

Containers and storage Containers—Tight containers.

Formalin

ホルマリン

Formalin contains not less than 35.0% and not more than 38.0% of formaldehyde (CH_2O : 30.03.)

It contains 5% to 13% of methanol to prevent polymerization.

Description Formalin is a clear, colorless liquid. Its vapor is irritating to the mucous membrane.

It is miscible with water and with ethanol (95).

When stored for a long time, especially in a cold place, it may become cloudy.

Identification (1) Dilute 2 mL of Formalin with 10 mL of water in a test tube, and add 1 mL of silver nitrate-ammonia TS: a gray precipitate is produced, or a silver mirror is formed on the wall of the test tube.

(2) To 5 mL of sulfuric acid in which 0.1 g of salicylic acid has been dissolved add 2 drops of Formalin, and warm the solution: a persistent, dark red color develops.

Purity Acid—Dilute 20 mL of Formalin with 20 mL of water, and add 5.0 mL of 0.1 mol/L sodium hydroxide VS and 2 drops of bromothymol blue TS: a blue color develops.

Residue on ignition Not more than 0.06 w/v% (5 mL, after evaporation).

Assay Weigh accurately a weighing bottle containing 5 mL of water, add about 1 g of Formalin, and weigh accurately again. Add water to make exactly 100 mL. Pipet 10 mL of this solution, add exactly 50 mL of 0.05 mol/L iodine VS and 20 mL of potassium hydroxide TS, and allow to stand for 15 minutes at an ordinary temperature. To this mixture add 15 mL of dilute sulfuric acid, and titrate the excess iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 1 mL

of starch TS). Perform a blank determination.

Each mL of 0.05 mol/L iodine VS = 1.5013 mg of CH₂O

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 (CH₂O: 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 CH₂O

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 apex bent backward; the inner surface of dehiscent 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