Xiao'er Fekie Keli

Reference to the peak of forsythin.

Reference solution Dissolve a quantity of forsythin CRS, accurately weighed, in methanol to produce a solution containing 0.1 mg of forsythin per ml.

Test solution Pulverize the contents obtained under the test of packing variation, weigh accurately about 2 g in a stoppered conical flask, add accurately 25 ml of methanol, stopper and weigh. Ultrasonicate (power 200 W, frequency 50 kHz) for 30 minutes. Allow to cool and weigh again, replenish the loss of weight with methanol, mix well and filter. Measure accurately 10 ml of the successive filtrate, evaporate to dryness, dissolve the residue with 5 ml of 70% ethanol, apply to a neutral aluminum oxide column (200-300 mesh, 2 g, 3.5 cm in diameter), elute with 95 ml of 70% ethanol, collect the eluates, evaporate to dryness, dissolve the residue with 5% methanol, transfer to 5 ml volumetric flask, dilute to volume with 50% methanol, mix well and filter, use the successive filtrate as the test solution.

Procedure Inject accurately 10 µl of each of the reference solution and test solution into the columns, determine and calculate the content.

It contains not less than 0.48 g of forsythin (C_{16}H_{22}O_{8}) per pack for [Strength (1) and (3)] and 1.16 g of forsythin (C_{16}H_{22}O_{8}) per pack for [Strength (2) and (4)], referred to Forsythia Extract.

Actions To disperse wind, release the exterior, clear heat and remove food stagnation.

Indications Pattern of wind-heat common cold with food stagnation, manifested as fever, cough, runny nose, runny tear, red and swollen throat, poor appetite, distention and fullness in the epigastrium and abdomen, constipation or loose stools, and deep yellow urination.

Administration and Dosage. Take the medicine orally after mixing it with hot water. 1.2 g per day for children between 6 months and 1 year old, 2-3 g per day for 1 to 3 year-old children, 3-4 g per day for 4 to 6 year-old children, 6-8 g per day for 7 to 9 year-old children, 6 g per day for children more than 10 years old. Three times a day.

Strength: (1) 2 g per pack, (2) 4 g per pack, (3) 2 g per pack (without sucrose), (4) 4 g per pack (without sucrose).

Storage Preserve in tightly closed containers.

Xiao'er Fekie Granules

Ingredients Gingseng Radix et Rhizoma 20 g, Poria 20 g, Macrocephala Rhinonia 8 g, Cinpi Pericarpium Reticulatum 20 g, Galli Gigeria Endothelium Cornum 20 g, Phleg Radix et Rhizoma (processed with wine) 12 g, Trionycis Carapax 20 g, Lythri Cortex 23 g, Glehniae Radix 30 g, Glycyrrhizae Radix et Rhizoma 12 g, Arthritini Auranti fructus 20 g, Phellodendri Cortex 39 g, Gentianos Rhinonia 8 g, Acuminati Lateralis Radix Preparata 8 g, Tribulosae Fructus 28 g, Farfarae Flav 20 g, Astri Radix et Rhizoma 30 g, Cortex Mori 28 g, Atractylis Cassie Bila 8 g, Astragali Radix 20 g, Lycii Fructus 20 g.

Procedure Decotum Astragali Radix, Lycii Cortex, Glehniae Radix, Ophiopogonis Radix, Glycyrrhizae Radix et Rhizoma, Artemisii Annuae Herba, Citromonii Ramulus, Trichocarpti Fructus, Astri Radix et Rhizoma et Coriistes Mori with water twice, 2 hours for each time, combine the decoctions, filter and concentrate to form a thin extract with a relative density of 1.20-1.30 (80°C), pulviscerate the other ingredients to fine powders, mix thoroughly with the above thin extract and an amount of sucrose, make granules dry and make to 5000 g.

Description Yellowish-brown to dark brown granules, taste, sweet.

Identification (1) Microscopic: Irregular branched masses coalesced, dissolved gradually on mounting in chloral hydrate solution, hypobasidia colorless or pale brown (Poria). Pollen granules spheroidal, 28-40 µm in diameter, showing spiny sculptures on the exine, spines, relatively sharp (Farfarae Flav). Stone cells of tissues irregular polygonal in surface view, anticlinal walls deep sinuous or slightly waved, with distinct striations (Lycii Fructus).

(2) Pulverize 50 g of the granules, add 120 ml of methanol, heat under reflux for 2 hours, filter, and evaporate the filtrate to dryness, dissolve the residue in 30 ml of 70% solution of sulfuric acid, and heat under reflux for 1 hour, extract with three 20-ml quantities of petroleum ether (80-90°C) by shaking, and combine the petroleum ether extract. Wash with three 20-ml quantities of water, combine the petroleum ether extract, evaporate to dryness, and dissolve the residue in 1 ml of dehydrated ethanol as the test solution. Prepare a solution with 1 g of Gingseng Radix et Rhizoma reference drug in 30 ml of methanol in the same manner as the reference drug solution. Dissolve, pass through CRS in ethanol to produce a solution containing 1 mg per ml as the reference solution. Carry out the method for thin layer chromatography (2052), using silica gel G as the mixing substance and a mixture of toluene and acetone (3:1) as the mobile phase. Apply separately 10 µl of each of the above solutions to the plate. After developing, remove the plate, dry in the air, Spray with a solution of sulfuric acid in ethanol (1:10), heat at 100°C to the spots clear, and examine separately in daylight and under ultraviolet light at 365 nm. The spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference drug solution and reference solution in daylight. Examine under ultraviolet light, the same fluorescent spots are shown.

(3) Pulverize 25 g of the granules, ultrasonicate in 50 ml of ethanol saturated with water for 30 minutes, filter, and wash the filtrate with three 20-ml quantities of water, and discard the washings. Evaporate the ethanol extract to dryness, and dissolve the residue in 1 ml of methanol as the test solution. Weight 0.5 g of Astragalos Rhinonia reference drug, decoct with water for 2 hours, filter, extract the filtrate with three 5-ml quantities of ethanol saturated with water by shaking, combine the ethanol extracts, evaporate the ethanol extract to dryness, and dissolve the residue in 1 ml of methanol as the reference drug solution. Carry out the method for thin layer chromatography (2052), using silica gel G as the mixing substance and a mixture of ethylacetate, acetone and formic acid (9:5:1) as the mobile phase. Apply separately 5 µl of each of the above two solutions to the plate. After developing, remove the plate, dry in the air. Examine under ultraviolet light at 365 nm. A blue fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the blue fluorescent spot in the chromatogram obtained with the
(4) Pulverize 10 g of the granules, add 30 ml of methanol, heat under reflux for 1 hour, filter, and evaporate the filtrate to dryness. Dissolve the residue in 4 ml of methanol, filter CMS in methanol, and use the filtrate as the test solution. Dissolve 1 mg per ml of reference solution. Carry out the method for thin layer chromatography (0502), using silica gel G as the coating substance and a mixture of chloroform, acetone, and methanol (80:15:5) as the mobile phase. Apply separately 5 μl of each of the above two solutions to the plate. After developing, remove the plate, dry in the air, and examine under ultraviolet light at 254 nm. The fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the fluorescent spots in the chromatogram obtained with the reference drug solution.

(5) Pulverize 10 g of the granules, ultrasonicate in 30 ml of chloroform for 20 minutes, filter, and evaporate the filtrate to dryness. Dissolve the residue in 1 ml of chloroform as the test solution. Weigh 0.5 g of Artemisia Annua Herba reference drug, decoct with water for 30 minutes, filter, and evaporate the filtrate to dryness, dissolve the residue in 20 ml of chloroform by stirring, filter, and evaporate the filtrate to dryness, and dissolve the residue in 1 ml of chloroform as the reference drug solution. Carry out the method for thin layer chromatography (0502), using silica gel G as the coating substance and a mixture of chloroform and methanol (68:32) as the mobile phase. Apply separately 5 μl of each of the above two solutions to the plate. After developing, remove the plate and dry in air. Examine under ultraviolet light at 365 nm. A blue fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the blue fluorescent spot in the chromatogram obtained with the reference drug solution.

(6) Pulverize 5 g of the granules, ultrasonicate in 20 ml of methanol for 20 minutes, filter, and evaporate the filtrate to dryness. Dissolve the residue in 10 ml of water, add 1 ml of hydrochloric acid, heat or water bath for 30 minutes, cool immediately, extract with two 20-ml quantities of ether by shaking, and combine the ether extracts. Evaporate the ether extract to dryness, and dissolve the residue in 1 ml of chloroform as the test solution. Prepare a solution with 0.1 g of Rhodiola Rosea reference drug solution in the same manner as the reference drug solution. Evaporate emden CMS in methanol to produce a solution containing 1 mg per ml as the reference solution. Carry out the method for thin layer chromatography (0502), using silica gel G as the coating substance and a mixture of petroleum ether (30-60° C), ethyl formate, and formic acid (80:15:5) as the mobile phase. Apply separately 3 μl of each of the above three solutions to the plate. After developing, remove the plate and dry in air. Examine under ultraviolet light at 365 nm. Five orange fluorescent spots in the chromatograms obtained with the test solution correspond in position and colour to the fluorescent spots in the chromatogram obtained with the reference drug solution. The orange fluorescent spot in the chromatogram obtained with the test solution corresponds in position and colour to the orange fluorescent spot in the chromatogram obtained with the reference solution. Upon exposure to ammonia vapour, the spot turns red in daylight.

(7) Pulverize 50 g of the granules, ultrasonicate in 100 ml of methanol for 1 hour, filter, and evaporate the filtrate to dryness. Dissolve the residue in 50 ml of water, extract with four 50-ml quantities of ethyl acetate by shaking, and combine the ethyl acetate extract. Evaporate the ethyl acetate extract to dryness, and dissolve the residue in 1 ml of methanol as the test solution. Weigh 1 g of Parafarine Flos reference drug, add 20 ml of methanol, ultrasonicate for 30 minutes, filter, and concentrate the filtrate to 1 ml as the reference drug solution. Carry out the method for thin layer chromatography (0502), using silica gel G as the coating substance and a mixture of petroleum ether (60-80° C) and acetone (4:1) as the mobile phase. Apply separately 5 μl of each of the above two solutions to the plate. After developing, remove the plate, dry in the air, and examine under ultraviolet light at 254 nm. The fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the fluorescent spots in the chromatogram obtained with the reference drug solution.

Limit test for acetonitrile: Pulverize a quantity of the containing to fine powder, weigh 0.5 g of the powder to a stoppered conical flask, add 10 ml of concentrated ammonia TS, add 80 ml of chloroform, ultrasonicate for 30 minutes, filter, and evaporate the filtrate to dryness. Dissolve the residue in 30 ml 3% solution of sulfuric acid, extract the filtrate with three 40 ml quantities of chloroform solution, adjust pH of the water layer to 10 with concentrated ammonia TS, and extract with five 30-ml quantities of chloroform. Combine and recover solvents, dissolve the residue with a quantity of chloroform, transfer to a 2 ml volumetric flask, dilute to the volume and mix well as the test solution. Dissolve acetonitrile CRS in chloroform to produce a solution containing 1.5 mg per ml as the reference solution. Carry out the method for thin layer chromatography (0502), using silica gel G as the coating substance and a mixture of cyclohexane, ethyl acetate and methanol (64:4:3) as the mobile phase. Apply separately 5 μl of each of the above two solutions to the plate. After developing, remove the plate, dry in air, spray with diluted solution of potassium iodide solution, and examine under ultraviolet light at 254 nm. The fluorescent spots in the chromatogram obtained with the test solution are smaller or no in position and colour than the spots in chromatogram obtained with the reference solution.

Other requirements: Comply with the general requirements for granules (0104).

Assay: Carry out the method for high performance liquid chromatography (0512).

Chromatographic systems and system suitability: Use octadecylamino bonded silica gel as the stationary phase and a mixture of methanol and 5% acetic acid solution (3:17) as the mobile phase. As a detector, a spectrophotometer set at 283 nm. The number of theoretical plates of the column is...