

(3) Ammonia-coloring substances—Mix 1.0 g of Honey with 2.0 mL of water, and filter. To the filtrate add 2 mL of ammonia TS: the solution does not change immediately.

(4) Resorcinol-coloring substances—Mix well 5 g of Honey with 15 mL of diethyl ether, filter, and evaporate the diethyl ether solution at ordinary temperature. To the residue add 1 to 2 drops of resorcinol TS: a yellow-red color may develop in the solution of resorcinol and in the residue, and a red to red-purple color which does not persist more than 1 hour.

(5) Starch or dextrin—(i) Shake 7.5 g of Honey with 15 mL of water, warm the mixture on a water bath, and add 0.5 mL of tannic acid TS. After cooling, filter, and to 1.0 mL of the filtrate add 1.0 mL of ethanol (99.5) containing 2 drops of hydrochloric acid: no turbidity is produced.

(ii) To 2.0 g of Honey add 10 mL of water, warm in a water bath, mix, and allow to cool. Shake 1.0 mL of the mixture with 1 drop of iodine TS: no blue, green or red-brown color develops.

(6) Foreign matter—Mix 1.0 g of Honey with 2.0 mL of water, centrifuge the mixture, and examine the precipitate microscopically: no foreign substance except pollen grains is observable.

Total ash Not more than 0.4%.

Containers and storage Containers—Tight containers.

Houttuynia Herb

Houttuynia Herba

ジュウヤク

Houttuynia Herb is the terrestrial part of *Houttuynia cordata* Thunberg (*Saururaceae*), collected during the flowering season.

Description Stem with alternate leaves and spikes; stem light brown, with longitudinal furrows and protruded nodes; when soaked in water and smoothed out, leaves wide ovate and cordate, 3–8 cm in length, 3–6 cm in width; light green-brown; margin entire, apex acuminate; petiole long, and membranous stipule at the base; spike, 1–3 cm in length, with numerous light yellow-brown achrilamyeous florets, and the base enclosed by 4 long ovate, light yellow to light yellow-brown involucre. Odor, slight; tasteless.

Identification Boil 2 g of pulverized Houttuynia Herb with 20 mL of ethyl acetate under a reflux condenser on a water bath for 15 minutes, and filter. Evaporate the filtrate to dryness, add 10 mL of water to the residue, warm the mixture on a water bath for 2 minutes, and, after cooling, filter. Shake well the filtrate with 20 mL of ethyl acetate in a separator, take 15 mL of ethyl acetate solution, and evaporate the solution on a water bath to dryness. Dissolve the residue in 5 mL of methanol, add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow the mixture to stand: a light red to red color develops.

Purity Foreign matter—The amount of the rhizome, roots and other foreign matter contained in Houttuynia Herb does not exceed 2.0%.

Total ash Not more than 14.0%.

Acid-insoluble ash Not more than 3.0%.

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

Hydrochloric Acid Lemonade

塩酸リモナーデ

Method of preparation

| | |
|--------------------------|-----------------------|
| Dilute Hydrochloric Acid | 5 mL |
| Simple Syrup | 80 mL |
| Purified Water | a sufficient quantity |
| To make 1000 mL | |

Prepare before use as directed under Lemonades, with the above ingredients.

Description Hydrochloric Acid Lemonade is a clear, colorless liquid. It has a sweet, cool, acid taste.

Containers and storage Containers—Tight containers.

Hydrocortisone and Diphenhydramine Ointment

ヒドロコルチゾン・ジフェンヒドรามミン軟膏

Method of preparation

| | |
|------------------------|-----------------------|
| Hydrocortisone Acetate | 5 g |
| Diphenhydramine | 5 g |
| White Petrolatum | a sufficient quantity |
| To make 1000 g | |

Prepare as directed under Ointments, with the above ingredients.

Description Hydrocortisone and Diphenhydramine Ointment is white to pale yellow in color.

Identification (1) To 1 g of Hydrocortisone and Diphenhydramine Ointment add 10 mL of ethanol (95), heat on a water bath for 5 minutes with occasional shaking, cool, and filter. Take 5 mL of the filtrate, distill off the ethanol, and to the residue add 2 mL of sulfuric acid: the solution shows a yellow-green fluorescence immediately and the color of the solution gradually changes through yellow to yellow-brown. Add carefully 10 mL of water to this solution: the color changes to yellow with green fluorescence, and a light yellow, flocculent precipitate is formed (hydrocortisone acetate).

(2) To 1 mL of the filtrate obtained in (1) add 5 mL of potassium hydrogen phthalate buffer solution, pH 4.6, and 2 mL of bromophenol blue TS, and add further 5 mL of chloroform. Shake well, and allow to stand: a yellow color develops in the chloroform layer (diphenhydramine).

(3) To 1 g of Hydrocortisone and Diphenhydramine Ointment add 5 mL of methanol, warm, and shake. After cooling, separate the methanol layer, and use this layer as the

sample solution. Dissolve 0.01 g each of hydrocortisone acetate and diphenhydramine in 10 mL each of methanol, and use these solutions as standard solutions (1) and (2). Perform the test with the sample solution and standard solutions (1) and (2) as directed under the Thin-layer Chromatography. Spot 5 μ L each of these solutions on a plate of silica gel with a complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and diethyl ether (4:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (broad spectrum wavelength): two spots from the sample solution show the same *R_f* value as the corresponding spots from standard solutions (1) and (2).

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

Hydrogenated Oil

硬化油

Hydrogenated Oil is the fat obtained by hydrogenation of fish oil or of other oils originating from animal or vegetable.

Description Hydrogenated Oil occurs as a white mass or powder and has a characteristic odor and a mild taste.

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

The oil obtained by hydrogenation of castor oil is slightly soluble in diethyl ether, very slightly soluble in ethanol (95), and practically insoluble in water.

Acid value Not more than 2.0.

Purity (1) Moisture and coloration—Hydrogenated Oil (5.0 g), melted by heating on a water bath, forms a clear liquid, from which no water separates. In a 10-mm thick layer of the liquid, it is colorless or slightly yellow.

(2) Alkali—To 2.0 g of Hydrogenated Oil add 10 mL of water, melt by heating on a water bath, and shake vigorously. After cooling, add 1 drop of phenolphthalein TS to the separated water layer: no color develops.

(3) Chloride—To 1.5 g of Hydrogenated Oil add 30 mL of ethanol (95), boil for 10 minutes under a reflux condenser, and filter after cooling. To 20 mL of the filtrate add 5 drops of a solution of silver nitrate in ethanol (95) (1 in 50): the turbidity of the solution does not exceed that of the following control solution.

Control solution: To 1.0 mL of 0.01 mol/L hydrochloric acid VS add ethanol (95) to make 20 mL, then add 5 drops of a solution of silver nitrate in ethanol (95) (1 in 50).

(4) Heavy metals—Heat 2.0 g of Hydrogenated Oil with 5 mL of dilute hydrochloric acid and 10 mL of water on a water bath for 5 minutes with occasional shaking. After cooling, filter, and make 5 mL of the filtrate weakly alkaline with ammonia TS, then add 3 drops of sodium sulfide TS: the solution remains unchanged.

(5) Nickel—Place 5.0 g of Hydrogenated Oil in a quartz or porcelain crucible, heat slightly with caution at the beginning, and, after carbonization, incinerate by strong heating ($500 \pm 20^\circ\text{C}$). Cool, add 1 mL of hydrochloric acid,

evaporate on a water bath to dryness, dissolve the residue in 3 mL of dilute hydrochloric acid, and add 7 mL of water. Then add 1 mL of bromine TS and 1 mL of a solution of citric acid monohydrate (1 in 5), make alkaline with 5 mL of ammonia TS, and cool in running water. To this solution add 1 mL of dimethylglyoxime TS, add water to make 20 mL, and use this solution as the test solution. Allow to stand for 5 minutes: the solution has no more color than the following control solution.

Control solution: Evaporate 1 mL of hydrochloric acid on a water bath to dryness, add 1 mL of Standard Nickel Solution and 3 mL of dilute hydrochloric acid, and add 6 mL of water. Then proceed as directed in the test solution, add water to make 20 mL, and allow to stand for 5 minutes.

Residue on ignition Not more than 0.10% (5 g).

Containers and storage Containers—Well-closed containers.

Hydrophilic Ointment

親水軟膏

Method of preparation

| | |
|---|-----------------------|
| White Petrolatum | 250 g |
| Stearyl Alcohol | 200 g |
| Propylene Glycol | 120 g |
| Polyoxyethylene hydrogenated castor oil 60 | 40 g |
| Glycerin Monostearate | 10 g |
| Methyl Parahydroxybenzoate | 1 g |
| Propyl Parahydroxybenzoate | 1 g |
| Purified Water | a sufficient quantity |

To make 1000 g

Melt White Petrolatum, Stearyl Alcohol, polyoxyethylene hydrogenated castor oil 60 and Glycerin Monostearate by heating on a water bath, stir, and keep temperature of the mixture at about 75°C . To Propylene Glycol add Methyl Parahydroxybenzoate and Propyl Parahydroxybenzoate, melt by warming if necessary, dissolve in Purified Water, and warm to about 75°C . Add this solution to the above mixture, stir to form emulsion, cool, and stir thoroughly until it congeals.

Description Hydrophilic Ointment is white in color. It has a slight, characteristic odor.

Containers and storage Containers—Tight containers.

Hydroxypropylcellulose

ヒドロキシプロピルセルロース

Hydroxypropylcellulose is a hydroxypropyl ether of cellulose.

Hydroxypropylcellulose, when dried, contains not less than 53.4% and not more than 77.5% of hydrox-