

1. Reagents and Test Solutions

P-Bridged Cellulose Cation-exchanger (-O·PO₃H₂ Type), Strongly Acidic Use strongly acidic cation-exchanger strengthened with bridging porous cellulose and introduced phosphoryl group.

Palladium Nitrate Pd(NO₃)₂ (Guaranteed)

Palladium Nitrate TS Add 10 ml of diluted nitric acid (1 : 2) to 0.108 g of palladium nitrate, add water to make exactly 500 ml. Measure exactly 20 ml of this solution, add water to make exactly 200 ml.

Paraffin, Liquid Use light liquid paraffin specified under the Japanese Pharmacopoeia.

Partial Hydrolyzed Saponin for Assay Partially Hydrolyzed Saponin for Assay occurs as white crystals having slightly odor.

Content: Partial Hydrolyzed Saponin for Assay, when dried, contains not less than 96.0 % of partial hydrolyzed saponin (C₄₇H₇₂O₂₀ = 956.5).

Identification: Proceed as directed in the Potassium Bromide Disk Method under Infrared Spectrophotometry. Partial Hydrolyzed Saponin for Assay exhibits absorbance at about 3,240 cm⁻¹, 2,920 cm⁻¹, 1,640 cm⁻¹, 1,150 cm⁻¹, 1,080 cm⁻¹, and 1,020 cm⁻¹.

Loss on Drying: Not more than 2.0 % (105 °C, 3 hours)

Assay: Dissolve 0.010g of Partial Hydrolyzed Saponin for Determination into a mixture of 0.1% phosphoric acid - acetonitrile (65 : 35), and use this solution as the test solution. Use 20 μl of the test solution, perform the Liquid Chromatography under the conditions given below, and measure the each peak area with the automatic integration method. Calculate the ratio of the peak area of the main peak appearing about 10 minutes after the solvent peak appears to the total of (as 100%) the peak areas of all peaks appearing within 30 minutes after the solvent peak appears.

Operating conditions

Detector: Detector for absorbances in the ultraviolet region (determination wavelength: 210 nm).

Packing material of column: 5- to 10-μm octadecylsilanized silica gel.

Column: A stainless steel pipe 4 - 6 mm in internal diameter and 15 - 30 cm in length.

Column temperature: 40 °C.

Mobile phase: Mixture of 0.1% phosphoric acid and acetonitrile (65 : 35)

Flow rate: Adjust the flow rate so that the retention time of partial hydrolyzed saponin can be about 10 minutes.

Peptone Use a product made for the Microbial Limit Tests.

Peptone, Casein Peptone, Casein occurs as a grayish-yellow powder. It has a characteristic but non-putrescent odor. It is soluble in water, but insoluble in ethanol and diethyl ether.

Loss on Drying: Not more than 7% (0.5 g, 105 °C, constant weight).

Residue on Ignition: Not more than 15% (0.5 g).

Degree of Digestion: Dissolve 1 g of Peptone, Casein in 10 ml of water, use the solution as the sample solution, and proceed following tests:

(1) Overlay 1 ml of the sample solution with 0.5 ml of a liquid prepared by 10 ml of a mixture of ethanol and water (1 : 1) and 1 ml of acetic acid. No ring or precipitate is formed at the junction of the two liquids, and when the liquid is shaken, no turbidity appears.

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(2) To 1 ml of the sample solution, add 4 ml of a saturated solution of zinc sulfate. A small quantity of precipitate is produced. (Proteose).

(3) Filter the mixed solution prepared under test (2). To 1 ml of the filtrate, add 3 ml of water and 4 drops of Bromine TS. The solution develops a red-violet color.

Content of Nitrogen: Not less than 10% (105, constant weight, after drying, Nitrogen Determination)

Peptone, Gelatin Prepared for the Microbiological Tests.

Peptone, Meat Prepared for the Microbiological Tests.

Peptone, Soybean Prepared for the Microbiological Tests.

Perchloric Acid HClO_4 [Perchloric Acid, Guaranteed]

Periodic Acid $\text{HIO}_4 \cdot 2\text{H}_2\text{O}$ (Periodic Acid Dihydrate, Guaranteed)

Petroleum Benzine (Guaranteed)

Petroleum Ether (Guaranteed)

Petroleum Ether for Vitamin A Determination Petroleum Ether for Vitamin A Determination is the fraction of petroleum ether distilled at 40.0 - 60.0 °C.

1,10-Phenanthroline Monohydrate $\text{C}_{12}\text{H}_8\text{N}_2 \cdot \text{H}_2\text{O}$ (Guaranteed)

***o*-Phenanthroline** $\text{C}_{12}\text{H}_8\text{N}_2 \cdot \text{H}_2\text{O}$ [1,10-Phenanthroline Monohydrate (*o*-Phenanthroline), Guaranteed]

***o*-Phenanthroline TS** Weigh 0.15 g of *o*-phenanthroline, and dissolve in 10 ml of freshly prepared iron(II) sulfate solution (37, 2,500). Prepare freshly before use.

Phenol $\text{C}_6\text{H}_5\text{OH}$ (Guaranteed)

Phenol Red $\text{C}_{19}\text{H}_{14}\text{O}_5\text{S}$ (Guaranteed)

Phenol Red TS Weigh 0.1 g of phenol red, and dissolve in 100 ml of ethanol. Filter if necessary.

Phenolphthalein $\text{C}_{20}\text{H}_{14}\text{O}_4$ (Guaranteed)

Phenolphthalein TS Weigh 1 g of phenolphthalein, and dissolve in 100 ml of ethanol.

1-Phenyl-3-methyl-5-pyrazolone $\text{C}_{10}\text{H}_{10}\text{N}_2\text{O}$ (1-Phenyl-3-methyl-5-pyrazolone)

***p*-Phenylenediamine, Hydrochloride** $\text{C}_6\text{H}_4(\text{NH}_2)_2 \cdot 2\text{HCl}$ *p*-Phenylenediamine Hydrochloride occurs as a white to light yellow or white to light red crystalline powder. It is freely soluble in water.

Clarity of solution: Clear (1.0 g, water 10 ml).

Molecular absorption coefficient: Weigh 60 mg of *p*-Phenylenediamine Hydrochloride, and dissolve in 100 ml of water. Measure 1.0 ml of the solution, and add phosphate buffer (pH 7) to make 50 ml. Determine the absorbance of this solution at a wavelength of 237 - 241 nm, using phosphate buffer (pH 7) as the reference solution. The molecular absorption coefficient is not less than 8,000.

Phenylhydrazine $\text{C}_6\text{H}_5\text{NHNH}_2$ (Guaranteed)

Phenylhydrazine Hydrochloride $\text{C}_6\text{H}_5\text{NHNH}_2 \cdot \text{HCl}$ [Phenylhydrazinium Chloride (Phenylhydrazine Hydrochloride), Guaranteed]

Phenylhydrazine Hydrochloride - Sodium Acetate TS Weigh 0.5 g of phenylhydrazine hydrochloride, and dissolve in 10 ml of sodium acetate solution (2, 15). Filter if necessary. Prepare freshly before use.

***p*-Phenylphenol** $\text{C}_6\text{H}_5\text{C}_6\text{H}_4\text{OH}$ *p*-Phenylphenol occurs as white crystals which tend to sublimate. It is soluble in ethanol, ether, and chloroform, and slightly soluble in petroleum ether.

Melting point: 163 - 167 °C.

Water content: Not more than 0.2%.

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Residue on ignition: Not more than 0.20%.

***p*-Phenylphenol TS** Weigh 0.75 g of *p*-phenylphenol, and dissolve in 50 ml of sodium hydroxide solution (1 : 25). Filter if necessary. Prepare freshly before use.

Phosphate Buffer (pH 6.8) Weigh 3.40 g of monopotassium phosphate and 3.55 g of anhydrous disodium phosphate, mix, and dissolve in water to make 1,000 ml.

Phosphate Buffer (pH 7)

Solution 1: Weigh 27.218 g of monopotassium phosphate for pH determination, and dissolve in water to make 1,000 ml.

Solution 2: Use 0.2 mol/l sodium hydroxide.

Mix 50.0 ml of Solution 1 and 29.54 ml of Solution 2, and add water to make 200 ml.

Phosphate Buffer (pH 7.5)

Solution 1: Weigh 53.7 g of disodium phosphate, and dissolve in water to make 1,000 ml.

Solution 2: Weigh 20.4 g of monopotassium phosphate, and dissolve in water to make 1,000 ml.

Mix 21 parts Solution 1 and 4 parts Solution 2 by volume, and adjust the pH to 7.5 using both solutions.

Phosphate Buffer (pH 7.6)

Solution 1: Weigh 4.54 g of monopotassium phosphate, and dissolve in water to make 500 ml.

Solution 2: Weigh 4.73 g of anhydrous disodium phosphate, and dissolve in water to make 500 ml.

Mix 13 parts Solution 1 and 87 parts Solution 2 by volume, and adjust the pH to 7.6 using both solutions.

Phosphate Buffer (pH 8)

Solution 1: Weigh 23.88 g of anhydrous disodium phosphate, and dissolve in water to make 1,000 ml.

Solution 2: Weigh 9.07 g of monopotassium phosphate, and dissolve in water to make 1,000 ml.

Mix 50 parts Solution 1 and 1 and 7 parts Solution 2 by volume, and adjust the pH to 8 using both solutions.

Phosphomolybdic Acid $P_2O_5 \cdot 24MoO_3 \cdot nH_2O$ (Guaranteed)

Phosphoric Acid H_3PO_4 (Guaranteed)

Phosphorus Trichloride PCl_3 (Guaranteed)

Phthalic Acid $C_8H_6O_4$ Phthalic Acid occurs as a white crystalline powder and is easily soluble in methanol but hardly soluble in water or ether.

Content: Phthalic Acid contains not less than 99.0% of phthalic acid ($C_8H_6O_4$).

Purity: Other Aromatic Compounds Weigh 10.0 mg of Phthalic Acid, dissolve in 30 ml of methanol, and add diluted acetic acid (1 : 100) to make exactly 100 ml. Measure 10.0 ml of this solution, add mixture of diluted acetic acid (1 : 100) and methanol (7 : 3) to make exactly 100 ml and perform Liquid Chromatography under the operating conditions specified in Purity (6) for Benzoic Acid in the Monographs, JSFA- . Only one peak of phthalic acid is observed.

Assay: Weigh accurately about 2 g of Phthalic Acid, dissolve in 50 ml of neutralized ethanol, and titrate with 0.1 mol/l sodium hydroxide (indicator: a few drops of phenolphthalene TS).

1 ml of 0.1 mol/l sodium hydroxide = 8.307 mg $C_8H_6O_4$.

Phthalic Anhydride $C_6H_4(CO)_2O$ (Guaranteed)

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Picric Acid See 2,4,6-Trinitrophenol.

Polyethylene Glycol 20M Use Polyethylene Glycol 20M for Gas Chromatography specified under the Japanese Pharmacopoeia.

Polyethylene Glycol 6,000 Use Macrogol 6,000 specified under the Japanese Pharmacopoeia.

Polysorbate 20 Polysorbate 20 is mainly obtained by addition polymerization of sorbitane monolaurate with ethylene oxide. Polysorbate 20 occurs as a pale yellow to yellow liquid having a slight characteristic odor.

Identification: (1) To 0.5 g of Polysorbate 20, add 10 ml of water and 10 ml of sodium hydroxide TS, and boil for 5 minutes. Acidify with dilute hydrochloric acid, and oily materials are separated.

(2) To 0.5 g of Polysorbate 20, add 10 ml of water, shake, and add 5 drops of bromine TS. The red color of the solution is not disappeared.

(3) Weigh 5 g of Polysorbate 20, saponify as directed under the Fats and Related Substances Tests. Use 50 ml of ethanolic potassium hydroxide TS for saponification. Evaporate ethanol well. Add 50 ml of water, and dissolve the residue. Acidify with hydrochloric acid (methyl orange), extract twice with 30 ml of ether each. Combine the extracts, wash repeatedly with 20 ml of water until the washing becomes neutral. Evaporate ether on the water bath. Acid value of the residue is 275 - 285.

Acid value: Not more than 4.0.

Saponification value: 43 - 55.

Loss on Drying: Not more than 3.0 (5 g, 105 °C, 1 hour).

Residue on Ignition: Not more than 1.0%.

Weigh accurately 3 g of Polysorbate 20, heat gently at first, then gradually ignite (800 - 1200 °C), and incinerate well. If carbonized material remains, add hot water and leach. Filter using filter paper for quantitative analysis (No. 5 C). Ignite the residue together with the filter paper. Add filtrate to it, and evaporate to dryness. Ignite carefully until the carbonized material disappears. When carbonized material still remains, add 15 ml of ethanol, break the carbonized materials with glass rod, burn ethanol, and then re-ignite carefully. Allow to cool in a desiccator (silica gel), and weigh accurately.

Polysorbate 80 Use Polysorbate 80 specified under the Japanese Pharmacopoeia.

Porous Anion-exchanger Use a product made for Ion Chromatography.

Potassium Acetate CH_3COOK (Guaranteed)

Potassium Aluminum Sulfate $\text{AlKSO}_4 \cdot 12\text{H}_2\text{O}$ (Guaranteed)

Potassium Benzylpenicillin $\text{C}_{16}\text{H}_{17}\text{KN}_2\text{O}_4\text{S}$ Use Potassium benzylpenicillin specified under the Japanese Pharmacopoeia.

Potassium Bromate KBrO_3 (Guaranteed)

Potassium Bromate - Potassium Bromide TS Weigh 1.4 g of potassium bromate and 8.1 g of potassium bromide, mix, and dissolve in water to make 100 ml.

Potassium Bromide KBr (Guaranteed)

Potassium Bromide for Infrared Absorption Spectrophotometry A powder prepared by the following manner: Crush single crystals of potassium bromide or potassium bromide, and pass through a 74- μm standard sieve. Dry the resulting powder at 120 °C for 10 hours or at 500 °C for 5 hours. The infrared spectrum of a disk prepared with this powder shows no characteristic absorption.

Potassium Carbonate, Anhydrous K_2CO_3 [Potassium Carbonate (Anhydrous), Guaranteed]

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- Potassium Chlorate** KClO_3 (Guaranteed)
- Potassium Chloride** KCl (Guaranteed)
- Potassium Chloride - Hydrochloric Acid TS** Weigh 250 g of potassium chloride, and dissolve in 8.5 ml of hydrochloric acid and 750 ml of water.
- Potassium Chromate** K_2CrO_4 (Guaranteed)
- Potassium Cyanide** KCN (Guaranteed)
- Potassium Dichromate** $\text{K}_2\text{Cr}_2\text{O}_7$ (Guaranteed)
- Potassium Dichromate (Standard reagent)** $\text{K}_2\text{Cr}_2\text{O}_7$ (Standard reagent)
- Potassium Ferricyanide** See Potassium Hexacyanoferrate().
- Potassium Ferrocyanide** See Potassium Hexacyanoferrate().
- Potassium Hexacyanoferrate ()** $\text{K}_4\text{Fe}(\text{CN})_6 \cdot 3\text{H}_2\text{O}$ (Guaranteed)
- Potassium Hexacyanoferrate ()** $\text{K}_3[\text{Fe}(\text{CN})_6]$ (Guaranteed)
- Potassium Hexahydroxo Antimonate (V)** $\text{K}[\text{Sb}(\text{OH})_6]$ (Extra grade)
- Potassium Hydrogen Phthalate** $\text{C}_6\text{H}_4(\text{COOK})(\text{COOH})$ (Guaranteed)
- Potassium Hydrogen Phthalate for pH Determination** $\text{C}_6\text{H}_4(\text{COOK})(\text{COOH})$
(For pH determination)
- Potassium Hydrogen Pyroantimonate** See Potassium Hexahydroxo Antimonate(V).
- Potassium Hydrogen Pyroantimonate TS** Weigh 2 g of potassium hydrogen pyroantimonate, add 100 ml of water, boil for about 5 minutes, and cool quickly. Add 10 ml of potassium hydroxide solution (3 20), allow to stand for 24 hours, and filter.
- Potassium Hydrogen Sulfate** KHSO_4 [Potassium Hydrogen Sulfate (Acid Potassium Sulfate), Guaranteed]
- Potassium Hydroxide** KOH (Guaranteed)
- Potassium Hydroxide TS, Ethanolic** Weigh 35 g of potassium hydroxide, dissolve in 20 ml of water, and add ethanol to make 1,000 ml. Stopper tightly, and store.
- 10% Potassium Hydroxide TS, Ethanolic** Weigh 10 g of potassium hydroxide, and dissolve in ethanol to make 100 ml. Prepare freshly before use.
- 35% Potassium Hydroxide TS, Methanolic** Weigh 35 g of potassium hydroxide, dissolve in 25 ml of water, and add methanol to make 100 ml.
- Potassium Iodate (Standard reagent)** KIO_3 (Standard reagent)
- Potassium Iodate TS** Weigh 7.1 g of potassium iodate (standard reagent), and dissolve in water to make 1,000 ml. Store protecting from light.
- Potassium Iodide** KI (Guaranteed)
- Potassium Iodide TS** Weigh 16.5 g of potassium iodide, and dissolve in water to make 100 ml. Store, protecting from light.
- Potassium Iodide - Starch Paper** Immerse a piece of filter paper in potassium iodide - starch TS, freshly prepared, and dry the filter paper in clean room. Store in a bottle with a ground-glass stopper, protecting from light and moisture.
- Potassium Iodide - Starch TS** Weigh 0.5 g of starch, add 50 to 60 ml of water, dissolve while heating, and dissolve 0.5 g of potassium iodide and water in the solution to make 100 ml.
- Potassium Nitrate** KNO_3 (Guaranteed)
- Potassium Periodate** KIO_4 [Potassium Periodate (Potassium Metaperiodate), Guaranteed]
- Potassium Permanganate** KMnO_4 (Guaranteed)
- Potassium Sodium Tartrate** $\text{NaOOCCH}(\text{OH})\text{CH}(\text{OH})\text{COOK} \cdot 4\text{H}_2\text{O}$ [Potassium Sodium Tartrate Tetrahydrate (Rochelle Salt, Seignett Salt), Guaranteed]
- Potassium Sulfate** K_2SO_4 (Guaranteed)
- Potassium Tetraoxalate for pH Determination** See Potassium Trihydrogen

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- Dioxalate Dihydrate for pH Determination.
- Potassium Thiocyanate** KSCN (Guaranteed)
- Potassium Trihydrogen Dioxalate Dihydrate for pH Determination** $\text{KH}_3(\text{C}_2\text{O}_4)_2 \cdot 2\text{H}_2\text{O}$
- Potato Extract** Use potato extract prepared for microbiological test.
- Powdered Cattle Bile** Use Powdered cattle bile produced for microbiological tests.
- 2-Propanol** $(\text{CH}_3)_2\text{CHOH}$ (Guaranteed)
- n*-Propanol** $\text{CH}_3\text{CH}_2\text{CH}_2\text{OH}$ [1-Propanol (*n*-Propyl Alcohol), Guaranteed]
- 2-Propanol for Vitamin A Determination** Determine the absorbance of 2-Propanol for Vitamin A Determination, using re-distilled water as the reference. The absorbance is not more than 0.01 at 320 - 350 nm and not more than 0.05 at 300 nm.
- Propionic Acid** $\text{C}_2\text{H}_5\text{COOH}$ " Propionic Acid "
- Propyl Alcohol, Iso** See 2-Propanol.
- Propyl Alcohol, Iso, for Vitamin A Determination** See 2-Propanol for Vitamin A Determination.
- Propylene Glycol** $\text{CH}_3\text{CH}(\text{OH})\text{CH}_2\text{OH}$ (Guaranteed)
- Purified Hydrochloric Acid** See Hydrochloric Acid, Purified.
- Purified Water** Use Purified Water specified under the Japanese Pharmacopoeia.
- Purified Water for Ion Chromatography** Distilled purified water, whose electric conductivity is not more than $1\mu\text{s}/\text{cm}$.
- Pyridine** $\text{C}_5\text{H}_5\text{N}$ (Guaranteed)
- Pyridine for Water Determination** $\text{C}_5\text{H}_5\text{N}$ Use pyridine containing not more than 0.1% w/v of water. Otherwise, use pyridine prepared by the following manner: To pyridine, add potassium hydroxide or barium oxide. Stopper tightly, allow to stand for several days, and distill the mixture, protecting from moisture. Store, protecting from moisture.
- Pyridine, Dehydrated** $\text{C}_5\text{H}_5\text{N}$ Measure 100 ml of pyridine, add 10 g of potassium hydroxide, and allow to stand for 24 hours. Collect the supernatant by decantation, and distill.
- Pyridine - Pyrazolone TS** Weigh 0.2 g of 1-phenyl-3-methyl-5-pyrazolone, add 100 ml of about 75 water, dissolve by shaking, and cool to room temperature (it does not need to be dissolved completely). Mix the solution in a solution prepared by weighing 20 mg of bis(1-phenyl-3-methyl-5-pyrazolone) and dissolving in 20 ml of pyridine.
- 1-(2-Pyridylazo)-2-naphthol** $\text{C}_{15}\text{H}_{11}\text{N}_3\text{O}$ 1-(2-Pyridylazo)-2-naphthol occurs as an orange-yellow or orange-red powder.
- Specific absorbance:* Weigh 0.025 g of 1-(2-Pyridylazo)-2-naphthol, dissolve in methanol to make exactly 100 ml. Measure 2.0 ml of this solution, add methanol to make exactly 50 ml. Use this solution as the test solution. Perform the test as directed under Spectrophotometry. The absorbance at the wavelength of 470 nm is not less than 0.55.
- Melting point:* 137 - 140 .
- Clarity and color of the solution:* Dissolve 0.025 g of 1-(2-Pyridylazo)-2-naphthol in 100 ml of methanol. The color of the solution is orange-yellow and is clear.
- Residue on ignition:* Not more than 1.0%.
- Sensitivity:* To 0.2 ml of 1-(2-Pyridylazo)-2-naphthol methanol solution (1 4,000), add 50 ml of water, 30 ml of methanol, and 10 ml of acetate buffer. A yellow color develops. To this solution, add 1 drop of copper() chloride

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dihydrate solution(1 : 600). The color of the solution changes to red-purple. Next, add 1 drop of disodium ethylenediaminetetraacetate TS, and the color of the solution returns to yellow.

Pyrogallol $C_6H_3(OH)_3$ (Guaranteed)

Pyrogallol Solution, Alkaline Transfer 4.5 g of pyrogallol in a gas washing bottle, and purge air with nitrogen by blowing 2 or 3 minutes into the bottle. Add the solution dissolving 65 g of potassium hydroxide in 85 ml of water into the bottle.

Purge air completely from the bottle with nitrogen in the same manner.

Pyrrole C_4H_4NH (Guaranteed)

Pyruvic Acid $C_3H_4O_3$ (Guaranteed)