length and width direction, prepare only the net, measure the length and the width, and calculate by making the necessary correction based on the mass of the standard area.

Total ash Not more than 0.25% (5 g, proceed as directed in the Total ash under the Crude Drugs).

Sterility Take Sterile Absorbent Gauze from package abacterially under an aseptic circumstances, sample about 1.0 g of it (whole content in the case of less than 1 g) evenly from 5 different parts around the center portion, put the samples in a test tube of 25 mm × 200 mm containing 60 mL each of fluid thioglycollate medium I for the Sterility Test and glucose-peptone medium for the Sterility Test, immerse the samples in the medium using an appropriate utensil, and perform the test as directed under the Sterility Test for the growth of bacteria and fungi: it meets the requirements of the Sterility Test. In the case of the test for the growth of fungi, a 200-mL Erlenmeyer flask can also be used. In this connection, perform an efficient test of the medium under a condition without the samples: the medium supports the substantial growth of the incubated microorganisms.

Sample number used in the Sterility Test is indicated in the following table.

Number of products of the same kind sterilized simultaneously	Number of products used for test
Not more than 100	4
100 to not more than 500	10
Not less than 500	20

Containers and storage Containers—Tight containers impervious to any microbe.

Absorptive Ointment

吸水軟膏

Method of preparation

White Petrolatum	400 g
Cetanol	100 g
White Beeswax	50 g
Sorbitan Sesquioleate	50 g
Lauromacrogol	5 g
Ethyl Parahydroxybenzoate or Methyl Parahydroxybenzoate	1 g
Butyl Parahydroxybenzoate or Propyl Parahydroxybenzoate	1 g
Purified Water	a sufficient quantity
	To make 1000 g

Melt White Petroleum, Cetanol, White Beeswax, Sorbitan Sesquioleate and Lauromacrogol by heating on a water bath, mix and maintain at about 75°C. Add Methyl Parahydroxybenzoate or Ethyl Parahydroxybenzoate and Propyl Parahydroxybenzoate or Butyl Parahydroxybenzoate to Purified Water, dissolve by warming at 80°C. Combine both solutions, mix to make emulsion, cool, and stir thoroughly until it congeals.

Description Absorptive Ointment is white in color and is lustrous. It has a slightly characteristic odor.

Containers and storage Containers—Tight containers.

Acacia

Gummi Arabicum

アラビアゴム

Acacia is the secretions obtained from the stems and branches of *Acacia senegal* Willdenow or other species of the same genus (*Leguminosae*).

Description Colorless or light yellow-brown, translucent or somewhat opaque spheroidal tears, or angular fragments with numerous fissures on the surface; very brittle; the fractured surface glassy and occasionally iridescent. Odorless; tasteless, but produces a mucilaginous sensation on the tongue.

Acacia (1.0 g) dissolves almost completely in 2.0 mL of water, and the solution is acid.

It is practically insoluble in ethanol (95).

Identification To 10 mL of a solution of Acacia (1 in 50) add 0.2 mL of dilute lead subacetate TS: a white, flocculent precipitate is produced.

Purity **(1)** Insoluble residue—To 5.0 g of pulverized Acacia add 100 mL of water and 10 mL of dilute hydrochloric acid, and dissolve by gentle boiling for 15 minutes with swirling. Filter the warm mixture through a tared glass filter (G3), wash the residue thoroughly with hot water, and dry at 105°C for 5 hours: the mass of the residue does not exceed 10.0 mg.

(2) Tannin-bearing gums—To 10 mL of a solution of Acacia (1 in 50) add 3 drops of iron (III) chloride TS: no dark green color is produced.

Loss on drying Not more than 17.0% (6 hours).

Total ash Not more than 4.0%.

Acid-insoluble ash Not more than 0.5%.

Powdered Acacia

Gummi Arabicum Pulveratum

アラビアゴム末

Powdered Acacia is the powder of Acacia.

Description Powdered Acacia occurs as a white to light yellowish white powder. It is odorless, tasteless, but produces a mucilaginous sensation on the tongue.

Under a microscope, Powdered Acacia, immersed in olive oil or liquid paraffin, reveals colorless, angular fragments or nearly globular grains. Usually starch grains or vegetable tissues are not observed; if any, very trace.

Powdered Acacia (1.0 g) dissolves almost completely in 2.0 mL of water, and the solution is acid.

It is practically insoluble in ethanol (95).

Identification To 10 mL of a solution of Powdered Acacia (1 in 50) add 0.2 mL of dilute lead subacetate TS: a white, flocculent precipitate is produced.

Purity **(1)** Insoluble residue—To 5.0 g of Powdered Acacia add 100 mL of water and 10 mL of dilute hydrochloric acid, and dissolve by gentle boiling for 15 minutes with swirling. Filter the warm mixture through a tared glass filter (G3), wash the residue thoroughly with hot water, and dry at 105°C for 5 hours: the mass of the residue does not exceed 10.0 mg.

(2) Tannin-bearing gums—To 10 mL of a solution of Powdered Acacia (1 in 50) add 3 drops of iron (III) chloride TS: no dark green color is produced.

(3) Starch or dextrin—Boil 0.20 g of Powdered Acacia in 10 mL of water. After cooling, add 1 drop of iodine TS: no dark blue or red-purple color appears.

Loss on drying Not more than 15.0% (6 hours).

Total ash Not more than 4.0%.

Acid-insoluble ash Not more than 0.5%.

Containers and storage Containers—Tight containers.

Acetic Acid

酢酸

Acetic Acid contains not less than 30.0 w/v% and not more than 32.0 w/v% of $C_2H_4O_2$: 60.05.

Description Acetic Acid is a clear, colorless liquid. It has a pungent, characteristic odor and an acid taste.

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

Specific gravity d_{20}^{20}: about 1.04

Identification Acetic Acid changes blue litmus paper to red, and responds to the Qualitative Tests for acetate.

Purity **(1)** Chloride—To 20 mL of Acetic Acid add 40 mL of water, and use this solution as the samplesolution. To 10 mL of the sample solution add 5 drops of silver nitrate TS: no opalescence is produced.

(2) Sulfate—To 10 mL of the sample solution obtained in (1) add 1 mL of barium chloride TS: no turbidity is produced.

(3) Heavy metals—Evaporate 10 mL of Acetic Acid on a water bath to dryness, and to the residue add 2 mL of dilute acetic acid and water to make 50 mL. Perform the test with this solution as the test solution. Prepare the control solution with 3.0 mL of Standard Lead Solution by adding 2 mL of dilute acetic acid and water to make 50 mL (not more than 3 ppm).

(4) Potassium permanganate-reducing substances—To 20 mL of the sample solution obtained in (1) add 0.02 mol/L potassium permanganate VS: the red color does not disappear within 30 minutes.

(5) Non-volatile residue—Evaporate 30 mL of Acetic Acid on a water bath to dryness, and dry at 105°C for 1 hour: the mass of the residue is not more than 1.0 mg.

Assay Measure exactly 5 mL of Acetic Acid, add 30 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).

Each mL of 1 mol/L sodium hydroxide VS
= 60.05 mg of $C_2H_4O_2$

Containers and storage Containers—Tight containers.

Glacial Acetic Acid

氷酢酸

$C_2H_4O_2$: 60.05
Acetic acid [*64-19-7*]

Glacial Acetic Acid contains not less than 99.0% of $C_2H_4O_2$.

Description Glacial Acetic Acid is a clear, colorless, volatile liquid, or colorless or white, crystalline masses. It has a pungent, characteristic odor.

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

Boiling point: about 118°C

Specific gravity d_{20}^{20}: about 1.049

Identification A solution of Glacial Acetic Acid (1 in 3) changes blue litmus paper to red, and responds to the Qualitative Tests for acetate.

Freezing point Not below 14.5°C.

Purity **(1)** Chloride—To 10 mL of Glacial Acetic Acid add water to make 100 mL, and use this solution as the sample solution. To 10 mL of the sample solution add 5 drops of silver nitrate TS: no opalescence is produced.

(2) Sulfate—To 10 mL of the sample solution obtained in (1) add 1 mL of barium chloride TS: no turbidity is produced.

(3) Heavy metals—Evaporate 2.0 mL of Glacial Acetic Acid on a water bath to dryness. Dissolve the residue in 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 2.0 mL of Standard Lead Solution by adding 2.0 mL of dilute acetic acid and water to make 50 mL (not more than 10 ppm).

(4) Potassium permanganate-reducing substances—To 20 mL of the sample solution obtained in (1) add 0.10 mL of 0.1 mol/L potassium permanganate VS: the red color does not disappear within 30 minutes.

(5) Non-volatile residue—Evaporate 10 mL of Glacial Acetic Acid on a water bath to dryness, and dry at 105°C for 1 hour: the mass of the residue is not more than 1.0 mg.

Assay Place 10 mL of water in a glass-stoppered flask, and weigh accurately. Add about 1.5 g of Glacial Acetic Acid, weigh accurately again, then add 30 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).