add 2 to 3 drops of sulfuric acid: a deep red-brown to deep red-purple color develops.

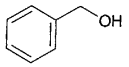
Purity Ethanol-insoluble substances—Boil gently 1.0 g of Benzoin with 30 mL of ethanol (95) on a water bath for 15 minutes under a reflux condenser. After cooling, collect the insoluble substances through a tared glass filter (G3), and wash with three 5-mL portions of ethanol (95). Dry the residue at 105°C for 4 hours: the mass of the residue does not exceed 0.30 g.

Total ash Not more than 2.0%.

Acid-insoluble ash Not more than 1.0%.

Benzyl Alcohol

ベンジルアルコール



C_7H_8O: 108.14
Benzyl alcohol [*100-51-6*]

Benzyl Alcohol contains not less than 98.0% of C_7H_8O.

Description Benzyl Alcohol is a clear, colorless liquid. It is odorless, or has a faint, aromatic odor. It has an irritative, burning taste.

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

It is soluble in water.

It is gradually affected by air and by light with decreasing solubility in water.

Identification Add 1 mL of Benzyl Alcohol to 5 mL of a solution of potassium permanganate (1 in 20), add 2 mL of dilute sulfuric acid, and shake for 2 minutes. Add 20 mL of chloroform, and shake well. Evaporate the chloroform layer on a water bath: the residue has the odor of benzaldehyde. Dissolve the residue in 5 mL of aldehyde-free ethanol, and add 1 mL of 2,4-dinitrophenylhydrazine TS: an orange precipitate is produced.

Refractive index n_D^{20}: 1.538 - 1.541

Specific gravity d_{20}^{20}: 1.043 - 1.053

Purity **(1)** Clarity and color of solution—Dissolve 1.0 mL of Benzyl Alcohol in 40 mL of water: the solution is clear and colorless.

(2) Acid—To 10 mL of Benzyl Alcohol add 10 mL of neutralized ethanol, 0.20 mL of 0.1 mol/L sodium hydroxide VS and 2 drops of phenolphthalein TS: a red color develops.

(3) Benzaldehyde—Dissolve 1.0 mL of Benzyl Alcohol in water to make 100 mL. Transfer 10.0 mL of the solution to a Nessler tube, add water to make 25 mL, add 1 mL of 2,4-dinitrophenyhydrazine TS, mix, and allow to stand for 5 minutes: no turbidity nor floating matters forms.

(4) Chlorinated compounds—Perform the test with 2 drops of Benzyl Alcohol according to the Flame Coloration Test (2): no green color appears.

Residue on ignition Not more than 0.005% (20 g, after evaporation).

Distilling range 202.5 - 206.5°C, not less than 96.0 v/v%.

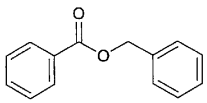
Assay Weigh accurately about 0.5 g of Benzyl Alcohol, add exactly 10 mL of a mixture of pyridine and acetic anhydride (17:3), and heat on a water bath under a reflux condenser for 30 minutes. Cool, add 25 mL of water, and titrate the excess acetic acid with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 1 mol/L sodium hydroxide VS
= 108.14 mg of C_7H_8O

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

Benzyl Benzoate

安息香酸ベンジル



$C_{14}H_{12}O_2$: 212.24
Benzyl benzoate [*120-51-4*]

Benzyl Benzoate contains not less than 99.0% of $C_{14}H_{12}O_2$.

Description Benzyl Benzoate is a colorless, clear, viscous liquid. It has a faint, aromatic odor and a pungent, burning taste.

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

It is practically insoluble in water.

Congealing point: about 17°C

Specific gravity d_{20}^{20}: about 1.123

Boiling point: about 323°C

Identification **(1)** Heat gently 1 mL of Benzyl Benzoate with 5 mL of sodium carbonate TS and 2 mL of potassium permanganate TS: the odor of benzaldehyde is perceptible.

(2) Warm the titrated mixture obtained in the Assay on a water bath to remove ethanol, and add 0.5 mL of iron (III) chloride TS: a light yellow-red precipitate is produced, which turns white on the addition of dilute hydrochloric acid.

Refractive index n_D^{20}: 1.568 - 1.570

Purity Acid—Dissolve 5.0 mL of Benzyl Benzoate in 25 mL of neutralized ethanol, and add 0.50 mL of 0.1 mol/L sodium hydroxide VS: a red color develops.

Residue on ignition Not more than 0.05% (2 g).

Assay Weigh accurately about 2 g of Benzyl Benzoate, add exactly 50 mL of 0.5 mol/L potassium hydroxide-ethanol VS, and boil gently for 1 hour under a reflux condenser with a carbon dioxide-absorbing tube (soda lime). Cool, and titrate the excess potassium hydroxide with 0.5 mol/L hydrochloric acid VS (indicator: 2 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.5 mol/L potassium hydroxide-ethanol VS = 106.12 mg of $C_{14}H_{12}O_2$

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

Bitter Cardamon

Alpiniae Fructus

ヤクチ

Bitter Cardamon is the fruit of *Alpinia oxyphylla* Miquer (*Zingiberaceae*).

Description Spherical to fusiform fruit, with both ends somewhat pointed; 1 - 2 cm in length, 0.7 - 1 cm in width; externally brown to dark brown, with numerous longitudinal, knob-like protruding lines; pericarp 0.3 - 0.5 mm in thickness, closely adhering to the seed mass, and difficult to separate; inside divided vertically into three loculi by thin membranes, each loculus containing 5 to 8 seeds adhering by aril; seeds irregularly polygonal, about 3.5 mm in diameter, brown to dark brown in color, and hard in texture. Odor, characteristic; taste, slightly bitter.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 2.5%.

Essential oil content Perform the test with 50.0 g of pulverized Bitter Cardamon as directed in the Essential oil content under Crude Drugs: the volume of essential oil is not less than 0.4 mL.

Bitter Orange Peel

Aurantii Pericarpium

トウヒ

Bitter Orange Peel is the pericarp of the ripe fruit of *Citrus aurantium* Linné or *Citrus aurantium* Linné var. *daidai* Makino (*Rutaceae*).

Description Usually quartered sections of a sphere, sometimes warped or flattened, 4 - 8 cm in length, 2.5 - 4.5 cm in width and 0.5 - 0.8 cm in thickness; the outer surface is dark red-brown to grayish yellow-brown, with numerous small dents associated with oil sacs; the inner surface is white to light grayish yellow-red, with irregular indented reticulation left by vascular bundles; light and brittle in texture. Odor, characteristic aroma; taste, bitter, somewhat mucilaginous and slightly pungent.

Identification To 1.0 g of pulverized Bitter Orange Peel add 10 mL of ethanol (95), allow to stand for 30 minutes with occasional shaking, filter, and use the filtrate as the sample solution. Separately, dissolve 10 mg of naringin for thin-layer chromatography in 10 mL of ethanol (95), and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine TS on the plate, and allow to stand in ammonia gas: a spot from the sample solution and a grayish green spot from the standard solution show the same color tone and the same *R*f value.

Loss on drying Not more than 14.0% (6 hours).

Total ash Not more than 5.5%.

Acid-insoluble ash Not more than 0.5%.

Essential oil content Perform the test with 50 g of pulverized Bitter Orange Peel as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the test sample in the flask: the volume of essential oil is not less than 0.2 mL.

Bitter Tincture

Tinctura Amara

苦味チンキ

Method of preparation

Bitter Orange Peel, in coarse powder	50 g
Swertia Herb, in coarse powder	5 g
Zanthoxylum Fruit, in coarse powder	5 g
70 vol% Ethanol	a sufficient quantity
	To make 1000 mL

Prepare as directed under Tinctures, with the above ingredients. An appropriate quantity of Ethanol and Purified Water may be used in place of 70 vol% Ethanol.

Description Bitter Tincture is a yellow-brown liquid. It has a characteristic aroma and a bitter taste.

Specific gravity d_{20}^{20}: about 0.90

Identification **(1)** To 1 mL of Bitter Tincture add 5 mL of methanol, then add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow to stand: the solution is red-purple in color.

(2) Use Bitter Tincture as the sample solution. Separately, to 5.0 g of pulverized Bitter Orange Peel add 100 mL of diluted ethanol (7 in 10), stopper the vessel tightly, shake for 30 minutes, filter, and use the filtrate as the standard solution (1). Proceed with 0.5 g each of pulverized Swertia Herb and Zanthoxylum Fruit in the same manner, and use the solutions so obtained as the standard solution (2) and the standard solution (3). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the standard solutions (1), (2) and (3) on the plate of silica gel with complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (95) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Examine the plate under ultraviolet light (broad spectrum wavelength): three of the several spots from the sample solution show the same color tone and *R*f value as those of the upper spot of the two bright blue to purple spots among the several spots from the standard solu-