Method of preparation

Powdered Opium	100 g
Powdered Ipecac	100 g
Starch or a suitable diluent	a sufficient quantity
To make	1000 g

Prepare as directed under Powders, with the above ingredients. Lactose should not be used.

Description Opium Ipecac Powder occurs as a light brown powder.

Identification (1) Proceed with 1 g of Opium Ipecac Powder as directed in the Identification (1) under Powdered Opium.

(2) Proceed with 1 g of Opium Ipecac Powder as directed in the Identification (2) under Powdered Opium.

(3) Shake frequently a mixture of 3 g of Opium Ipecac Powder and 5 mL of hydrochloric acid, and allow to stand for 1 hour. Filter the solution into an evaporating dish. Add 5 mg of chlorinated lime to the filtrate: an orange color is produced at the circumference of the chlorinated lime (emetine).

Assay Weigh accurately about 50 g of Opium Ipecac Powder in a glass stoppered flask, add 250 mL of dilute ethanol, warm in a water bath at 40°C for 1 hour with stirring, and filter through a glass filter (G3). Transfer the residue on the filter to the first glass-stoppered flask, add 50 mL of dilute ethanol, warm in a water bath at 40°C for 10 minutes with stirring, and filter through the glass filter. Repeat the extraction with three 50-mL portions of dilute ethanol. Combine all the filtrates in a mortar, evaporate on a water bath to dryness, add 10 mL of ethanol (99.5) to the residue, and evaporate again. After cooling, triturate the residue with an exactly measured 10 mL of water, add 2 g of calcium hydroxide and an exactly measured 40 mL of water, stir the mixture for 20 minutes, and filter. To 30 mL of the filtrate add 0.1 g of magnesium sulfate heptahydrate, shake for 1 minute, then add 0.3 g of calcium hydroxide, shake for 1 minute, allow to stand for 1 hour, and filter. To an exactly measured 20 mL of the filtrate add 5 mL of sodium hydroxide TS, and adjust the pH to between 9.0 and 9.2 with ammonium chloride. Extract the solution successively with 60 mL, 40 mL and 30 mL of a mixture of chloroform and ethanol (95) (3:1). Combine all the extracts, distil, then evaporate off the solvent on a water bath. Dissolve the residue in 20 mL of dilute sodium hydroxide TS and 10 mL of diethyl ether with shaking, add 0.5 g of ammonium chloride, shake vigorously with caution, and proceed as directed in the Assay under Powdered Opium.

Each mL of 0.05 mol/L sulfuric acid VS
= 28.534 mg of $C_{17}H_{19}NO_3$

Containers and storage Containers—Tight containers.

Orange Oil

Oleum Aurantii

オレンジ油

Orange Oil is the essential oil obtained by expression from the peel of the edible fruit of *Citrus* species (*Rutaceae*).

Description Orange Oil is a yellow to yellow-brown liquid. It has a characteristic, aromatic odor, and a slightly bitter taste.

It is miscible with an equal volume of ethanol (95) with turbidity.

Refractive index n_D^{20}: 1.472 - 1.474

Optical rotation α_D^{20}: +85 - +99° (100 mm).

Specific gravity d_{20}^{20}: 0.842 - 0.848

Purity Heavy metals—Proceed with 1.0 mL of Orange Oil according to Method 2, and perform the test. Prepare the control solution with 4.0 mL of Standard Lead Solution (not more than 40 ppm).

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

Orange Peel Syrup

トウヒシロップ

Method of preparation

Orange Peel Tincture	200 mL
Simple Syrup	a sufficient quantity
To make	1000 mL

Prepare as directed under Syrups, with the above ingredients. An appropriate quantity of Sucrose and Purified Water may be used in place of Simple Syrup.

Description Orange Peel Syrup is a brownish yellow to reddish brown liquid. It has a characteristic odor, a sweet taste and a bitter aftertaste.

Specific gravity d_{20}^{20}: about 1.25

Identification To 25 mL of Orange Peel Syrup add 50 mL of ethyl acetate, shake for 5 minutes, allow to stand until clear ethyl acetate layer separate, and take the ethyl acetate layer, and evaporate on a water bath to dryness. Dissolve the residue in 10 mL of ethanol (95), filter if necessary, and use this solution 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 *Rf* value.

Containers and storage Containers—Tight containers.

Orange Peel Tincture

トウヒチンキ

Method of preparation

Bitter Orange Peel, in coarse powder	200 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 Orange Peel Tincture is a yellowish brown liquid. It has a characteristic odor, and a bitter taste.

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

Identification To 5.0 mL of Orange Peel Tincture add 5 mL of ethanol (95), filter if necessary, and use the filtrate as the sample solution. Proceed as directed in the Identification under Bitter Orange Peel.

Alcohol number Not less than 6.6 (Method 2).

Containers and storage Containers—Tight containers.

Oriental Bezoar

Bezoar Bovis

ゴオウ

Oriental Bezoar is a stone formed in the gall sac of *Bos taurus* Linné var. *domesticus* Gmelin (*Bovidae*).

Description Spherical or massive stone, 1 - 4 cm in diameter; externally yellow-brown to red-brown; light, fragile and easily broken. Fractured surface shows yellow-brown to red-brown annular rings, often containing white granular substances or thin layers in these annular rings. Odor, slight; taste, slightly bitter, followed by slight sweetness.

Identification **(1)** Shake 0.1 g of pulverized Oriental Bezoar with 10 mL of petroleum ether for 30 minutes, filter, and wash the residue with 10 mL of petroleum ether. Shake 0.01 g of the residue with 3 mL of acetic anhydride for 1 to 2 minutes, add a mixture of 0.5 mL of acetic anhydride and 2 drops of sulfuric acid, and shake: a yellow-red to deep red color develops, and changes through dark red-purple to dark red-brown.

(2) Shake well 0.01 g of Oriental Bezoar with 1 mL of hydrochloric acid and 10 mL of chloroform, separate the chloroform layer when it acquires a yellow-brown color, and shake with 5 mL of barium hydroxide TS: a yellow-brown precipitate is produced.

Purity **(1)** Synthetic dye—To 2 mg of pulverized Oriental Bezoar add 1 mL dilute hydrochloric acid: no violet color develops.

(2) Starch—To 5 mg of pulverized Oriental Bezoar add 2 mL of water, and heat on a water bath for 5 minutes. Cool and add 2 to 3 drops of iodine TS: no blue-purple color develops.

(3) Sucrose—To 0.02 g of pulverized Oriental Bezoar add 10 mL of water, shake for 15 minutes, and filter. To 1 mL of the filtrate add 2 mL of anthrone TS, and shake: no deep blue-green to dark green color develops.

Total ash Not more than 10.0%.

Content of the active principle Weigh accurately about 0.5 g of pulverized Oriental Bezoar in a flask, add 50 mL of petroleum ether, warm under a reflux condenser on a water bath for 2 hours, and filter. Replace the residue along with the filter paper in the flask, add 2 mL of hydrochloric acid and 40 mL of chloroform, warm under a reflux condenser on a water bath for 1 hour, and filter into a tared flask. Wash the filter paper with a small quantity of chloroform, combine the washings with the filtrate, and distil off the chloroform. Dry the residue in a desiccator (silica gel) for 24 hours, and weigh: the mass of the residue is not less than 12.0%.

Compound Oxycodone Injection

Compound Hycodenone Injection

複方オキシコドン注射液

Compound Oxycodone Injection is an aqueous solution for injection.

It contains not less than 0.74 w/v% and not more than 0.86 w/v% of oxycodone hydrochloride ($C_{18}H_{21}NO_4.HCl.3H_2O$: 405.87), and not less than 0.18 w/v% and not more than 0.22 w/v% of hydrocotarnine hydrochloride ($C_{12}H_{15}NO_3.HCl.H_2O$: 275.73).

Method of preparation

Oxycodone Hydrochloride	8 g
Hydrocotarnine Hydrochloride	2 g
Water for Injection	a sufficient quantity
To make	1000 mL

Prepare as directed under Injections, with the above ingredients.

Description Compound Oxycodone Injection is a clear, colorless to pale yellow liquid.

It is affected by light.

pH: 2.5 - 4.0

Identification **(1)** To 1 mL of Compound Oxycodone Injection add 1 mL of 2,4-dinitrophenylhydrazine-ethanol TS: a yellow precipitate is formed (oxycodone).

(2) Evaporate 1 mL of Compound Oxycodone Injection on a water bath. Dissolve the residue in 2 mL of sulfuric acid: a yellow color is produced. Heat the solution: it changes to red, and then to deep orange-red (hydrocotarnine).