

## Compound Rhubarb and Senna Powder

複方ダイオウ・センナ散

### Method of preparation

Powdered Senna Leaves	110 g
Powdered Rhubarb	110 g
Sulfur	555 g
Magnesium Oxide	225 g
To make	1000 g

Prepare as directed under Powders, with the above ingredients.

**Description** Compound Rhubarb and Senna Powder occurs as a yellow-brown powder, having a characteristic odor and a bitter taste.

**Identification** To 2 g of Compound Rhubarb and Senna Powder add 50 mL of water, warm on a water bath for 30 minutes, and filter. Add 2 drops of dilute hydrochloric acid to the filtrate, shake with two 20-mL portions of diethyl ether, and remove the diethyl ether layer. Add 5 mL of hydrochloric acid to the aqueous layer, and heat it on a water bath for 30 minutes. Cool, shake with 20 mL of diethyl ether, take the diethyl ether layer, add 10 mL of sodium hydrogen carbonate TS, and shake: the aqueous layer is red in color.

**Containers and storage** Containers—Well-closed containers.

## Rice Starch

*Amylum Oryzae*

コメデンプン

Rice Starch consists of the starch granules obtained from the seeds of *Oryza sativa* Linné (*Gramineae*).

**Description** Rice Starch occurs as white masses or powder. It is odorless and tasteless.

Under a microscope, Rice Starch appears as polyhedral, simple grains 3 – 10  $\mu\text{m}$ , mostly 4 – 6  $\mu\text{m}$ , in size. These simple grains often gather in ellipsoidal, compound grains 50 – 100  $\mu\text{m}$  in diameter. Hilum and striation are not observable.

It is practically insoluble in water and in ethanol (95).

**Identification** (1) To 1 g of Rice Starch add 50 mL of water, boil, and allow to cool: a turbid, neutral and pasty liquid is formed.

(2) To a portion of Rice Starch add iodine TS: a dark blue-purple color is produced.

**Purity** Foreign matter—Under a microscope, Rice Starch does not contain starch grains of any other origin. It may contain a minute quantity, if any, of fragments of the tissue of the original plant.

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

**Total ash** Not more than 1.0%.

## Ringer's Solution

リンゲル液

Ringer's Solution is an aqueous solution for injection. It contains not less than 0.53 w/v% and not more than 0.58 w/v% of chlorine [as (Cl: 35.45)], and not less than 0.030 w/v% and not more than 0.036 w/v% of calcium chloride ( $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ : 147.01).

### Method of preparation

Sodium Chloride	8.6 g
Potassium Chloride	0.3 g
Calcium Chloride	0.33 g
Water for Injection	a sufficient quantity
To make	1000 mL

Prepare as directed under Injections, with the above ingredients.

No preservative may be added.

**Description** Ringer's Solution is a clear and colorless liquid. It has a slightly saline taste.

**Identification** (1) Evaporate 10 mL of Ringer's Solution to 5 mL: the solution responds to the Qualitative Tests for potassium salt and calcium salt.

(2) Ringer's Solution responds to the Qualitative Tests for sodium salt and chloride.

**pH** 5.0 – 7.5

**Purity** (1) Heavy metals—Evaporate 100 mL of Ringer's Solution to about 40 mL on a water bath. Add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Control solution: to 3.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 0.3 ppm).

(2) Arsenic—Perform the test with 20 mL of Ringer's Solution as the test solution using Apparatus B (not more than 0.1 ppm).

**Bacterial endotoxins** Less than 0.50 EU/mL.

**Assay** (1) Chlorine—To 20 mL of Ringer's Solution, accurately measured, add 30 mL of water. Titrate with 0.1 mol/L silver nitrate VS while shaking vigorously (indicator: 3 drops of sodium fluorescein TS).

Each mL of 0.1 mol/L silver nitrate VS  
= 3.5453 mg of Cl

(2) Calcium chloride—To 50 mL of Ringer's Solution, exactly measured, add 2 mL of 8 mol/L potassium hydroxide TS and 0.05 g of NN indicator, and titrate immediately with 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS, until the color of the solution changes from red-purple to blue.

Each mL of 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS  
= 1.4701 mg of  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$

**Containers and storage** Containers—Hermetic containers. Plastic containers for aqueous infusions may be used.

## Rose Fruit

### *Rosae Fructus*

エイジツ

Rose Fruit is the pseudocarp of fruit of *Rosa multiflora* Thunberg (*Rosaceae*).

**Description** The pseudocarp, spherical, ellipsoidal or spheroidal, 5 – 9.5 mm in length, 3.5 – 8 mm in diameter; the external surface red to dark brown in color, smooth and lustrous; often with peduncle about 10 mm in length at one end, and with pentagonal remains of calyx without sepal at the other end; internal wall of receptacle covered densely with silvery hairs; the interior containing 5 – 10 mature nuts; the nut, irregularly angular ovoid, about 4 mm in length, about 2 mm in diameter; external surface, light yellow-brown; obtuse at one end, and slightly acute at the other. Odor, slight; taste of receptacle, sweet and acid, and of nut, mucilaginous at first, later astringent, bitter and irritative.

**Identification** Boil gently 1 g of pulverized Rose Fruit with 20 mL of methanol for 2 minutes, and filter. To 5 mL of the filtrate add 0.1 g of magnesium in ribbon form and 0.5 mL of hydrochloric acid, and allow the mixture to stand: a light red to red color develops.

**Purity** Foreign matter—The amount of the peduncle and other foreign matter contained in Rose Fruit does not exceed 1.0%.

**Total ash** Not more than 6.0%.

## Powdered Rose Fruit

### *Rosae Fructus Pulveratus*

エイジツ末

Powdered Rose Fruit is the powder of Rose Fruit.

**Description** Powdered Rose Fruit occurs as a grayish yellow-brown powder. It has a slight odor, and has a slightly mucilaginous, astringent, bitter, and slightly acid taste.

Under a microscope, Powdered Rose Fruit reveals fragments of extremely thick-walled hairs 35 – 70  $\mu\text{m}$  in diameter, fragments of epidermis and hypodermis containing brown tannin masses, fragments of thin-walled fundamental tissue containing grayish brown substances, fragments of fine vessels, and solitary or twin crystals or rosette aggregates of calcium oxalate (components of receptacle); fragments of sclerenchyma, fiber groups, fine vessels, and fragments of epidermis containing brown tannin and mucilage (components of pericarp); fragments of endosperm composed of polygonal cells containing aleuron grains and fatty oil, fragments of outer epidermis composed of polygonal cells containing tannin, and fragments of inner epidermis composed

of elongated cells having wavy lateral walls (components of seed).

**Identification** Boil gently 1 g of Powdered Rose Fruit with 20 mL of methanol for 2 minutes, and filter. To 5 mL of the filtrate add 0.1 g of magnesium in ribbon form and 0.5 mL of hydrochloric acid, and allow the mixture to stand: a light red to red color develops.

**Total ash** Not more than 6.0%.

## Rosin

### Colophonium

#### *Resina Pini*

ロジン

Rosin is the resin obtained from the exudation of plants of *Pinus* species (*Pinaceae*) from which essential oil has been removed.

**Description** Rosin occurs as a light yellow to light brown, glassily transparent, brittle mass, the surfaces of which are often covered with a yellow powder. The fractured surface is shell-like and lustrous.

It has a slight odor.

It melts easily, and burns with a yellow-brown flame.

It is freely soluble in ethanol (95), in acetic acid (100) and in diethyl ether.

A solution of Rosin in ethanol (95) is acidic.

**Acid value** 150 – 177

**Total ash** Not more than 0.1%.

## Freeze-dried Live Attenuated Rubella Vaccine

乾燥弱毒生風しんワクチン

Freeze-dried Live Attenuated Rubella Vaccine is a preparation for injection which is dissolved before use. It contains live attenuated rubella virus.

It conforms to the requirements of Freeze-dried Live Attenuated Rubella Vaccine in the Minimum Requirements for Biological Products.

**Description** Freeze-dried Live Attenuated Rubella Vaccine becomes a colorless, yellowish or reddish clear liquid on addition of solvent.