

10 minutes: a yellow color is produced (paraformaldehyde).

(2) To the diethyl ether layer obtained in (1) add 5 mL of dilute hydrochloric acid and 20 mL of water, shake well, and separate the water layer: the solution responds to the Qualitative Tests for primary aromatic amines (procaine hydrochloride).

(3) To 0.15 g of Dental Paraformaldehyde Paste add 25 mL of diethyl ether and 25 mL of water, shake, separate the water layer, filter, and use the filtrate as the sample solution. Separately, dissolve 0.01 g of procaine hydrochloride in 5 mL of water, and use this solution as standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5  $\mu$ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5) and ammonia solution (28) (50:5:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): spots from the sample solution and the standard solution show the same *R<sub>f</sub>* value.

**Containers and storage** Containers—Tight containers.

## Peach Kernel

### *Persicae Semen*

トウニン

Peach Kernel is the seed of *Prunus persica* Batsch or *Prunus persica* Batsch var. *dauidiana* Maximowicz (*Rosaceae*).

**Description** Flattened, asymmetric ovoid seed, 1.2 – 2.0 cm in length, 0.6 – 1.2 cm in width, and 0.3 – 0.7 cm in thickness; somewhat sharp at one end, and round at the other end with chalaza; seed coat red-brown to light brown; externally, its surface being powdery by easily detachable stone cells of epidermis; numerous vascular bundles running and rarely branching from chalaza through the seed coat, and, appearing as dented longitudinal wrinkles; when soaked in boiling water and softened, the seed coat and thin, translucent, white albumen easily separated from the cotyledone; cotyledone white in color. Almost odorless; taste, slightly bitter and oily.

Under a microscope, the outer surface of seed coat reveals polygonal, long polygonal, or obtuse triangular stone cells on the protrusion from vascular bundles, shape of which considerably different according to the position, and their membranes almost equally thickened; in lateral view, appearing as a square, rectangle or obtuse triangle.

**Identification** To 1.0 g of ground Peach Kernel add 10 mL of methanol, immediately heat under a reflux condenser on a water bath for 10 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 2 mg of amygdalin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10  $\mu$ L 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, methanol and water (7:3:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid upon the plate, and heat at 105°C for 10 minutes: one spot among the spots from the sample solution and a brown to dark green spot from the standard solution show the same color tone and the same *R<sub>f</sub>* value.

**Purity** (1) Rancidity—Grind Peach Kernel with boiling water: no odor of rancid oil is perceptible.

(2) Foreign matter—Peach Kernel does not contain broken pieces of endocarp or other foreign matter.

## Powdered Peach Kernel

### *Persicae Semen Pulveratum*

トウニン末

Powdered Peach Kernel is the powder of the Peach Kernel.

**Description** Powdered Peach Kernel occurs as a reddish-light brown to light brown powder. It has a almost odorless and slightly bitter taste and oily.

Under a microscope, Powdered Peach Kernel fragments of outer seed coat epidermis; elliptical to ovoid, containing yellowish brown compound 50 to 80  $\mu$ m in diameter and stone cell; cap-like shape to ovoid, yellowish brown in color. The stone cell is element of epidermis, 50 to 80  $\mu$ m in diameter and 70 to 80  $\mu$ m in height, cell wall of the top, 12 to 25  $\mu$ m thickness, the base 4  $\mu$ m in thickness, with obvious and numerous pits. Inner seed coat, yellowish brown, irregular and somewhat long polygon, 15 to 30  $\mu$ m in diameter; and fragments of cotyledon and albumen containing aleurone grains and fatted oil, Aleurone grains are almost spherical grains, 5 to 10  $\mu$ m in diameter.

**Identification** Grind Powdered Peach Kernel with water: the odor of benzaldehyde is perceptible.

**Loss on drying** Not more than 8.5% (6 hours).

**Total ash** Not more than 3.5%.

**Acid-insoluble ash** Not more than 0.5%.

**Containers and storage** Containers—Tight containers.

## Peanut Oil

### *Oleum Arachidis*

ラッカセイ油

Peanut Oil is the fixed oil obtained from the seeds of *Arachis hypogaea* Linné (*Leguminosae*).

**Description** Peanut Oil is a pale yellow, clear oil. It is odorless or has a slight odor. It has a mild taste.

It is miscible with diethyl ether and with petroleum ether.

It is slightly soluble in ethanol (95).

Specific gravity  $d_{25}^{25}$ : 0.909 – 0.916

Congealing point of the fatty acids: 22 – 33°C

**Identification** Saponify 5 g of Peanut Oil by boiling with 2.5 mL of sodium hydroxide solution (3 in 10) and 12.5 mL of ethanol (95). Evaporate the ethanol, dissolve the residue in 50 mL of hot water, and add dilute hydrochloric acid in excess until the free fatty acids separate as an oily layer. Cool the mixture, remove the separated fatty acids, and dissolve them in 75 mL of diethyl ether. To the diethyl ether solution add a solution of 4 g of lead (II) acetate trihydrate in 40 mL of ethanol (95), and allow the mixture to stand for 18 hours. Filter the supernatant liquid, transfer the precipitate to the filter with the aid of diethyl ether, and filter by suction. Place the precipitate in a beaker, heat it with 40 mL of dilute hydrochloric acid and 20 mL of water until the oily layer is entirely clear, cool, and decant the water layer. Boil the fatty acids with 50 mL of diluted hydrochloric acid (1 in 100). When the solution prepared by dissolving 0.1 g of the fatty acids in 10 mL of ethanol (95) is not darkened by the addition of 2 drops of sodium sulfide TS, allow the fatty acids to solidify, and press them between dry filter papers to exclude moisture. Dissolve the solid fatty acid in 25 mL of diluted ethanol (9 in 10) with the aid of gentle heat, and then cool to 15°C to crystallize the fatty acids. Recrystallize them from diluted ethanol (9 in 10) and dry in a desiccator (phosphorus (V) oxide, in vacuum) for 4 hours: the melting point of the dried crystals is between 73°C and 76°C.

**Acid value** Not more than 0.2.

**Saponification value** 188 – 196

**Unsaponifiable matters** Not more than 1.5%.

**Iodine value** 84 – 103

**Containers and storage** Containers—Tight containers.

## Peony Root

### *Paeoniae Radix*

シャクヤク

Peony Root is the root of *Paeonia lactiflora* Pallas (*Paeoniaceae*).

It contains not less than 2.0% of peoniflorin, calculated on the dried basis.

**Description** Cylindrical root, 7–20 cm in length, 1–2.5 cm in diameter; externally brown to light grayish brown, with distinct longitudinal wrinkles, with warty scars of lateral roots, and with laterally elongated lenticels; fractured surface dense in texture, light grayish brown, and with light brown radial lines in xylem. Odor, characteristic; taste, slightly sweet at first, followed by an astringency and a slight bitterness.

**Identification** (1) Shake 0.5 g of pulverized Peony Root with 30 mL of ethanol (95) for 15 minutes, and filter. Shake 3 mL of the filtrate with 1 drop of iron (III) chloride TS: a blue-purple to blue-green color is produced, and it changes to dark blue-purple to dark green.

(2) To 2 g of pulverized Peony Root add 10 mL of methanol, warm on a water bath for 5 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dis-

solve 1 mg of paeoniflorin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10  $\mu$ L 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 acetone, ethyl acetate and acetic acid (100) (10:10:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS upon the plate, and heat at 105°C for 5 minutes: one spot among the spots from the sample solution and the purple-red spot from the standard solution show the same color tone and the same Rf value.

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

**Total ash** Not more than 6.5%.

**Acid-insoluble ash** Not more than 0.5%.

**Assay** Weigh accurately about 0.5 g of pulverized Peony Root, add 50 mL of diluted methanol (1 in 2), heat under a reflux condenser on a water bath for 30 minutes, cool, and filter. To the residue add 50 mL of diluted methanol (1 in 2), and proceed in the same manner. Combine the filtrates, add diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Paeoniflorin Reference Standard, dissolve in diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the standard solution. Pipet 20  $\mu$ L each of the sample solution and the standard solution, and perform the test as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas,  $A_T$  and  $A_S$ , of paeoniflorin in each solution.

$$\begin{aligned} & \text{Amount (mg) of paeoniflorin (C}_{23}\text{H}_{28}\text{O}_{11}) \\ &= \text{amount (mg) of Paeoniflorin Reference Standard,} \\ & \quad \text{calculated on the anhydrous basis} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

**Operating conditions—**

**Detector:** An ultraviolet absorption photometer (wavelength: 230 nm).

**Column:** A stainless steel column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel (5 to 10  $\mu$ m in diameter).

**Column temperature:** a constant temperature of about 20°C.

**Mobile phase:** A mixture of water and acetonitrile (4:1).

**Flow rate:** Adjust the flow rate so that the retention time of paeoniflorin is about 10 minutes.

**Selection of column:** Dissolve 1 mg each of Paeoniflorin Reference Standard and *p*-hydroxyacetophenone in diluted methanol (1 in 2) to make 10 mL. Perform the test with 20  $\mu$ L of this solution under the above operating conditions. Use a column giving elution of paeoniflorin and *p*-hydroxyacetophenone in this order with the resolution between these peaks being not less than 3.

**System repeatability:** Repeat the test five times with the standard solution under the above operating conditions: the relative standard deviation of the peak areas of paeoniflorin is not more than 1.5%.