changes to reddish brown, and the upper layer acquires a somewhat red color. Shake gently to mix the two layers together, and allow to stand: a persistent reddish brown color is produced.

Bearberry Leaf

Uvae Ursi Folium

ウワウルシ

Bearberry Leaf is the leaf of *Arctostaphylos uva-ursi* (Linné) Sprengel (*Ericaceae*).

It contains not less than 7.0% of arbutin.

Description Obovate to spatulate leaves, 1 - 3 cm in length, 0.5 - 1.5 cm in width; upper surface yellow-green to dark green; lower surface light yellow-green; margin entire; apex obtuse or round, sometimes retuse; base cuneate; petiole very short; lamina thick with characteristic reticular vein, and easily broken. Odor, slight; taste, slightly bitter and astringent.

Under a microscope, the transverse section reveals thick cuticula; parenchyma cells of palisade tissue and sponge tissue being similar in form; in the vascular bundle, medullary ray consisting of 2 to 7 rows of one-cell line, appearing as bones of Japanese fan; polygonal solitary crystals and clustered crystals of calcium oxalate present sparsely in cells on both outer and inner sides of the vascular bundle, but no crystals in mesophyll.

Identification **(1)** Macerate 0.5 g of pulverized Bearberry Leaf with 10 mL of boiling water, shake the mixture for a few minutes, allow to cool, and filter. Place 1 drop of the filtrate on filter paper, and add 1 drop of iron (III) chloride TS: a dark purple color appears.

(2) To 0.2 g of pulverized Bearberry Leaf add 10 mL of a mixture of ethanol (95) and water (7:3), shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of arbutin for thin-layer chromatography in 1 mL of a mixture of ethanol (95) and water (7:3), and use this solution as the standard solution. Perform the test with the sample solution and the standard solution as directed under the Thin-layer Chromatography. Spot 10 μL each of these solutions on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl formate, formic acid and water (8:1:1) to a distance of about 15 cm, and air-dry the plate. Spray evenly diluted sulfuric acid (1 in 2) upon the plate, and heat at 105°C for 10 minutes: one spot among several spots from the sample solution and that from the standard solution show a yellow-brown to blackish brown color and the same *Rf* value.

Purity **(1)** Twig—The amount of twigs contained in Bearberry Leaf does not exceed 4.5%.

(2) Foreign matter—The amount of foreign matter other than twigs contained in Bearberry Leaf does not exceed 2.0%.

Total ash Not more than 4.0%.

Acid-insoluble ash Not more than 1.5%.

Component determination Weigh accurately about 0.5 g of pulverized Bearberry Leaf in a glass-stoppered centrifuge tube, add 40 mL of water, shake for 30 minutes, centrifuge, and separate the supernatant liquid. To the residue add 40 mL of water, and proceed in the same manner. To the combined extracts add water to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.04 g of arbutin for component determination, previously dried for 12 hours (in vacuum, silica gel), dissolve in water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas, A_T and A_S, of arbutin in each solution.

$$\text{Amount (mg) of arbutin} = \text{amount (mg) of arbutin for component determination} \times \frac{A_T}{A_S}$$

Operating conditions—

Detector: An ultraviolet spectrophotometer (wavelength: 280 nm).

Column: A stainless steel column 4 - 6 mm in inside diameter and 15 - 25 cm in length, packed with octadecylsilanized silica gel (5 - 10 μm in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase: A mixture of water, methanol and 0.1 mol/L hydrochloric acid TS (94:5:1).

Flow rate: Adjust the flow rate so that the retention time of arbutin is about 6 minutes.

Selection of column: Dissolve 0.05 g each of arbutin for component determination, hydroquinone and gallic acid in water to make 100 mL. Proceed with 10 μL of this solution under the above operating conditions, and calcutate the resolution. Use a column giving elution of arbutin, hydroquinone and gallic acid in this order, and clearly dividing each peak.

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

Beef Tallow

Sevum Bovinum

牛脂

Beef Tallow is a purified fat obtained by wet steam rendering from the fresh fatty tissues of *Bos taurus* Linné var. *domesticus* Gmelin (*Bovidae*).

Description Beef Tallow occurs as a white, uniform mass. It has a characteristic odor and a mild taste.

It is freely soluble in diethyl ether and in petroleum ether, very slightly soluble in ethanol (95), and practically insoluble in water.

It is breakable at a low temperature, but softens above 30°C.

Melting point: 42 - 50°C (Method 2)

Acid value Not more than 2.0.

Saponification value 193 - 200

Iodine value 33-50 (When the sample is insoluble in 20 mL of cyclohexane, dissolve it by shaking a glass-stoppered flask in warm water. Then, if insoluble, increase the volume of solvent.)

Purity (1) Moisture and coloration—Beef Tallow (5.0 g), melted by heating on a water bath, forms a clear liquid, from which no water separates. In a 10-mm thick layer of the liquid, it is colorless or slightly yellow.

(2) Alkali—To 2.0 g of Beef Tallow add 10 mL of water, melt by heating on a water bath, and shake vigorously. After cooling, add 1 drop of phenolphthalein TS to the separated water layer: no color develops.

(3) Chloride—To 1.5 g of Beef Tallow add 30 mL of ethanol (95), boil for 10 minutes under a reflux condenser, and filter after cooling. To 20 mL of the filtrate add 5 drops of a solution of silver nitrate in ethanol (95) (1 in 50): the turbidity of the mixture does not exceed that of the following control solution.

Control solution: To 1.0 mL of 0.01 mol/L hydrochloric acid VS add ethanol (95) to make 20 mL, then add 5 drops of an ethanolic solution of silver nitrate (1 in 50).

Containers and storage Containers—Well-closed containers.

White Beeswax

Cera Alba

サラシミツロウ

White Beeswax is bleached Yellow Beeswax.

Description White Beeswax occurs as white to yellowish white masses. It has a characteristic odor. It is comparatively brittle when cooled, and the fractured surface is granular, and non-crystalline.

It is slightly soluble in diethyl ether, and practically insoluble in water and in ethanol (99.5).

Acid value 5 - 9 or 17 - 22 Weigh accurately about 6 g of White Beeswax, place in a glass-stoppered 250-mL flask, and add 50 mL of ethanol (99.5). Warm the mixture to dissolve the wax, add 1 mL of phenolphthalein TS, and proceed as directed in the Acid value under the Fats and Fatty Oils. Perform a blank determination using solvent which is not previously neutralized, and make any necessary correction.

Saponification value 80 - 100 Weigh accurately about 3 g of White Beeswax, place in a glass-stoppered 250-mL flask, and add exactly 25 mL of 0.5 mol/L potassium hydroxide-ethanol VS and 50 mL of ethanol (95), heat for 4 hours on a water bath under a reflux condenser, and proceed as directed in the Saponification value under the Fats and Fatty Oils.

Melting point 60 - 67°C (Method 2).

Purity Paraffin, fat, Japan wax or resin—Melt White Beeswax at the lowest possible temperature, drip the liquid into a vessel containing ethanol (95) to form granules, and allow them to stand in air for 24 hours. Drop the granules into two mixtures of ethanol (95) and water, one adjusted so as to have a specific gravity of 0.95 and the other 0.97: the granules sink or are suspended in the mixture with the specific gravity of 0.95, and float or are suspended in the other mixture.

Containers and storage Containers—Well-closed containers.

Yellow Beeswax

Cera Flava

ミツロウ

Yellow Beeswax is the purified wax obtained from honeycombs such as those of *Apis indica* Radoszkowski or *Apis mellifera* Linné (*Apidae*).

Description Yellow Beeswax occurs as light yellow to brownish yellow masses. It has a characteristic odor, which is not rancid. It is comparatively brittle when cooled, and the fractured surface is granular, and non-crystalline.

Acid value 5 - 9 or 17 - 22 Weigh accurately about 6 g of Yellow Beeswax, place in a glass-stoppered 250-mL flask, and add 50 mL of ethanol (99.5). Warm the mixture to dissolve the wax, add 1 mL of phenolphthalein TS, and proceed as directed in the Acid value under the Fats and Fatty Oils. Perform a blank determination using solvent which is not previously neutralized, and make any necessary correction.

Saponification value 80 - 100 Weigh accurately about 3 g of Yellow Beeswax, place in a 250-mL glass-stoppered flask, and add 25 mL of 0.5 mol/L potassium hydroxide-ethanol and 50 mL of ethanol (95), insert a reflux condenser, heat for 4 hours on a water bath, and proceed as directed in the Saponification value under the Fats and Fatty Oils.

Melting point 60 - 67°C (Method 2).

Purity Paraffin, fat, Japan wax or resin—Melt Yellow Beeswax at the lowest possible temperature, drip the liquid into a glass vessel containing ethanol (95) to form granules, and allow them to stand in air for 24 hours. Drop the granules into two mixtures of ethanol (95) and water, one adjusted so as to have a specific gravity of 0.95 and the other 0.97: the granules sink or are suspended in the mixture with the specific gravity of 0.95, and float or are suspended in the other mixture.

Containers and storage Containers—Well-closed containers.

Belladonna Extract

Extractum Belladonnae

ベラドンナエキス

Belladonna Extract contains not less than 0.85%