

Shell in 10 mL of dilute hydrochloric acid by heating: it evolves a gas, and forms a very slightly red, turbid solution in which a transparent, thin suspended matter remains. Pass the evolved gas through calcium hydroxide TS: a white precipitate is produced.

(2) The solution obtained in (1) has a slight, characteristic odor. Filter this solution and neutralize with ammonia TS: the solution responds to the Qualitative Tests for calcium salt.

(3) Ignite 1 g of pulverized Oyster Shell: it turns blackish brown in color at first, and evolves a characteristic odor. Ignite it further: it becomes almost white.

Purity Barium—Dissolve 1 g of pulverized Oyster Shell in 10 mL of dilute hydrochloric acid: the solution does not respond to the Qualitative Tests (1) for barium salt.

Powdered Oyster Shell

Ostreae Testa Pulverata

ボレイ末

Powdered Oyster Shell is the powder of Oyster Shell.

Description Powdered Oyster Shell occurs as a grayish white powder. It is odorless and tasteless.

Identification (1) Dissolve 1 g of Powdered Oyster Shell in 10 mL of dilute hydrochloric acid by heating: it evolves a gas, and forms a very slightly red, turbid solution. Pass the gas evolved through calcium hydroxide TS: a white precipitate is produced.

(2) The solution obtained in (1) has a slight, characteristic odor. Filter this solution, and neutralize with ammonia TS: the solution responds to the Qualitative Tests for calcium salt.

(3) Ignite 1 g of Powdered Oyster Shell: it turns blackish brown in color at first evolving a characteristic odor, and becomes almost white by further ignition.

Purity (1) Water-soluble substances—Shake 3.0 g of Powdered Oyster Shell with 50 mL of freshly boiled and cooled water for 5 minutes, filter, and evaporate 25 mL of the filtrate to dryness. Dry the residue at 105°C for 1 hour, cool, and weigh: the mass of the residue does not exceed 15 mg.

(2) Acid-insoluble substances—To 5.0 g of Powdered Oyster Shell add 100 mL of water, and add hydrochloric acid in small portions with stirring until the solution becomes acid. Boil the acidic mixture with additional 1 mL of hydrochloric acid. After cooling, collect the insoluble substance by filtration, and wash it with hot water until the last washing no longer gives any reaction in Qualitative test (2) for chloride. Ignite the residue and weigh: the mass of the residue does not exceed 25 mg.

(3) Barium—Dissolve 1 g of Powdered Oyster Shell in 10 mL of dilute hydrochloric acid: the solution does not respond to the Qualitative Tests (1) for barium salt.

Loss on drying Not more than 4.0% (1 g, 180°C, 4 hours).

Containers and storage Containers—Tight containers.

Panax Rhizome

Panacis Japonici Rhizoma

チクセツニンジン

Panax Rhizome is the rhizome of *Panax japonicus* C. A. Meyer (*Araliaceae*), usually after being treated with hot water.

Description Irregularly cylindrical rhizome with distinct nodes, 3 – 20 cm in length, 1 – 1.5 cm in diameter, internode 1 – 2 cm; externally light yellow-brown, with fine longitudinal wrinkles; stem scars, hollowed at the center, protruding on the upper surface, and root scars protruding as knobs on internodes; easily broken; fractured surface approximately flat, and light yellow-brown in color; horny in texture; odor, slight; taste, slightly bitter.

Identification Shake 0.5 g of pulverized Panax Rhizome with 10 mL of methanol for 10 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 2 mg of chikusetsusaponin IV 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 5 μ 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, water and formic acid (5:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat the plate at 110°C for 5 minutes: one of several spots obtained from the sample solution shows the same color and the same R_f value with the purple-red spot from the standard solution.

Total ash Not more than 5.0%.

Extract content Dilute ethanol-soluble extract: not less than 30.0%.

Powdered Panax Rhizome

Panacis Japonici Rhizoma Pulveratum

チクセツニンジン末

Powdered Panax Rhizome is the powder of Panax Rhizome.

Description Powdered Panax Rhizome occurs as a light grayish yellow-brown powder, and has a slight odor and a slightly bitter taste.

Under a microscope, Powdered Panax Rhizome reveals mainly starch grains or gelatinized starch masses, and fragments of parenchyma cells containing them; also fragments of cork tissue, somewhat thick-walled collenchyma, phloem tissue, and reticulate vessels; rarely fragments of scalariform vessels with a simple perforation, fibers and fiber bundles, rosette aggregates of calcium oxalate, and parenchyma cells containing them; yellow to orange-yellow resin; starch grains consisting of simple grains or 2- to 4-compound grains, simple grains, 3 – 18 μ m in diameter; rosette aggregates of calci-

um oxalate are 20 – 60 μ m in diameter.

Identification (1) Shake vigorously 0.5 g of Powdered Panax Rhizome with 10 mL of water: a lasting fine foam is produced.

(2) Warm 0.2 g of Powdered Panax Rhizome with 2 mL of acetic anhydride on a water bath for 2 minutes, and filter. To 1 mL of the filtrate add carefully 0.5 mL of sulfuric acid to make two layers: a red-purple color develops at the zone of contact.

Total ash Not more than 5.0%.

Extract content Dilute ethanol-soluble extract: not less than 30.0%.

Pancreatin

パンクレアチン

Pancreatin is a substance containing enzymes prepared from the pancreas of edible animals, mostly the hog, and has amylolytic, proteolytic and lipolytic activities. It contains not less than 2800 starch saccharifying activity units, not less than 28,000 proteolytic activity units, and not less than 960 lipolytic activity units per g. It is usually diluted with suitable excipients.

Description Pancreatin occurs as a white to light yellow powder. It has a characteristic odor.

Purity (1) Rancidity—Pancreatin has no unpleasant or rancid odor and is tasteless.

(2) Fat—Add 20 mL of diethyl ether to 1.0 g of Pancreatin, extract with occasional shaking for 30 minutes, and filter. Wash the residue with 10 mL of diethyl ether, combine the washing with the filtrate, evaporate the diethyl ether, and dry the residue at 105°C for 2 hours: the mass of the residue does not exceed 20 mg.

Loss on drying Not more than 4.0% (1 g, in vacuum, phosphorus (V) oxide, 24 hours).

Residue on ignition Not more than 5.0% (1 g).

Assay (1) Starch digestive activity (i) Substrate solution—Use potato starch TS for amylolytic activity test, prepared by adding 10 mL of phosphate buffer solution for pancreatin instead of 10 mL of 1 mol/L acetic acid-sodium acetate buffer solution, pH 5.0.

(ii) Sample solution—Weigh accurately about 0.1 g of Pancreatin, add a suitable amount of ice-cold water, stir, and add ice-cold water to make exactly 100 mL. Pipet 10 mL of this solution, and add ice-cold water to make exactly 100 mL.

(iii) Procedure—Proceed as directed in (i) Measurement of starch saccharifying activity of (1) Assay for starch digestive activity under the Digestion Test.

(2) Protein digestive activity (i) Substrate solution—Use the substrate solution 2 described in (2) Assay for protein digestive activity under the Digestion Test after adjusting the pH to 8.5.

(ii) Sample solution—Weigh accurately about 0.1 g of Pancreatin, add a suitable amount of ice-cold water, stir,

and add ice-cold water to make exactly 200 mL.

(iii) Procedure—Proceed as directed in (2) Assay for protein digestive activity under the Digestion Test, using trichloroacetic acid TS B as the precipitation reagent.

(3) Fat digestive activity (i) Emulsifier—Prepare with 18 g of polyvinyl alcohol I and 2 g of polyvinyl alcohol II as directed in (3) Assay for fat digestive activity under the Digestion Test.

(ii) Substrate solution—Use the substrate solution described in (3) Assay for fat digestive activity under the Digestion Test.

(iii) Sample solution—Weigh accurately about 0.1 g of Pancreatin, add a suitable amount of ice-cold water, stir, and add ice-cold water to make exactly 100 mL.

(iv) Procedure—Proceed as directed in (3) Assay for fat digestive activity under the Digestion Test, using phosphate buffer solution, pH 8.0, as the buffer solution.

Containers and storage Containers—Tight containers.

Storage—Not exceeding 30°C.

Paraffin

パラフィン

Paraffin is a mixture of solid hydrocarbons obtained from petroleum.

Description Paraffin occurs as a colorless or white, more or less transparent, crystalline mass. It is odorless and tasteless. Paraffin is sparingly soluble in diethyl ether and practically insoluble in water, in ethanol (95) and in ethanol (99.5).

Specific gravity d_{20}^{20} : about 0.92 (proceed as directed in the Specific gravity (2) under the Fats and Fatty Oils).

Identification (1) Heat Paraffin strongly in a porcelain dish, and ignite: it burns with a bright flame and the odor of paraffin vapor is perceptible.

(2) Heat 0.5 g of Paraffin with 0.5 g of sulfur with shaking carefully: the odor of hydrogen sulfide is perceptible.

Melting point 50 – 75°C (Method 2).

Purity (1) Acid or alkali—Boil 10.0 g of Paraffin with 10 mL of hot water and 1 drop of phenolphthalein TS in a water bath for 5 minutes, and shake vigorously: a red color is not produced. Add 0.20 mL of 0.02 mol/L sodium hydroxide VS to this solution, and shake: a red color is produced.

(2) Heavy metals—Ignite 2.0 g of Paraffin in a crucible, first moderately until charred, then between 450°C and 550°C to ash. Cool, add 2 mL of hydrochloric acid, and evaporate on a water bath to dryness. To the residue add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: to 2.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 10 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Paraffin according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Sulfur compounds—To 4.0 g of Paraffin add 2 mL of ethanol (99.5), further add 2 drops of a clear saturated solu-