um oxalate are 20 - 60 μm 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-