

Each mL of 0.2 mol/L sodium hydroxide VS
= 30.018 mg of C₄H₆O₆

Containers and storage Containers—Tight containers.

Dried Yeast

乾燥酵母

Dried Yeast is dried and powdered cells of yeast belonging to *Saccharomyces*.

Dried Yeast contains not less than 400 mg of protein and not less than 100 µg of thiamine compounds [as thiamine hydrochloride (C₁₂H₁₇ClN₄OS.HCl: 337.27)] in each 1 g.

Description Dried Yeast occurs as a light yellowish white to brown powder. It has a characteristic odor and taste.

Identification Dried Yeast, when examined under a microscope, shows isolated cells, spheroidal or oval in shape, and 6 to 12 µm in length.

Purity (1) Rancidity—Dried Yeast is free from any unpleasant or rancid odor or taste.

(2) Starch—Add iodine TS to Dried Yeast, and examine microscopically: no or only a few granules are tinted blackish purple.

Loss on drying Not more than 8.0% (1 g, 100°C, 8 hours).

Total ash Not more than 9.0% (1 g, proceed as directed in the Total ash under the Crude Drugs).

Assay (1) Protein—Weigh accurately about 0.05 g of Dried Yeast and perform the test as directed under the Nitrogen Determination.

$$\begin{aligned} &\text{Amount (mg) of protein in 1 g of Dried Yeast} \\ &= \text{amount (mg) of nitrogen (N)} \\ &\quad \times 6.25 \times \frac{1}{\text{amount (g) of sample}} \end{aligned}$$

(2) Thiamine—Weigh accurately about 1 g of Dried Yeast, add 1 mL of dilute hydrochloric acid and 80 mL of water, and heat in a water bath at 80°C to 85°C for 30 minutes with occasional shaking. After cooling, add water to make exactly 100 mL, and centrifuge for 10 minutes. Pipet 4 mL of the supernatant liquid, add exactly 5 mL of acetic acid-sodium acetate TS and exactly 1 mL of enzyme TS, and allow to stand at 45°C to 50°C for 3 hours. Place exactly 2 mL of this solution onto a chromatographic column prepared by pouring 2.5 mL of a weakly acidic CM-bridged cellulose cation exchanger (H type) (40 to 110 µm in particle diameter) into a chromatographic tube about 1 cm in inside diameter and about 17 cm in length, and elute at the flow rate of about 0.5 mL per minute. Wash the upper part of the column with a small amount of water, and wash the column with two 10-mL portions of water at the flow rate of about 1 mL per minute. Elute the column with two 2.5-mL portions of diluted phosphoric acid (1 in 50) at the flow rate of about 0.5 mL per minute, and combine the eluate. To the eluate add exactly 1 mL of the internal standard solution and 0.01 g of sodium 1-octanesulfonate, and after dissolving, use this

solution as the sample solution. Separately, weigh accurately about 0.015 g of the Thiamine Hydrochloride Reference Standard (determine the water content in the same manner as for Thiamine Hydrochloride), dissolve in 0.001 mol/L hydrochloric acid TS to make exactly 100 mL. Pipet 1 mL of this solution, and add the mobile phase to make exactly 100 mL. Pipet 1 mL of this solution, add exactly 1 mL of the internal standard solution and 3 mL of the mobile phase, and use this solution as the standard solution. Perform the test with 200 µL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S , of the peak area of thiamine to that of the internal standard.

$$\begin{aligned} &\text{Amount (}\mu\text{g) of thiamine in 1 g of Dried Yeast} \\ &= \text{amount (mg) of Thiamine Hydrochloride Reference} \\ &\quad \text{Standard, calculated on the anhydrous basis} \\ &\quad \times \frac{Q_T}{Q_S} \times \frac{1}{\text{amount (g) of the sample}} \times 12.5 \end{aligned}$$

Internal standard solution—Dissolve 0.01 g of phenacetin in acetonitrile to make 100 mL, and to 1 mL of this solution add diluted acetonitrile (1 in 5) to make 100 mL.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and 15 to 30 cm in length, packed with octadecylsilylanized silica gel for liquid chromatography (5 to 10 µm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 2.7 g of potassium dihydrogenphosphate in 1000 mL of water, and adjust the pH to 3.5 with diluted phosphoric acid (1 in 10). Dissolve 1.6 g of sodium 1-octanesulfonate in 800 mL of this solution, and add 200 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of thiamine is about 8 minutes.

Selection of column: Proceed with 200 µL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of thiamine and the internal standard in this order with the resolution between these peaks being not less than 8.

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Zanthoxylum Fruit

Zanthoxyli Fructus

サンショウ

Zanthoxylum Fruit is the pericarps of the ripe fruit of *Zanthoxylum piperitum* De Candolle (*Rutaceae*), from which the seeds separated from the pericarps have been mostly removed.

Description Capsules of 2 or 3 flattened spheroidal mericarps, which are dehiscent in 2 pieces about 5 mm in diameter; the outer surface of pericarp, dark yellow-red to

dark red-brown, with numerous dented spots originated from oil sacs; the inner surface, light yellowish white. Odor, characteristically aromatic; taste, acrid, which gives numbing sensation to the tongue.

Under a microscope, transverse section of Zanthoxylum Fruit reveals the external epidermis and the adjoined unicellular layer containing red-brown tannin; the pericarp holds oil sacs being up to approximately 500 μm in diameter and sporadically vascular bundles consisting mainly of spiral vessels; the endocarp consists of stone cell layers; inner epidermal cells very small.

Identification To 0.5 g of pulverized Zanthoxylum Fruit add 100 mL of diluted ethanol (7 in 10), stopper the vessel tightly, shake for 30 minutes, filter, and use this filtrate as the sample solution. Perform the test with the sample solution as directed under the Thin-layer Chromatography. Spot 10 μL of the sample solution on a plate of silica gel with complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (95) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (broad spectrum wavelength): one spot showing a grayish red to red color at the *Rf* value of about 0.7 appears.

Purity (1) Seed—The amount of the seeds contained in Zanthoxylum Fruit does not exceed 20.0%.

(2) Peduncle and twig—The amount of the peduncles and twigs contained in Zanthoxylum Fruit does not exceed 5.0%.

(3) Foreign matter—The amount of foreign matter other than peduncles and twigs contained in Zanthoxylum Fruit does not exceed 1.0%.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.5%.

Essential oil content Perform the test with 30.0 g of pulverized Zanthoxylum Fruit as directed in the Essential oil content under the Crude Drugs: the volume of essential oil is not less than 1.0 mL.

Powdered Zanthoxylum Fruit

Zanthoxyli Fructus Pulveratus

サンショウ末

Powdered Zanthoxylum Fruit is the powder of Zanthoxylum Fruit.

Description Powdered Zanthoxylum Fruit occurs as a dark yellow-brown powder. It has a strong, characteristic aroma and an acrid taste leaving a sensation of numbness on the tongue.

Under a microscope, Powdered Zanthoxylum Fruit reveals fragments of inner tissue of pericarp consisting of stone cells with membranes about 2.5 μm in thickness; fragments of spiral and annular vessels 10 to 15 μm in diameter; fragments of oil sacs containing essential oil or resin; fragments of epidermal cells, polygonal in surface view, containing tannin; numerous oil drops; masses of tannin, colored red by adding vanillin-hydrochloric acid TS.

Identification To 0.5 g of Powdered Zanthoxylum Fruit add 100 mL of diluted ethanol (7 in 10), stopper the vessel tightly, shake for 30 minutes, filter, and perform the test with the filtrate as the sample solution as directed under the Thin-layer Chromatography. Spot 10 μL of the sample solution on a plate of silica gel with complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, methanol and water (30:10:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (broad spectrum wavelength): one spot showing a grayish red to red color at the *Rf* value of about 0.85 appears.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.5%.

Essential oil content Perform the test with 30.0 g of Powdered Zanthoxylum Fruit as directed in the Essential oil content under the Crude Drugs: the volume of essential oil is not less than 0.8 mL.

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Zedoary

Zedoariae Rhizoma

ガジュツ

Zedoary is the rhizome of *Curcuma zedoaria* Roscoe (*Zingiberaceae*), usually after being passed through hot water.

Description Nearly ovoid rhizome, 4–6 cm in length, 2.5–4 cm in diameter; externally grayish yellow-brown to grayish brown; nodes protruded as rings; internode of 0.5–0.8 cm, with thin, longitudinal wrinkles, scars of removed roots, and small protrusions of branched rhizomes; under a magnifying glass, external surface covered with coarse hairs; horny in texture and difficult to cut; cross section grayish brown in color; cortex 2–5 mm in thickness, stele thick, a light grayish brown ring separating them. Odor, characteristic; taste, pungent, bitter and cooling.

Total ash Not more than 7.0%.

Essential oil content Perform the test as directed in the Essential oil content under the Crude Drugs using 50.0 g of pulverized Zedoary, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.5 mL.

Zinc Chloride

塩化亜鉛

ZnCl₂: 136.30

Zinc Chloride contains not less than 97.0% of ZnCl₂.