

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  $\mu\text{m}$  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  $\mu\text{L}$  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 *R<sub>f</sub>* 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  $\mu\text{m}$  in thickness; fragments of spiral and annular vessels 10 to 15  $\mu\text{m}$  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  $\mu\text{L}$  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 *R<sub>f</sub>* 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.

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

## 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

ZnCl<sub>2</sub>: 136.30

Zinc Chloride contains not less than 97.0% of ZnCl<sub>2</sub>.

**Description** Zinc Chloride occurs as white, crystalline powder, rods, or masses. It is odorless.

It is very soluble in water, and freely soluble in ethanol (95), and its solution may sometimes be slightly turbid. The solution becomes clear on addition of a small amount of hydrochloric acid.

The pH of an aqueous solution of Zinc Chloride (1 in 2) is between 3.3 and 5.3.

It is deliquescent.

**Identification** An aqueous solution of Zinc Chloride (1 in 30) responds to the Qualitative Tests for zinc salt and chloride.

**Purity** (1) Clarity and color of solution—Dissolve 1.0 g of Zinc Chloride in 10 mL of water and 2 drops of hydrochloric acid: the solution has no color, and is clear.

(2) Sulfate—Perform the test with 2.0 g of Zinc Chloride. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.010%).

(3) Ammonium—Dissolve 0.5 g of Zinc Chloride in 5 mL of water, and warm with 10 mL of a solution of sodium hydroxide (1 in 6): the evolving gas does not change moistened red litmus paper to blue.

(4) Heavy metals—Dissolve 0.5 g of Zinc Chloride in 5 mL of water in a Nessler tube, shake thoroughly with 15 mL of potassium cyanide TS, add 1 drop of sodium sulfide TS, allow to stand for 5 minutes, and immediately observe from the top downward against a white background: the solution has no more color than the following control solution.

Control solution: To 2.5 mL of Standard Lead Solution add 3 mL of water and 15 mL of potassium cyanide TS, shake thoroughly, and add 1 drop of sodium sulfide TS (not more than 50 ppm).

(5) Alkali earth metals and alkali metals—Dissolve 2.0 g of Zinc Chloride in 120 mL of water, add ammonium sulfide TS to complete precipitation, add water to make 200 mL, shake thoroughly, and filter through dry filter paper. Discard the first 20 mL of the filtrate, take the following 100 mL of the filtrate, evaporate with 3 drops of sulfuric acid to dryness, and heat the residue strongly at 600°C to constant mass: the mass is not more than 10.0 mg.

(6) Arsenic—Prepare the test solution with 0.40 g of Zinc Chloride according to Method 1, and perform the test using Apparatus B (not more than 5 ppm).

(7) Oxychloride—Shake gently 0.25 g of Zinc Chloride with 5 mL of water and 5 mL of ethanol (95), and add 0.3 mL of 1 mol/L hydrochloric acid VS: the solution is clear.

**Assay** Weigh accurately about 0.3 g of Zinc Chloride, add 0.4 mL of dilute hydrochloric acid and water to make exactly 200 mL. Measure exactly 20 mL of the solution, add 80 mL of water, 2 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and titrate with 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS (indicator: 0.04 g of eriochrome black T-sodium chloride indicator).

Each mL of 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS  
= 1.3630 mg of  $ZnCl_2$

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

## Zinc Oxide Oil

チンク油

Zinc Oxide Oil contains not less than 45.0% and not more than 55.0% of zinc oxide (ZnO: 81.39).

### Method of preparation

Zinc Oxide	500 g
Fixed oil	a sufficient quantity
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To make 1000 g	

Mix the above ingredients. An appropriate quantity of Castor Oil or polysorbate 20 may be used partially in place of fixed oil.

**Description** Zinc Oxide Oil is a white to whitish, slimy substance, separating a part of its ingredients when stored for a prolonged period.

**Identification** Mix thoroughly, and place 0.5 g of Zinc Oxide Oil in a crucible, heat gradually raising the temperature until the mass is thoroughly charred, and then ignite it strongly: a yellow color is produced, and disappears on cooling. To the residue add 10 mL of water and 5 mL of dilute hydrochloric acid, shake well, and filter. To the filtrate add 2 to 3 drops of potassium hexacyanoferrate (II) TS: a white precipitate is formed (zinc oxide).

**Assay** Weigh accurately about 0.8 g of Zinc Oxide Oil, mixed well, place in a crucible, heat gradually raising the temperature until the mass is thoroughly charred, and then ignite until the residue becomes yellow, and cool. Dissolve the residue in 1 mL of water and 1.5 mL of hydrochloric acid, and add water to make exactly 100 mL. Pipet 20 mL of this solution, add 80 mL of water, and add a solution of sodium hydroxide (1 in 50) until a small amount of precipitates begins to form in the solution. Add 5 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and titrate with 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS (indicator: 0.04 g of eriochrome black T-sodium chloride indicator).

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS  
= 4.069 mg of ZnO

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

## Zinc Oxide Ointment

亜鉛華軟膏

Zinc Oxide Ointment contains not less than 18.5% and not more than 21.5% of zinc oxide (ZnO: 81.39).

### Method of preparation

Zinc Oxide	200 g
Liquid Paraffin	30 g
White Ointment	a sufficient quantity
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To make 1000 g	