

(2) Unsaponified matter—To 1.0 mL of Saponated Cresol Solution add 5 mL of water, and shake: the solution is clear.

(3) Cresol fraction—Transfer 180 mL of Saponated Cresol Solution to a 2000-mL distilling flask, add 300 mL of water and 100 mL of dilute sulfuric acid, and distil with steam until the distillate becomes clear. Draw off the water from the condenser, and continue the distillation until water vapor begins to come out of the tip of the condenser. Cool the condenser again, and continue distillation for 5 minutes. Dissolve 20 g of sodium chloride per 100 mL of the distillate, allow to stand, and collect the separated clear oil layer. After adding about 15 g of powdered calcium chloride for drying in small portions with frequent shaking, allow to stand for 4 hours. Filter, and distil exactly 50 mL of the filtrate: the distillate is not less than 43 mL between 196°C and 206°C.

Assay Transfer 5 mL of Saponated Cresol Solution, exactly measured, to a 500-mL distilling flask, holding the pipet vertically for 15 minutes to draw off the solution into the flask. Add 200 mL of water, 40 g of sodium chloride and 3 mL of dilute sulfuric acid, connect the distilling apparatus with the distilling flask, and distil into a cassia flask which contains 30 g of powdered sodium chloride and exactly 3 mL of kerosene, until the distillate reaches 90 mL. Draw off the water from the condenser, and continue the distillation until water vapor begins to come out of the tip of the condenser. Allow the cassia flask to stand in warm water for 15 minutes to dissolve the sodium chloride with frequent shaking. Cool to 15°C, add a saturated solution of sodium chloride, and allow to stand for more than 3 hours with occasional shaking. Allow to stand for 1 to 2 minutes with gentle shaking, and combine the separated oil drops with the oil layer. The volume (mL) subtracted 3 (mL) from the oil layer measured represents the amount (mL) of cresol.

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Cyperus Rhizome

Cyperi Rhizoma

コウブシ

Cyperus Rhizome is the rhizome of *Cyperus rotundus* Linné (*Cyperaceae*).

Description Fusiform rhizome, 1.5–2.5 cm in length, 0.5–1 cm in diameter; externally grayish brown to grayish blackish brown, with 5 to 8 irregular ring nodes, and with hair-like fiber bundles on each node; hard in texture. The transverse section red-brown to light yellow in color, with waxy luster; thickness of cortex approximately equal to or slightly smaller than the diameter of stele. Under a magnifying glass, a transverse section reveals fiber bundles as brown spots lined in rings along circumference; here and there in the cortex, vascular bundles appear as red-brown spots, and numerous secretory cells scattered as minute yellow-brown spots; in the stele, numerous vascular bundles scattered as spots or lines. Characteristic odor and taste.

Total ash Not more than 3.0%.

Essential oil content Perform the test with 50.0 g of pulverized *Cyperus Rhizome* as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added on the sample in the flask: the volume of essential oil is not less than 0.3 mL.

Powdered Cyperus Rhizome

Cyperi Rhizoma Pulveratum

コウブシ末

Powdered *Cyperus Rhizome* is the powder of *Cyperus Rhizome*.

Description Powdered *Cyperus Rhizome* occurs as a light red-brown powder, and has a characteristic odor and taste.

Under a microscope, Powdered *Cyperus Rhizome* reveals fragments of polygonal parenchyma cells, scalariform vessels, and seta-like fibers; a large quantity of starch, mostly gelatinized; an extremely small number of stone cells.

Purity Foreign matter—Under a microscope, Powdered *Cyperus Rhizome* does not show extremely lignified cells, except stone cells, or crystals.

Total ash Not more than 3.0%.

Acid-insoluble ash Not more than 1.5%.

Essential oil content Perform the test with 50.0 g of Powdered *Cyperus Rhizome* as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added on the sample in the flask: the volume of essential oil is not less than 0.2 mL.

Containers and storage Containers—Tight containers.

Dextrin

デキストリン

Description Dextrin occurs as a white or light yellow, amorphous powder or granules. It has a slight, characteristic odor and a sweet taste. It does not irritate the tongue. Dextrin is freely soluble in boiling water, soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

Identification To 0.1 g of Dextrin add 100 mL of water, shake, and filter if necessary. To 5 mL of the filtrate add 1 drop of iodine TS: a light red-brown or light red-purple color develops.

Purity (1) Clarity and color of solution—Take 2.0 g of Dextrin in a Nessler tube, add 40 mL of water, dissolve by heating, cool, and add water to make 50 mL: the solution is colorless or light yellow. It is clear, and even if turbid, the turbidity is not more than that of the following control solution.

Control solution: To 1.0 mL of 0.005 mol/L sulfuric acid VS add 1 mL of dilute hydrochloric acid, 46 mL of water and 2 mL of barium chloride TS, allow to stand for 10 minutes,

and shake before use.

(2) Acid—To 1.0 g of Dextrin add 5 mL of water, dissolve by heating, cool, and add 1 drop of phenolphthalein TS and 0.50 mL of 0.1 mol/L sodium hydroxide VS: a red color develops.

(3) Chloride—To 2.0 g of Dextrin add 80 mL of water, dissolve by heating, cool, add water to make 100 mL, and filter. Take 40 mL of the filtrate, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.013%).

(4) Sulfate—To 45 mL of the filtrate obtained in (3) add 1 mL of dilute hydrochloric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.019%).

(5) Oxalate—To 1.0 g of Dextrin add 20 mL of water, dissolve by heating, cool, add 1 mL of acetic acid (31), and filter. To 5 mL of the filtrate add 5 drops of calcium chloride TS: no turbidity is produced immediately.

(6) Calcium—To a 5-mL portion of the filtrate obtained in (5) add 5 drops of ammonium oxalate TS: no turbidity is immediately produced.

(7) Heavy metals—Proceed with 0.5 g of Dextrin according to Method 2, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 50 ppm).

Loss on drying Not more than 10% (0.5 g, 105°C, 4 hours).

Residue on ignition Not more than 0.5% (0.5 g).

Containers and storage Containers—Well-closed containers.

Diastase

ジアスターゼ

Diastase is an enzyme drug mainly prepared from malt. It has amylolytic activity. It contains not less than 440 starch saccharifying activity units per g. It is usually diluted with suitable diluents.

Description Diastase occurs as a light yellow to light brown powder.

It is hygroscopic.

Purity Rancidity—Diastase has no unpleasant or rancid odor, and has no unpleasant or rancid taste.

Loss on drying Not more than 4.0% (1 g, 105°C, 5 hours).

Assay (i) Substrate solution—Use potato starch TS for amylolytic activity test.

(ii) Sample solution—Weigh accurately about 0.1 g of Diastase, and dissolve in 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.

Containers and storage Containers—Tight containers.

Storage—Not exceeding 30°C.

Diastase and Sodium Bicarbonate Powder

ジアスターゼ・重曹散

Method of preparation

Diastase	200 g
Sodium Bicarbonate	300 g
Precipitated Calcium Carbonate	400 g
Magnesium Oxide	100 g

To make 1000 g

Prepare before use as directed under Powders, with the above ingredients.

Description Diastase and Sodium Bicarbonate Powder occurs as a light yellow powder. It has a characteristic, salty taste.

Containers and storage Containers—Well-closed containers.

Compound Diastase and Sodium Bicarbonate Powder

複方ジアスターゼ・重曹散

Method of preparation

Diastase	200 g
Sodium Bicarbonate	600 g
Magnesium Oxide	150 g
Powdered Gentian	50 g

To make 1000 g

Prepare before use as directed under Powders, with the above ingredients.

Description Compound Diastase and Sodium Bicarbonate Powder occurs as a slightly brownish, light yellow powder. It has a characteristic odor and a bitter taste.

Containers and storage Containers—Well-closed containers.

Dibasic Sodium Phosphate

リン酸水素ナトリウム

$\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$: 358.14

Dibasic Sodium Phosphate, when dried, contains not less than 98.0% of disodium hydrogenphosphate (Na_2HPO_4 : 141.96)

Description Dibasic Sodium Phosphate occurs as colorless or white crystals. It is odorless.

It is freely soluble in water, and practically insoluble in