

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

ethanol (95) and in diethyl ether.

It effloresces in warm, dry air.

Identification A solution of Dibasic Sodium Phosphate (1 in 10) responds to the Qualitative Tests (1) and (2) for sodium salt, and the Qualitative Tests for phosphate.

pH Dissolve 1.0 g of Dibasic Sodium Phosphate in 50 mL of water: the pH of this solution is between 9.0 and 9.4.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Dibasic Sodium Phosphate in 20 mL of water: the solution is clear and colorless.

(2) Chloride—Dissolve 1.0 g of Dibasic Sodium Phosphate in 7 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 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.014%).

(3) Sulfate—Dissolve 0.5 g of Dibasic Sodium Phosphate in 2 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.038%).

(4) Carbonate—To 2.0 g of Dibasic Sodium Phosphate add 5 mL of water, boil, and add 2 mL of hydrochloric acid after cooling: the solution does not effervesce.

(5) Heavy metals—Dissolve 2.0 g of Dibasic Sodium Phosphate in 4 mL of acetic acid (31) and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 2.0 mL of Standard Lead Solution by adding 2 mL of dilute acetic acid and water to make 50 mL (not more than 10 ppm).

(6) Arsenic—Prepare the test solution with 1.0 g of Dibasic Sodium Phosphate according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying 57.0–61.0% (10 g, at 40°C for 3 hours at first and then at 105°C for 5 hours).

Assay Dissolve about 3 g of Dibasic Sodium Phosphate, previously dried and accurately weighed, in 50 mL of water. Titrate it with 0.5 mol/L sulfuric acid VS at 15°C until the green color of the solution changes to dark-greenish red-purple (indicator: 3 to 4 drops of methyl orange-xylene cyanol FF TS).

Each mL of 0.5 mol/L sulfuric acid VS
= 141.96 mg of Na₂HPO₄

Containers and storage Containers—Tight containers.

Digenea

Digenea

マクリ

Digenea is the whole algae of *Digenea simplex* C. Agardh (*Rhodomelaceae*).

Description Rounded, string-like algae, 2–3 mm in diameter; externally, dark red-purple to dark grayish red or grayish brown; a few branched rods irregularly forked, covered with short hairy twigs; calcified weeds and other small algae often attached. Odor, seaweed-like; taste, disagreeable

and slightly salty.

Identification To 5 g of Digenea add 50 mL of water, macerate between 50°C and 60°C for 1 hour, and filter while warm. Add 50 mL of water to the residue, macerate again between 50°C and 60°C for 1 hour, and filter while warm. Evaporate all the filtrate on a water bath to about 25 mL, and use this solution as the sample solution. Separately, dissolve 0.05 g of kainic acid in 10 mL of water, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with the upper layer of a mixture of water, 1-butanol and acetic acid (100) (5:4:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly a water-saturated solution of ninhydrin in 1-butanol (1 in 500) upon the plate, and heat at 90°C for 10 minutes: the spots obtained from the sample solution and the standard solution show a light yellow color and the same R_f values.

Purity Foreign matter—The amount of other algae in Digenea does not exceed 20.0%.

Loss on drying Not more than 22.0%.

Acid-insoluble ash Not more than 8.0%.

Digitalis

Digitalis

ジギタリス

Digitalis is the leaf of *Digitalis purpurea* Linné (*Scrophulariaceae*), dried at a temperature not exceeding 60°C, with petiole and midrib removed, and finely cut.

It contains not less than 8 and not more than 15 Digitalis Units in 1 g.

Description Digitalis occurs as grayish green to grayish yellow-green, fine fragments of thin lamina. The upper surface is glabrous and dented along the vein, and the lower surface is generally densely pubescent and protruded along the vein. It has a slight odor, and a very bitter taste.

Under a microscope, Digitalis reveals upper epidermal cells possessing almost linear or slightly wavy walls, and rarely stomata; lower epidermal cells with prominently wavy walls, and numerous stomata, each being accompanied by 3 to 4 subsidiary cells; the acute multicellular hairs of 2 to 8 cells and glandular hairs are on both surfaces but more prominently along the veins on the lower surface; crystals of calcium oxalate are absent in the tissues.

Identification To 1 g of Digitalis add 10 mL of diluted ethanol (7 in 10), boil for 2 minutes, and filter. To 5 mL of the filtrate add 10 mL of water and 0.5 mL of lead subacetate TS, shake, and filter. To the filtrate add 5 mL of chloroform, shake, and separate the chloroform layer. Evaporate the chloroform gently on a water bath. Cool, add 1 mL of a solution of iron (III) chloride hexahydrate in acetic acid (100) (1 in 10000) to the residue, shake well, and underlay gently with 1 mL of sulfuric acid: at the zone of contact of the two liquids