Saccharated Pepsin

含糖ペプシン

Saccharated Pepsin is a mixture of pepsin obtained from the gastric mucosa of hog or cattle and Lactose, and it is an enzyme drug having a proteolytic activity. Saccharated Pepsin contains not less than 3800 units and not more than 6000 units per g.

Description Saccharated Pepsin occurs as a white powder. It has a characteristic odor, and has a slightly sweet taste.

It dissolves in water to give a slightly turbid liquid, and does not dissolve in ethanol (95) and in diethyl ether.

It is slightly hygroscopic.

Purity **(1)** Rancidity—Saccharated Pepsin has no unpleasant or rancid odor.

(2) Acid—Dissolve 0.5 g of Saccharated Pepsin in 50 mL of water, and add 0.50 mL of 0.1 mol/L sodium hydroxide VS and 2 drops of phenolphthalein TS: the solution is red in color.

Loss on drying Not more than 1.0% (1 g, 80°C, 4 hours).

Residue on ignition Not more than 0.5% (1 g).

Assay (i) Substrate solution—Use the substrate solution 1 described in (2) Assay for protein digestive activity under the Digestion Test after adjusting the pH to 2.0.

(ii) Sample solution—Weigh accurately an amount of Saccharated Pepsin equivalent to about 1250 units, dissolve in ice-cold 0.01 mol/L hydrochloric acid TS to make exactly 50 ml.

(iii) Standard solution—Weigh accurately a suitable amount of Saccharated Pepsin Reference Standard, and dissolve in ice-cold 0.01 mol/L hydrochloric acid TS to make a solution containing about 25 units per ml.

(iv) Procedure—Proceed as directed in (2) Assay for protein digestive activity under the Digestion Test, and determine the absorbances, A_T and A_{TB}, of the sample solution, using trichloroacetic acid TS A as the precipitation reagent. Separately, determine the absorbances, A_S and A_{SB}, of the standard solution in the same manner as the sample solution.

$$\text{Units in 1 g of Saccharated Pepsin} = U_S \times \frac{A_T - A_{TB}}{A_S - A_{SB}} \times \frac{1}{W}$$

U_S: Units per ml of the standard solution

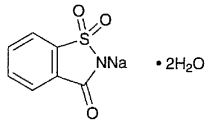
W: Amount (g) of Saccharated Pepsin per ml of the sample solution

Containers and storage Containers—Tight containers.

Storage—Not exceeding 30°C.

Saccharin Sodium

サッカリンナトリウム



$C_7H_4NNaO_3S.2H_2O$: 241.20

Monosodium 3-oxo-1,2-benzisothiazolinate 1,1-dioxide dihydrate [*6155-57-3*]

Saccharin Sodium, when dried, contains not less than 98.0% of $C_6H_4NNaO_3S$: 205.17.

Description Saccharin Sodium occurs as colorless crystals or a white, crystalline powder. It has an intensely sweet taste, even in 10,000 dilutions.

It is freely soluble in water, sparingly soluble in ethanol (95), and practically insoluble in diethyl ether.

It effloresces slowly and loses about half the amount of water of crystallization in air.

Identification **(1)** Dissolve 0.1 g of Saccharin Sodium in 5 mL of sodium hydroxide TS, evaporate to dryness, and fuse carefully the residue avoiding carbonization until it ceases to evolve the odor of ammonia. Allow the residue to cool, dissolve it in 20 mL of water, neutralize the solution with dilute hydrochloric acid, and filter. Add 1 drop of iron (III) chloride TS to the filtrate: the solution produces a red-purple to purple color.

(2) Mix 0.02 g of Saccharin Sodium with 0.04 g of resorcinol, add 10 drops of sulfuric acid, and gently heat the mixture until it acquires a dark green color. Allow it to cool, add 10 mL of water and 10 mL of sodium hydroxide TS: a green fluorescence is produced.

(3) Dissolve 0.5 g of Saccharin Sodium in 5 mL of water, and add 0.5 mL of hydrochloric acid: a white, crystalline precipitate is produced. Collect the precipitate, wash with water, and dry at 105°C for 1 hour: the precipitate melts between 226°C and 230°C.

(4) A solution of Saccharin Sodium (1 in 10) responds to the Qualitative Tests for sodium salt.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Saccharin Sodium in 1.5 mL of water or in 50 mL of ethanol (95): the solution is clear and colorless.

(2) Acid or alkali—Dissolve 1.0 g of Saccharin Sodium in 10 mL of water, and add 1 drop of phenolphthalein TS: the solution is colorless. Add 1 drop of 0.1 mol/L sodium hydroxide VS to the solution: the color changes to red.

(3) Heavy metals—Dissolve 2.0 g of Saccharin Sodium in 40 mL of water, add 0.7 mL of dilute hydrochloric acid, dilute with water to make 50 mL, and rub the inner wall of the vessel with a glass rod until crystallization begins. Allow the solution to stand for 1 hour after the beginning of crystallization, and then filter through dry filter paper. Reject the first 10 mL of the filtrate, and take 25 mL of the subsequent filtrate. Add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test, using this solution as the test solution. To 2.0 mL of Standard Lead Solution add 2 mL of di-

lute acetic acid and water to make 50 mL, and use this solution as the control solution (not more than 20 ppm).

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

(5) Benzoate and salicylate—Dissolve 0.5 g of Saccharin Sodium in 10 mL of water, add 5 drops of acetic acid (31) and 3 drops of iron (III) chloride TS: no turbidity is produced, and no red-purple to purple color develops.

(6) Orthotoluene sulfonamide—Dissolve 10 g of Saccharin Sodium in 50 mL of water, and extract with three 30-mL portions of ethyl acetate. Combine all the ethyl acetate extracts, wash with 30 mL of a solution of sodium chloride (1 in 4), dehydrate with 5 g of anhydrous sodium sulfate, and evaporate ethyl acetate. Dissolve the residue in exactly 5 mL of the internal standard solution, and use this solution as the sample solution. Separately, dissolve 0.10 g of orthotoluene sulfonamide in ethyl acetate to make exactly 100 mL. Pipet 1 mL of this solution, evaporate on a water bath to dryness, dissolve the residue in exactly 5 mL of the internal standard solution, and use this solution as the standard solution. Perform the test with 1 μL each of the sample solution and the standard solution as directed under the Gas Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak height of orthotoluene sulfonamide to that of the internal standard: Q_T is not more than Q_S.

Internal standard solution—A solution of caffeine in ethyl acetate (1 in 500).

Operating conditions—

Detector: A hydrogen flame-ionization detector.

Column: A column about 3 mm in inside diameter and about 1 m in length, packed with siliceous earth for gas chromatography (180 to 250 μm in diameter), coated with diethyleneglycol polyester succinate at the ratio of 3%.

Column temperature: Constant temperature between 195°C and 205°C.

Carrier gas: Nitrogen.

Flow rate: Adjust the flow rate so that the retention time of caffeine is about 6 minutes.

Selection of column: Proceed with 1 μL of the standard solution under the above operating conditions. Use a column giving elution of the internal standard and orthotoluene sulfonamide in this order with the resolution between these peaks being not less than 2.0.

(7) Readily carbonizable substances—Perform the test with 0.20 g of Saccharin Sodium. Allow the solution to stand between 48°C and 50°C for 10 minutes: the solution has no more color than Matching Fluid A.

Loss on drying Not more than 15.0% (1 g, 120°C, 4 hours).

Assay Weigh accurately about 0.5 g of Saccharin Sodium, previously dried, and dissolve in 20 mL of water in a separator. Add 2 mL of dilute hydrochloric acid, extract the produced precipitate with one 50-mL portion and four 20-mL portions of a mixture of chloroform and ethanol (99.5) (9:1), and filter each extract through absorbent cotton moistened with the mixture at each extraction. Wash the extremity of the separator and the absorbent cotton with the mixture, and combine the washings with the extract. Evaporate the solution on a water bath to dryness, dissolve the residue in 75 mL of hot water, cool, and titrate the solution with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS).

Each mL of 0.1 mol/L sodium hydroxide VS
= 20.517 mg of $C_7H_4NNaO_3S$

Containers and storage Containers—Well-closed containers.

Safflower

Carthami Flos

コウカ

Safflower is the tubulous flower of *Carthamus tinctorius* Linné (*Compositae*) without any treatment or with most of the yellow pigment removed, and pressed into a flat slab.

Description Red to red-brown corolla, yellow style and stamen, rarely mixed with immature ovary; total length about 1 cm; corolla, tubular and with 5 lobes; 5 stamens surrounding long pistil; pollen grains yellow and approximately spherical, about 50 μm in diameter, with fine protrusions on the surface. The pressed slab, about 0.5 cm in thickness, consists of a collection of numerous corollas. Odor, characteristic; taste, slightly bitter.

Identification Boil 0.2 g of Safflower with 10 mL of dilute ethanol under a reflux condenser for 15 minutes, and after cooling, filter. Place 3 mL of the filtrate in a small glass vessel about 3 cm in both internal diameter and height, hang a piece of filter paper, 20 mm by 300 mm, so that one end of the filter paper reaches the bottom of the vessel, and allow the paper to soak up the liquid for 1 hour. Transfer and immediately hang the paper in another glass vessel of the same type, containing 3 mL of water, and allow the paper to soak up the water for 1 hour: most of the upper part of the paper is colored light yellow, and the lower portion, light red.

Purity Foreign matter—The amount of ovaries, stems, leaves and other foreign matter contained in Safflower does not exceed 2.0%.

Total ash Not more than 18.0%.

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Saffron

Crocus

サフラン

Saffron is the stigma of *Crocus sativus* Linné (*Iridaceae*).

Description Thin cord-like stigma, externally dark yellow-red to red-brown, 1.5 - 3.5 cm in length, tripartite or separate; the end of partite part widened and the other end