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

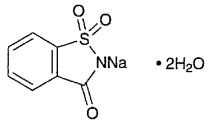
W: Amount (g) of Saccharated Pepsin per ml of the sample solution

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-