Sodium Starch Glycolate (Type B)

Sodium Starch Glycolate (Type B) is the sodium salt of a cross linked partly O- carboxymethylated starch.

Sodium Starch Glycolate (Type B) contains not less than 2.0 per cent and not more than 3.4 per cent of sodium, Na, calculated on the material washed with *Ethanol (95 per cent)* and dried as described under Assay.

Category. Pharmaceutical aid (tablet disintegrant).

Description. A white or almost white, fine, free-flowing powder, very hygroscopic.

Identification

A. pH (see Test)

B. Shake 4.0 g of the substance under examination with 20 ml of *carbon-dioxide-free water*, without heating. This has the appearance of a gel. Add 100 ml of *carbon-dioxide-free water* and shake. A suspension forms that settles after standing.

C. To an acidified solution, add *iodinated potassium iodide solution*; a blue or violet colour produced.

D. Solution A (see Tests) gives reaction (a) of sodium salts (2.3.1).

Tests

Solution A. Dissolve 2.5 g of substance under examination in 2 ml of a 50 per cent w/v solution of *sulphuric acid*. Heat on a water-bath, then cautiously over a naked flame, raising the temperature progressively, then incinerate in a muffle furnace at 600 ± 25˚. Continue heating until all black particles have disappeared. Allow to cool, add a few drops of *dilute sulphuric acid,* heat and incinerate as above. Allow to cool, add a few drops of *ammonium carbonate solution*, evaporate to dryness and incinerate. Allow to cool and dissolve the residue in 50 ml of *water.*

Appearance of solution. Centrifuge the suspension obtained in identification test B at 2500 rpm for 10 minutes. The supernatant liquid is clear (2.4.1) and colourless (2.4.1).

pH (2.4.24). 3.0 to 5.0, determined in a 3.3 per cent w/v solution in *carbon-dioxide-free water*.

Heavy metals (2.3.13). To 4.0 g in a silica or platinum dish, add 2 ml of a 50 per cent w/v solution of *sulphuric acid;* heat in a water-bath and then cautiously over a flame at about 600°. Continue heating until all black particles have disappeared, allow to cool, add 0.1 ml of *1 M sulphuric acid,* heat to ignition once again and allow to cool. Add 0.1 ml of *2M ammonium carbonate,* evaporate to dryness and cautiously ignite. To the residue, add 5 ml of *hydrochloric acid,* evaporate to dryness on a water-bath and dissolve the residue in 100 ml of *water.* 25 ml of a solution complies with the limit test for heavy metals, Method A (20 ppm).

Iron (2.3.14). 10 ml of solution A, complies with the limit test for iron (20 ppm).

Sodium Chloride. Not more than 7.0 per cent.

Weigh 0.5 g, suspend in a mixture of 100 ml of *water* add 1 ml of *nitric acid* and mix. Titrate with *0.1 M silver nitrate,* determining the end point potentiometrically (2.4.25), using a silver indicator electrode. Carry out a blank titration.

1 ml of *0.1 M silver nitrate* is equivalent to 0.005844 g of NaCI.

Sodium glycolate

Test solution. To 0.2 g add 5 ml of *glacial acetic acid,* mix well and add 5 ml of *water,* stirring until dissolution is complete (about 10 minutes). Add 50 ml of *acetone* and 1 g of *sodium chloride.* Filter through a fast filter paper impregnated with *acetone*, and filter with *acetone*. Combine the filtrate and washing and dilute to 100.0 ml with *acetone*. Allow to stand for 24 hours without shaking. Use the clear supernatant.

Reference solution. Dissolve 0.31 g of *glycolic acid* previously dried under vacuum over *phosphorus pentoxide* at room temperature overnight with *water* and dilute to 500 ml with *water*. Take 5.0 ml of the solution, add 5 ml of *acetic acid* and allow to stand for about 30 minutes. Add 50 ml of *acetic acid* and allow to stand for 30

minutes. Add 50 ml of *acetone* and 1 g of *sodium chloride*, filter through a fast filter paper impregnated with *acetone*. Combine the filtrate and washing and dilute to 100.0 ml with *acetone*. Allow to stand for 24 hours without shaking. Use the clear supernatant.

Transfer 2.0 ml of the test solution to an open flask, heat on a water-bath for 20 minutes, cool to room temperature, add 20.0 ml of *2,7-dihydroxynaphthalene solution*. Shake and heat on water-bath for 20 minutes. Cool under running water, transfer to a volumetric flask and diluted to 25.0 ml with *sulphuric acid*, maintaining the flask under running water. Within 10 minutes, measure the absorbance at 540 nm using water as blank. The absorbance of the solution prepared with the test solution is not more than the solution prepared at the same time and in the same manner using 2.0 ml of the reference solution (2.0 per cent).

Settling volume. To 70 ml of *water* in a 100 ml graduated cylinder, add 1 g of the substance under examination (dried substance), stir with a glass rod to avoid lumps and dilute to 100.0 ml with *water* and stir again until the substance is homogeneously distributed. Allow to stand for 2 hours. The volume of the sediment is less than 45.0 ml.

Microbial contamination (2.2.9). 1.0 g is free from *Escherichia coli* and 10.0 g is free from *Salmonellae.*

Loss on drying (2.4.19). Not more than 10.0 per cent, determined on 1.0 g by drying in an oven at 130° for 1.5 hours.

Assay. Weigh 1.0 g, add 20 ml of *ethanol (80 per cent)*, shake for 10 minutes and filter. Repeat the extraction three times, or until a test for chloride ions is negative using *silver nitrate solution*. Dry the residue at 105° to constant weight. Weigh 0.7 g of the residue, add 80 ml of *anhydrous glacial acetic acid,* heat under a reflux condenser for 2 hours, cool. Titrate with *0.1 M perchloric acid,* determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M perchloric acid* is equivalent to 0.0023 g of sodium.

Storage. Store protected from light and moisture.