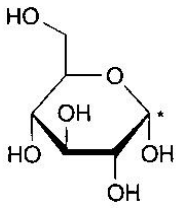
01/2002:0177

GLUCOSE, ANHYDROUS

Glucosum anhydricum



and epimer at C*

$C_6H_{12}O_6$ M_r180.2

DEFINITION

Anhydrous glucose is (+)-n-glucopyranose.

CHARACTERS

A white, crystalline powder, with a sweet taste, freely soluble in water, sparingly soluble in alcohol.

IDENTIFICATION

A. Specific optical rotation (see Tests): +52.5 to +53.3.

B. Examine by thin-layer chromatography (2.2.27), using *silica gel G R* as the coating substance.

Test solution. Dissolve 10 mg of the substance to be examined in a mixture of 2 volumes of *water R* and 3 volumes of *methanol R* and dilute to 20 ml with the same mixture of solvents.

Reference solution (a). Dissolve 10 mg of *glucose CRS* in a mixture of 2 volumes of *water R* and 3 volumes of *methanol R* and dilute to 20 ml with the same mixture of solvents.

Reference solution (b). Dissolve 10 mg each of *fructose CRS, glucose CRS, lactose CRS* and *sucrose CRS* in a mixture of 2 volumes of water R and 3 volumes of *methanol R* and dilute to 20 ml with the same mixture of solvents.

Apply separately to the plate 2 µl of each solution and thoroughly dry the starting points. Develop over a path of 15 cm using a mixture of 10 volumes of *water R,* 15 volumes of *methanol R,* 25 volumes of *anhydrous acetic acid R* and 50 volumes of *ethylene chloride R*. The solvents should be measured accurately since a slight excess of water produces cloudiness. Dry the plate in a current of warm air. Repeat the development immediately, after renewing the mobile phase. Dry the plate in a current of warm air and spray evenly with a solution of 0.5 g of *thymol R* in a mixture of 5 ml of *sulphuric acid R* and 95 ml of *alcohol R*. Heat at 130 °C for 10 min. The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a). The test is not valid unless the chromatogram obtained with reference solution (b) shows four clearly separated spots.

C. Dissolve 0.1 g in 10 ml of *water R*. Add 3 ml of *cupri-tartaric solution R* and heat. A red precipitate is formed.

TESTS

Solution S. Dissolve 10.0 g in *distilled water R* and dilute to 100 ml with the same solvent.

Appearance of solution. Dissolve 10.0 g in 15 ml of *water R*. The solution is clear (2.2.1), odourless, and not more intensely coloured than reference solution BY, (2.2.2, *Method II).*

Acidity or alkalinity. Dissolve 6.0 g in 25 ml of *carbon dioxide-free water R* and add 0.3 ml of *phenolphthalein solution R*. The solution is colourless. Not more than 0.15 ml of *0.1 M sodium hydroxide* is required to change the colour of the indicator to pink.

Specific optical rotation (2.2.7). Dissolve 10.0 g in 80 ml of *water R,* add 0.2 ml of *dilute ammonia R1,* allow to stand for 30 min and dilute to 100.0 ml with *water R*. The specific optical rotation is + 52.5 to + 53.3, calculated with reference to the anhydrous substance.

Foreign sugars, soluble starch, dextrins. Dissolve 1.0 g by boiling in 30 ml of *alcohol (90 per cent V/V) R*. Cool; the appearance of the solution shows no change.

Sulphites. Dissolve 5.0 g in 40 ml of *water R,* add 2.0 ml of *0.1 M sodium hydroxide* and dilute to 50.0 ml with *water R*. To 10.0 ml of the solution, add I ml of a 310 g/I solution of *hydrochloric acid R,* 2.0 ml of *decolorised fuchsin solution R1* and 2.0 ml of a 0.5 per cent *V/V* solution of *formaldehyde R*. Allow to stand for 30 min and measure the absorbance *(2.2.25)* at the maximum at 583 nm. Prepare a standard as follows. Dissolve 76 mg of *sodium metabisulphite R* in *water R* and dilute to 50.0 ml with the same solvent. Dilute 5.0 ml of this solution to 100.0 ml with *water R*. To 3.0 ml of this solution add 4.0 ml of *0.1 M sodium hydroxide* and dilute to 100.0 ml with *water R*. Immediately add to 10.0 ml of this solution 1 ml of a 310 g/I solution of *hydrochloric acid R,* 2.0 ml of *decolorised fuchsin solution R1* and 2.0 ml of a 0.5 per cent *V/V* solution of *formaldehyde R*. Allow to stand for 30 min and measure the absorbance at the maximum at 583 nm. Use as compensation liquid for both measurements a solution prepared in the same manner using 10.0 ml of *water R*. The

absorbance of the test solution is not greater than that of the standard (15 ppm of SO_2)

Chlorides (2.4.4). 4 ml of solution S diluted to 15 ml with *water R* complies with the limit test for chlorides (125 ppm).

Sulphates (2.4.13). 7.5 ml of solution S diluted to 15 ml with *distilled water R* complies with the limit test for sulphates (200 ppm).

Arsenic (2.4.2). 1.0 g complies with limit test A for arsenic (1 ppm).

Barium. To 10 ml of solution S add I ml of *dilute sulphuric acid R*. When examined immediately and after 1 h, any opalescence in the solution is not more intense than that in a mixture of 1 ml of *distilled water R* and 10 ml of solution S.

Calcium (2.4.3). 5 ml of solution S diluted to 15 ml with *distilled water R* complies with the limit test for calcium (200 ppm).

Lead in sugars (2.4.10). It complies with the limit test for lead in sugars (0.5 ppm).

Water (2.5.12). Not more than 1.0 per cent, determined on 0.50 g by the semi-micro determination of water.

Sulphated ash *(24.14).* Not more than 0.1 per cent. Dissolve 5.0 g in 5 ml of *water R,* add 2 ml of *sulphuric acid R,* evaporate to dryness on a water-bath and ignite to constant mass. If necessary, repeat the heating with *sulphuric acid R.*

Pyrogens (2.6.8). If intended for use in large-volume preparations for parenteral use, the competent authority may require that it comply with the test for pyrogens carried out *as* follows. Inject per kilogram of the rabbit's mass 10 ml of a solution containing 50 mg per millilitre of the substance to *be* examined in *water for injections R.*

LABELLING

The label states where applicable, that the substance is apyrogenic.