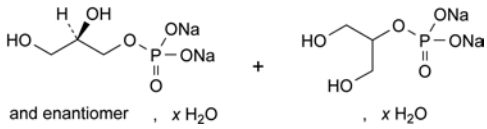
01/2009:1995
corrected 6.6

SODIUM GLYCEROPHOSPHATE, HYDRATED

Natrii glycerophosphas hydricus



$C_3H_7Na_2O_6P, xH_2O$ M_r 216.0 (anhydrous substance)

DEFINITION

Mixture of variable proportions of sodium (2*RS*)-2,3-dihydroxypropyl phosphate and sodium 2-hydroxy-1-(hydroxymethyl)ethyl phosphate. The mixture may contain various amounts of other glycerophosphate esters. The degree of hydration is 4 to 6.

Content: 98.0 per cent to 105.0 per cent (anhydrous substance).

CHARACTERS

Appearance: white or almost white, crystalline powder or crystals.

Solubility: freely soluble in water, practically insoluble in acetone and in ethanol (96 per cent).

IDENTIFICATION

A. Solution S (see Tests) gives reaction (a) of sodium (*2.3.1*).

B. To 0.1 g add 5 mL of *dilute nitric acid R*. Heat to boiling and boil for 1 min. Cool. The solution gives reaction (b) of phosphates (*2.3.1*).

C. In a test-tube fitted with a glass tube, mix 0.1 g with 5 g of *potassium hydrogen sulfate R*. Heat strongly and direct the white vapour into 5 mL of *decolorised fuchsin solution R*. A violet-red colour develops which becomes violet upon heating for 30 min on a water-bath.

TESTS

Solution S. Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100 mL with the same solvent.

Appearance of solution. Solution S is not more opalescent than reference suspension II (*2.2.1*) and not more intensely coloured than reference solution Y_6 (*2.2.2, Method II*).

Alkalinity. To 10 mL of solution S add 0.2 mL of *phenolphthalein solution R*. Not more than 1.0 mL of *0.1 M hydrochloric acid* is required to change the colour of the indicator (n_2).

Glycerol and ethanol (96 per cent)-soluble substances: maximum 1.0 per cent.

Shake 1.000 g with 25 mL of *ethanol (96 per cent) R* for 10 min. Filter. Evaporate the filtrate on a water-bath and dry the residue at 70 °C for 1 h. The residue weighs not more than 10 mg.

Chlorides (*2.4.4*): maximum 200 ppm.

Dilute 2.5 mL of solution S to 15 mL with *water R*.

Phosphates (*2.4.11*): maximum 0.1 per cent.

Dilute 1 mL of solution S to 10 mL with *water R*. Dilute 1 mL of this solution to 100 mL with *water R*.

Sulfates (*2.4.13*): maximum 500 ppm.

Dilute 3 mL of solution S to 15 mL with *water R*.

Iron (*2.4.9*): maximum 20 ppm.

Dilute 5 mL of solution S to 10 mL with *water R*.

Heavy metals (*2.4.8*): maximum 20 ppm.

Dilute 10 mL of solution S to 20 mL with *water R*. 12 mL of the solution complies with test A. Prepare the reference solution using 10 mL of *lead standard solution (1 ppm Pb) R*.

Water (*2.5.12*): 25.0 per cent to 35.0 per cent, determined on 0.100 g.

ASSAY

Dissolve 0.250 g in 30 mL of *water R*. Titrate with *0.05 M sulfuric acid*, determining the end-point potentiometrically (*2.2.20*), (n_1).

Calculate the percentage content of sodium glycerophosphate (anhydrous substance) using the following expression:

$$\frac{216.0\left(n_1 - \frac{n_2}{4}\right)}{m\,(100 - a)}$$

a = percentage content of water;

n_1 = volume of *0.05 M sulfuric acid* used in the assay, in millilitres;

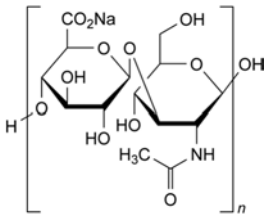
n_2 = volume of *0.1 M hydrochloric acid* used in the test for alkalinity, in millilitres;

m = mass of the substance to be examined, in grams.

01/2011:1472

SODIUM HYALURONATE

Natrii hyaluronas



$(C_{14}H_{20}NNaO_{11})_n$
[9067-32-7]

DEFINITION

Sodium salt of hyaluronic acid, a glycosaminoglycan consisting of D-glucuronic acid and *N*-acetyl-D-glucosamine disaccharide units. It is extracted from cocks' combs or obtained by fermentation from *Streptococci*, Lancefield Groups A and C.

Content: 95.0 per cent to 105.0 per cent (dried substance).

Intrinsic viscosity: 90 per cent to 120 per cent of the value stated on the label.

PRODUCTION

Where applicable, the animals from which sodium hyaluronate is derived must fulfil the requirements for the health of animals suitable for human consumption.

When produced by fermentation of gram-positive bacteria, the process must be shown to reduce or eliminate pyrogenic or inflammatory components of the cell wall.

CHARACTERS

Appearance: white or almost white, very hygroscopic powder or fibrous aggregate.

Solubility: sparingly soluble or soluble in water, practically insoluble in acetone and in anhydrous ethanol.

IDENTIFICATION

A. Infrared absorption spectrophotometry (*2.2.24*).
Comparison: *Ph. Eur. reference spectrum of sodium hyaluronate.*