than that of a standard prepared at the same time and in the same manner using 4 mL of a 50 mg/L solution of *oxalic acid R*.

Sulfates (*2.4.13*): maximum 0.2 per cent.

Dilute 3.0 mL of solution S to 15 mL with *distilled water R*.

Calcium (*2.4.3*): maximum 0.2 per cent.

To a mixture of 2 mL of solution S and 8 mL of *distilled water R*, add about 0.2 mL of *ammonia R* and dilute to 15 mL with *distilled water R*.

Iron (*2.4.9*): maximum 100 ppm.

Dilute 4.0 mL of solution S to 10 mL with *distilled water R*.

Loss on drying (*2.2.32*): 24.0 to 28.0 per cent, determined on 1.000 g by drying in an oven at 180 ± 10 °C for 5 h.

ASSAY

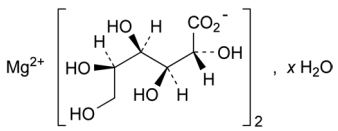
Dissolve 0.200 g in 5 mL of *dilute hydrochloric acid R* with heating. Cool and add 50 mL of *water R*. Adjust to pH 7.0 with *ammonia R*. Carry out the complexometric titration of magnesium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 2.431 mg of Mg.

01/2017:2161

MAGNESIUM GLUCONATE

Magnesii gluconas



$C_{12}H_{22}MgO_{14},xH_2O$ M_r 414.6 (anhydrous substance)

DEFINITION

Anhydrous or hydrated magnesium bis[(2*R*,3*S*,4*R*,5*R*)-2,3,4,5,6-pentahydroxyhexanoate] (anhydrous or hydrated magnesium di(D-gluconate)).

Content: 98.0 per cent to 102.0 per cent (anhydrous substance).

CHARACTERS

Appearance: white or almost white, amorphous, hygroscopic, crystalline or granular powder.

Solubility: freely soluble in water, slightly soluble in ethanol (96 per cent), very slightly soluble in methylene chloride.

IDENTIFICATION

A. Thin-layer chromatography (*2.2.27*).

Test solution. Dissolve 20 mg of the substance to be examined in 1 mL of *water R*.

Reference solution. Dissolve 20 mg of *calcium gluconate CRS* in 1 mL of *water R*, heating if necessary in a water-bath at 60 °C.

Plate: *TLC silica gel plate R* (5-40 µm) [or *TLC silica gel plate R* (2-10 µm)].

Mobile phase: *concentrated ammonia R*, *ethyl acetate R*, *water R*, *ethanol (96 per cent) R* (10:10:30:50 *V/V/V/V*).

Application: 1 µL.

Development: over 3/4 of the plate.

Drying: at 105 °C for 20 min, then allow to cool to room temperature.

Detection: spray with a solution containing 25 g/L of *ammonium molybdate R* and 10 g/L of *cerium sulfate R* in *dilute sulfuric acid R*, then heat at 105 °C for about 10 min.

Results: 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 the reference solution.

B. To 10 mL of solution S (see Tests) add 3 mL of *ammonium chloride solution R*. A slight opalescence may be observed. Add 10 mL of *disodium hydrogen phosphate solution R*. A white precipitate is formed that does not dissolve upon the addition of 2 mL of *dilute ammonia R1*.

TESTS

Solution S. Dissolve 1.0 g in *water R* and dilute to 50 mL with the same solvent.

Appearance of solution. Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution Y_7 (*2.2.2, Method II*).

Sucrose and reducing sugars. Dissolve 0.5 g in a mixture of 2 mL of *hydrochloric acid R1* and 10 mL of *water R*. Boil for 5 min, allow to cool, add 10 mL of *sodium carbonate solution R* and allow to stand for 10 min. Dilute to 25 mL with *water R* and filter. To 5 mL of the filtrate add 2 mL of *cupri-tartaric solution R* and boil for 1 min. Allow to stand for 2 min. No red precipitate is formed.

Chlorides (*2.4.4*): maximum 500 ppm.

Dilute 5 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*): maximum 500 ppm.

Dissolve 2.0 g in a mixture of 10 mL of *acetic acid R* and 90 mL of *distilled water R*.

Water (*2.5.32*): maximum 12.0 per cent, determined on 80 mg.

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

ASSAY

Dissolve 0.350 g in 100 mL of *water R* and carry out the complexometric titration of magnesium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 41.46 mg of $C_{12}H_{22}MgO_{14}$.

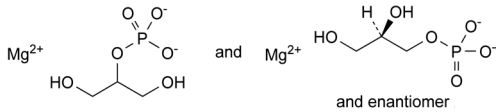
STORAGE

In an airtight container.

01/2017:1446

MAGNESIUM GLYCEROPHOSPHATE

Magnesii glycerophosphas



$C_3H_7MgO_6P$ M_r 194.4

DEFINITION

Mixture, in variable proportions, of magnesium salts of (*RS*)-2,3-dihydroxypropyl phosphate and 2-hydroxy-1-(hydroxymethyl)ethyl phosphate, which may be hydrated.

Content: 11.0 per cent to 12.5 per cent of Mg (dried substance).

CHARACTERS

Appearance: white or almost white powder, hygroscopic.

Solubility: practically insoluble in ethanol (96 per cent). It dissolves in dilute solutions of acids.

IDENTIFICATION

A. Mix 1 g with 1 g of *potassium hydrogen sulfate R* in a test tube fitted with a glass tube. Heat strongly and direct the white vapour towards a piece of filter paper impregnated with a freshly prepared 10 g/L solution of *sodium nitroprusside R*. The filter paper develops a blue colour in contact with *piperidine R*.

B. Ignite 0.1 g in a crucible. Take up the residue with 5 mL of *nitric acid R* and heat on a water-bath for 1 min. Filter. The filtrate gives reaction (b) of phosphates (*2.3.1*).

C. It gives the reaction of magnesium (*2.3.1*).

TESTS

Solution S. Dissolve 2.5 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 50 mL with the same solvent.

Appearance of solution. Solution S is not more opalescent than reference suspension III (*2.2.1*).

Acidity. Dissolve 1.0 g in 100 mL of *carbon dioxide-free water R*. Add 0.1 mL of *phenolphthalein solution R*. Not more than 1.5 mL of *0.1 M sodium hydroxide* is required to change the colour of the indicator.

Glycerol and ethanol (96 per cent)-soluble substances: maximum 1.5 per cent.

Shake 1.0 g with 25 mL of *ethanol (96 per cent) R* for 2 min. Filter and wash the residue with 5 mL of *ethanol (96 per cent) R*. Combine the filtrate and the washings, evaporate to dryness on a water-bath and dry the residue at 70 °C for 1 h. The residue weighs a maximum of 15 mg.

Chlorides (*2.4.4*): maximum 0.15 per cent.

Dissolve 1.0 g in *water R* and dilute to 100 mL with the same solvent. Dilute 3.5 mL of this solution to 15 mL with *water R*.

Phosphates (*2.4.11*): maximum 0.5 per cent.

Dilute 4 mL of solution S to 100 mL with *water R*. Dilute 1 mL of this solution to 100 mL with *water R*.

Sulfates (*2.4.13*): maximum 0.1 per cent.

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

Iron (*2.4.9*): maximum 150 ppm.

Dissolve 67 mg in *water R* and dilute to 10 mL with the same solvent.

Loss on drying (*2.2.32*): maximum 12.0 per cent, determined on 1.000 g by drying in an oven at 150 °C for 4 h.

ASSAY

Dissolve 0.200 g in 40 mL of *water R*. Carry out the complexometric titration of magnesium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 2.431 mg of Mg.

STORAGE

In an airtight container.

01/2017:0039

MAGNESIUM HYDROXIDE

Magnesii hydroxidum

$Mg(OH)_2$ M_r 58.32

[1309-42-8]

DEFINITION

Content: 95.0 per cent to 100.5 per cent of $Mg(OH)_2$.

CHARACTERS

Appearance: white or almost white, fine, amorphous powder.

Solubility: practically insoluble in water. It dissolves in dilute acids.

IDENTIFICATION

A. Dissolve about 15 mg in 2 mL of *dilute nitric acid R* and neutralise with *dilute sodium hydroxide solution R*. The solution gives the reaction of magnesium (*2.3.1*).

B. Loss on ignition (see Tests).

TESTS

Solution S. Dissolve 5.0 g in a mixture of 50 mL of *acetic acid R* and 50 mL of *distilled water R*. Not more than slight effervescence is produced. Boil for 2 min, cool and dilute to 100 mL with *dilute acetic acid R*. Filter, if necessary, through a previously ignited and tared porcelain or silica filter crucible of suitable porosity to give a clear filtrate.

Appearance of solution. Solution S is not more intensely coloured than reference solution B_3 (*2.2.2, Method II*).

Soluble substances: maximum 2.0 per cent.

Mix 2.00 g with 100 mL of *water R* and boil for 5 min. Filter whilst hot through a sintered-glass filter (40) (*2.1.2*), allow to cool and dilute to 100 mL with *water R*. Evaporate 50 mL of the filtrate to dryness and dry at 100-105 °C. The residue weighs not more than 20 mg.

Substances insoluble in acetic acid: maximum 0.1 per cent.

Any residue obtained during the preparation of solution S, washed, dried, and ignited at 600 ± 50 °C, weighs not more than 5 mg.

Chlorides (*2.4.4*): maximum 0.1 per cent.

Dilute 1 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*): maximum 1.0 per cent.

Dilute 0.3 mL of solution S to 15 mL with *distilled water R*.

Arsenic (*2.4.2, Method A*): maximum 4 ppm, determined on 5 mL of solution S.

Calcium (*2.4.3*): maximum 1.5 per cent.

Dilute 1.3 mL of solution S to 150 mL with *distilled water R*.

Iron (*2.4.9*): maximum 0.07 per cent.

Dissolve 0.15 g in 5 mL of *dilute hydrochloric acid R* and dilute to 10 mL with *water R*. Dilute 1 mL of the solution to 10 mL with *water R*.

Loss on ignition: 29.0 per cent to 32.5 per cent.

Heat 0.5 g gradually to 900 ± 50 °C and ignite to constant mass.

ASSAY

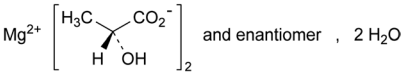
Dissolve 0.100 g in a mixture of 2 mL of *dilute hydrochloric acid R* and 20 mL of *water R*. Carry out the complexometric titration of magnesium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 5.832 mg of $Mg(OH)_2$.

01/2017:2160

MAGNESIUM LACTATE DIHYDRATE

Magnesii lactas dihydricus



$C_6H_{10}MgO_6,2H_2O$ M_r 238.5