Edition: BP 2025 (Ph. Eur. 11.6 update)

Magnesium Chloride Hexahydrate

General Notices

(Ph. Eur. monograph 0402)

$MgCl_2,6H_2O$ 203.3 *7791-18-6*

Action and use

Used in the treatment of electrolyte deficiencies and in dialysis solutions.

Preparation

Magnesium Chloride Injection

Ph Eur

DEFINITION

Content

98.0 per cent to 101.0 per cent of $MgCl_2,6H_2O$.

CHARACTERS

Appearance

Colourless crystals, hygroscopic.

Solubility

Very soluble in water, freely soluble in ethanol (96 per cent).

IDENTIFICATION

A. Water (see Tests).
B. It gives reaction (a) of chlorides (*2.3.1*).
C. It gives the reaction of magnesium (*2.3.1*).

TESTS

Solution S

Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100.0 mL with the same solvent.

Appearance of solution

Solution S is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Acidity or alkalinity

To 5 mL of solution S add 0.05 mL of *phenol red solution R*. Not more than 0.3 mL of *0.01 M hydrochloric acid* or *0.01 M sodium hydroxide* is required to change the colour of the indicator.

Bromides

Maximum 500 ppm.

Dilute 2.0 mL of solution S to 10.0 mL with *water R*. To 1.0 mL of this solution add 4.0 mL of *water R*, 2.0 mL of *phenol red solution R3* and 1.0 mL of *chloramine solution R2* and mix immediately. After exactly 2 min, add 0.30 mL of *0.1 M sodium thiosulfate*, mix and dilute to 10.0 mL with *water R*. The absorbance (*2.2.25*) of the solution measured at 590 nm, using *water R* as the compensation liquid, is not greater than that of a standard prepared at the same time and in the same manner using 5.0 mL of a 3 mg/L solution of *potassium bromide R*.

Sulfates (*2.4.13*)

Maximum 100 ppm, determined on solution S.

Aluminium (*2.4.17*)

Maximum 1 ppm, if intended for use in the manufacture of peritoneal dialysis solutions, haemodialysis solutions, or haemofiltration solutions.

Prescribed solution Dissolve 4 g in 100 mL of *water R* and add 10 mL of *acetate buffer solution pH 6.0 R*.

Reference solution Mix 2 mL of *aluminium standard solution (2 ppm Al) R*, 10 mL of *acetate buffer solution pH 6.0 R* and 98 mL of *water R*.

Blank solution Mix 10 mL of *acetate buffer solution pH 6.0 R* and 100 mL of *water R*.

Calcium (*2.4.3*)

Maximum 0.1 per cent.

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

Iron (*2.4.9*)

Maximum 10 ppm, determined on solution S.

Potassium

Maximum 500 ppm, if intended for use in the manufacture of parenteral preparations.

Atomic emission spectrometry (*2.2.22, Method I*).

Test solution Dissolve 1.00 g in *water R* and dilute to 100.0 mL with the same solvent.

Reference solutions Prepare the reference solutions using the following solution, diluted as necessary with *water R*: dissolve 1.144 g of *potassium chloride R*, previously dried at 100-105 °C for 3 h in *water R* and dilute to 1000.0 mL with the same solvent (600 µg of K per millilitre).

Wavelength 766.5 nm.

Water (*2.5.12*)

51.0 per cent to 55.0 per cent, determined on 50.0 mg.

ASSAY

Dissolve 0.300 g in 50 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 20.33 mg of $MgCl_2,6H_2O$.

STORAGE

In an airtight container.

LABELLING

The label states:

— where applicable, that the substance is suitable for use in the manufacture of peritoneal dialysis solutions, haemodialysis solutions or haemofiltration solutions,

— where applicable, that the substance is suitable for use in the manufacture of parenteral preparations.