

01/2008:0402
corrected 7.0**MAGNESIUM CHLORIDE
HEXAHYDRATE****Magnesii chloridum hexahydricum** $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$
[7791-18-6] M_r 203.3**DEFINITION***Content:* 98.0 per cent to 101.0 per cent of $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$.**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*.**Arsenic** (2.4.2, *Method A*): maximum 2 ppm, determined on 0.5 g.**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.**Heavy metals** (2.4.8): maximum 10 ppm.12 mL of solution S complies with test A. Prepare the reference solution using *lead standard solution* (1 ppm Pb) *R*.**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 $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$.**STORAGE**

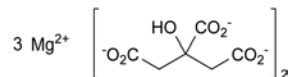
In an airtight container.

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.

04/2009:2339

MAGNESIUM CITRATE, ANHYDROUS**Magnesii citras anhydricus** $\text{Mg}_3(\text{C}_6\text{H}_5\text{O}_7)_2$
[3344-18-1] M_r 451.1**DEFINITION**

Trimagnesium bis(2-hydroxypropane-1,2,3-tricarboxylate).

Content: 15.0 per cent to 16.5 per cent of Mg (dried substance).**CHARACTERS***Appearance:* white or almost white, fine, slightly hygroscopic powder.*Solubility:* soluble in water, practically insoluble in ethanol (96 per cent). It dissolves in dilute hydrochloric acid.**IDENTIFICATION**

- A. It gives the reaction of citrates (2.3.1).
 B. It gives the reaction of magnesium (2.3.1).
 C. pH (see Tests).
 D. Loss on drying (see Tests).

TESTS**Solution S.** Dissolve 5.0 g in *carbon dioxide-free water R*, heating at 60 °C, cool and dilute to 100 mL with the same solvent.**Appearance of solution.** Solution S is not more opalescent than reference suspension III (2.2.1) and not more intensely coloured than reference solutions Y_7 or BY_6 (2.2.2, *Method II*).**pH** (2.2.3): 6.0 to 8.5 for solution S.**Oxalates:** maximum 280 ppm.Dissolve 0.50 g in 4 mL of *water R*. Add 3 mL of *hydrochloric acid R* and 1 g of *activated zinc R*. Allow to stand for 5 min. Transfer the liquid to a tube containing 0.25 mL of a 10 g/L