



MAGNESII SULFATIS INJECTIO MAGNESIUM SULFATE INJECTION

Final text for addition to *The International Pharmacopoeia*

This monograph was adopted at the Forty-second WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2007 for addition to the 4th edition of The International Pharmacopoeia.

[**Note from the Secretariat:** Inclusion of a monograph for magnesium sulfate injection was agreed in view of the potential for errors in dosage due to confusion concerning the strength of this injection since "Magnesium sulfate" is the heptahydrate (mol wt 246.5 compared with 120 for anhydrous substance). This injection is included in the WHO Model list of essential medicines and within the "Making Pregnancy Safer" programme of the Family and Community Health cluster of WHO.]

Description. A clear, colourless solution.

Category. Used in the prevention of seizures in eclampsia and pre-eclampsia.

Labelling. The designation of the container of Magnesium sulfate injection should indicate the quantity in terms of the amount of magnesium sulfate heptahydrate and as the approximate concentration of magnesium ions (Mg^{2+}) in millimoles per ml.

Additional information. Strength in the current WHO Model list of essential medicines: 500 mg of magnesium sulfate heptahydrate/ml; the concentration of magnesium ions (Mg^{2+}) is approximately 2 millimoles per ml (2 mmol Mg^{2+} /ml).

Requirements

Complies with the monograph for "Parenteral Preparations".

Definition. Magnesium sulfate injection is a sterile solution of Magnesium Sulfate Heptahydrate in water for injections. The solution is sterilized by "Heating in an Autoclave" or by another suitable method (see 5.8 Methods of Sterilization).

Magnesium sulfate injection contains not less than 90.0% and not more than 110.0% of the amount of $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ stated on the label.

Identity tests

A. Dilute the injection to give a solution containing 5 mg of magnesium sulfate heptahydrate per ml. To 2 ml of this solution, add 1 ml of ammonia (100g/l) TS; a white precipitate is produced

which redissolves after adding 1 ml of ammonium chloride (100g/l) TS. Add 1 ml of disodium hydrogen phosphate (40g/l) TS; a white, fine crystalline precipitate is formed.

- B. Dilute the injection to give a solution containing 20 mg of magnesium sulfate heptahydrate per ml; yields reaction A described under 2.1 General identification tests as characteristic of sulfates.

pH value. (1.13) pH of the injection, diluted to contain 50 mg of magnesium sulfate heptahydrate /ml: 5.5 - 7.0.

Assay. Dilute an accurately measured volume of the injection containing about 0.50 g of magnesium sulfate heptahydrate to 100 ml with water R and proceed with the titration as described under 2.5 Complexometric titrations for magnesium*. Each ml of disodium edetate (0.05 mol/l) VS is equivalent to 12.32 mg of $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$.

[*Note from the Secretariat: The general method text will be amended with respect to the description of the end-point. For "until the solution turns from violet to green" read: "until the solution turns from violet to blue".]
