

Magnesium sulfate injection (Magnesii sulfatis injectio)

2015-01

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 (EML): 500 mg of magnesium sulfate heptahydrate per 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 magnesium sulfate heptahydrate, $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, 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 (100 g/L) TS; a white precipitate is produced which redissolves after adding 1 mL of ammonium chloride (100 g/L) TS. Add 1 mL of disodium hydrogen phosphate (40 g/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 per 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 $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$.

Bacterial endotoxins. Carry out the test as described under [3.4 Test for bacterial endotoxins](#); contains less than 0.18 IU of endotoxin per mg Magnesium sulfate heptahydrate.