## Magnesium sulfate heptahydrate (Magnesii sulfatis heptahydras)

MgSO<sub>4</sub>,7H<sub>2</sub>O

Relative molecular mass. 246.5

Chemical name. Magnesium sulfate (1:1) heptahydrate; CAS Reg. No. 10034-99-8.

Other name. Epsom salt.

**Description.** Brilliant, colourless crystals or a white, crystalline powder; odourless.

Solubility. Freely soluble in water; practically insoluble in ethanol (~750 g/l) TS.

Category. Cathartic drug.

**Storage.** Magnesium sulfate heptahydrate should be kept in a well-closed container.

Additional information. Magnesium sulfate heptahydrate effloresces in warm, dry air.

## Requirements

Magnesium sulfate heptahydrate contains not less than **99.0%** and not more than the equivalent of **100.5%** of MgSO<sub>4</sub>, calculated with reference to the dried substance.

## **Identity tests**

A. Dissolve 10 mg in 2 mL of water and add 1 mL of ammonia (~100g/l) TS; a white precipitate is produced which redissolves after adding 1 mL of ammonium chloride (100 g/l) TS. Then add 1 mL of disodium hydrogen phosphate (40 g/l) TS; a white, fine crystalline precipitate is formed.

B. A 20 mg/mL solution yields reaction A described under <u>2.1 General identification tests</u> as characteristic of sulfates.

**Heavy metals.** Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 1; determine the heavy metals content according to Method A; not more than 10 μg/g.

**Arsenic.** Use a solution of 5 g in 35 mL of water and proceed as described under  $\underline{2.2.5 \text{ Limit test for arsenic}}$ ; the arsenic content is not more than 2  $\mu$ g/g.

**Chlorides.** Dissolve 0.85 g in a mixture of 2 mL of nitric acid (~130 g/l) TS and 20 mL of water, and proceed as described under 2.2.1 Limit test for chlorides; the chloride content is not more than 300 µg/g.

Iron. Use 2.0 g; the solution complies with the 2.2.4 Limit test for iron; not more than 20 μg/g.

Clarity and colour of solution. A solution of 1 g in 10 mL of water is clear and colourless.

**Loss on drying.** Dry 0.5 g at 110 - 120 °C for 1 hour and then at 400 °C to constant mass; it loses not less than 0.48 g/g and not more than 0.52 g/g.

Acidity or alkalinity. Dissolve 1.0 g in 10 mL of water and add 0.05 mL of phenol red/ethanol TS; not more than 0.2 mL of hydrochloric acid (0.01 mol/l) VS or sodium hydroxide (0.01 mol/l) VS is required to obtain the midpoint of the indicator (pink).

**Assay.** Dissolve about 0.25 g, accurately weighed, in 100 mL of water, and proceed with the titration as described under <u>2.5</u> Complexometric titrations for magnesium.

Each mL of disodium edetate (0.05 mol/l) VS is equivalent to 6.018 mg of MgSO<sub>4</sub>.

## Additional requirements for Magnesium sulfate heptahydrate for parenteral use

Complies with the monograph for "Parenteral preparations".

**Bacterial endotoxins.** Carry out the test as described under <u>3.4 Test for bacterial endotoxins</u>; contains not more than 0.09 IU of endotoxin RS per mg.