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

Magnesium Sulfate Injection

General Notices

Magnesium Sulphate Injection

DEFINITION

Magnesium Sulfate Injection is a sterile solution of Magnesium Sulfate Heptahydrate in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of magnesium sulfate heptahydrate, $MgSO_4,7H_2O$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A clear, colourless solution.

IDENTIFICATION

A. Yields reaction A characteristic of *magnesium salts*, Appendix VI.
B. Yields the reactions characteristic of *sulfates*, Appendix VI.

TESTS

Acidity or alkalinity

pH of the injection diluted, if necessary, to contain 5% w/v of Magnesium Sulfate Heptahydrate, 5.5 to 7.0, Appendix V L.

ASSAY

Dilute a volume containing 1.25 g of Magnesium Sulfate Heptahydrate to 100 mL with *water*. To 20 mL of this solution add 10 mL of *ammonia buffer pH 10.9* and titrate with 0.05M *disodium edetate VS* using 0.1 g of *mordant black 11 triturate* as indicator, until the pink tint is discharged from the blue colour. Each mL of 0.05M *disodium edetate VS* is equivalent to 12.32 mg of $MgSO_4,7H_2O$.

LABELLING

The strength is stated as the percentage w/v of Magnesium Sulfate Heptahydrate and as the approximate concentration of magnesium ions (Mg^{2+}) in millimoles per mL.

For a preparation containing 50% w/v of Magnesium Sulfate Heptahydrate ($MgSO_4,7H_2O$) the concentration of magnesium ions is approximately 2 millimoles per millilitre (2 mmol Mg^{2+}/mL).