Quality standards

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

Magnesium Sulfate, Potassium Chloride and Sodium Chloride Infusion

General Notices

NOTE: This monograph has been developed to cover unlicensed formulations.

Action and use

Hydrating agent; adjunctive therapy for use with platinum based cytotoxics.

DEFINITION

Magnesium Sulfate, Potassium Chloride and Sodium Chloride Infusion is a sterile, isotonic solution containing Magnesium Sulfate Heptahydrate, Potassium Chloride and Sodium Chloride. It is supplied as a ready-to-use solution.

The infusion complies with the requirements stated under <u>Parenteral Preparations</u> and with the following requirements. Where appropriate, the infusion also complies with the requirements stated under <u>Unlicensed Medicines</u>.

Content of magnesium, Mg

95.0 to 105.0% of the stated amount.

Content of potassium, K

95.0 to 105.0% of the stated amount.

Content of sodium, Na

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. Yields reaction B characteristic of <u>magnesium salts</u> and the reactions characteristic of <u>potassium salts</u> and of <u>sodium salts</u>, Appendix VI.
- B. Yields reaction A characteristic of *chlorides* and reaction A characteristic of *sulfates*, Appendix VI.

TESTS

Acidity

pH, 5.0 to 6.0, Appendix V L.

ASSAY

For magnesium

Transfer 100 mL into a 500 mL conical flask and carry out the <u>complexometric titration of magnesium</u>, <u>Appendix VIII D</u>, beginning at the words 'and dilute to 300 mL with <u>water</u>...'. Each mL of 0.1 m <u>disodium edetate VS</u> is equivalent to 0.1

https://nhathuocngocanh.com/bp/mmol (2.431 mg) of Mg.

For potassium

Dilute appropriately with <u>water</u> and determine by <u>atomic emission spectrophotometry</u>, <u>Appendix II D</u>, measuring at 767 nm and using <u>potassium standard solution (600 ppm K)</u>, suitably diluted with <u>water</u>, to prepare the standard solutions.

For sodium

Dilute appropriately with <u>water</u> and determine by <u>atomic emission spectrophotometry</u>, <u>Appendix II D</u>, measuring at 589 nm and using <u>sodium standard solution (200 ppm Na)</u>, suitably diluted with <u>water</u>, to prepare the standard solutions.

STORAGE

Magnesium Sulfate, Potassium Chloride and Sodium Chloride Infusion should be protected from light.

LABELLING

The strength is stated as the approximate concentration, in millimoles per litre, of Magnesium Sulfate and of Potassium Chloride and as the percentage w/v of Sodium Chloride.