## **Quality standards**

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

# **Magnesium Glycerophosphate Oral Solution**

#### **General Notices**

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

#### Action and use

Used in the treatment of magnesium deficiency.

## **DEFINITION**

Magnesium Glycerophosphate Oral Solution is a solution of Magnesium Glycerophosphate in a suitable flavoured vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral solution also complies with the requirements stated under Unlicensed Medicines.

#### Content of magnesium, Mg

95.0 to 105.0% of the stated amount.

## **IDENTIFICATION**

- A. To a quantity of the oral solution containing the equivalent of about 25 mg of magnesium in a test tube fitted with a glass tube add 1 g of *potassium <u>hydrogen</u> sulfate*. Heat strongly and direct the white vapour towards a piece of filter paper impregnated with a freshly prepared 1% w/v solution of <u>sodium nitroprusside</u>. The filter paper develops a blue colour in contact with <u>piperidine</u>.
- B. Reduce a quantity of the oral solution containing the equivalent of about 25 mg of magnesium in a crucible and ignite. Add 5 mL of <u>nitric acid</u> to the residue, heat on a water-bath for 1 minute and filter. The filtrate yields reaction B characteristic of <u>phosphates</u>, <u>Appendix VI</u>.
- C. Yields reaction A characteristic of *magnesium* salts, *Appendix VI*.

#### **TESTS**

### **Acidity**

Dilute a quantity of the oral solution containing the equivalent of about 25 mg of magnesium to 100 mL with <u>carbon</u> <u>dioxide-free water</u>. Add 0.1 mL of <u>phenolphthalein solution</u>. Not more than 2.0 mL of 0.1 m <u>sodium hydroxide</u> is required to change the colour of the solution.

#### **Phosphate**

Dilute a quantity of the oral solution containing the equivalent of about 25 mg of magnesium to 100 mL with <u>water</u> and dilute 1 mL of the solution to 100 mL with <u>water</u>. The resulting solution complies with the <u>limit test for phosphates</u>, <u>Appendix VII</u> (0.5%).

## **ASSAY**

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To a quantity of the oral solution containing the equivalent of about 120 mg of magnesium add 25 mL of water. Transfer 10 mL of the solution into a 500 mL conical flask and carry out the complexometric titration of magnesium, Appendix VIII D, beginning at the words 'and dilute to 300 mL with water...'. Each mL of 0.1 m disodium edetate VS is equivalent to 2.431 mg of Mg.

## **LABELLING**

The quantity of the active ingredient is stated both as the amount of Magnesium Glycerophosphate and in terms of the equivalent amount of magnesium or magnesium ions  $(Mg^{2+})$ .

For a preparation containing 250 milligrams per mL of Magnesium Glycerophosphate, the concentration of magnesium is approximately 24.25 milligrams per mL and the concentration of magnesium ions is approximately 1 millimole per millilitre (1 mmol Mg<sup>2+</sup>/mL).