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

Magaldrate Oral Suspension

General Notices

Action and use

Antacid.

DEFINITION

Magaldrate Oral Suspension contains Magaldrate in a suitable flavoured vehicle.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.

Content of anhydrous magaldrate, $Al_5Mg_{10}(OH)_{31}(SO_4)_2$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Dissolve a quantity of the oral suspension containing the equivalent of 0.8 g of anhydrous magaldrate in 20 mL of *3M hydrochloric acid*, add 30 mL of *water* and heat to boiling. Add 6M *ammonia* until a pH of 6.2 is obtained, continue boiling for a further 2 minutes, filter and retain the precipitate and the filtrate. To 2 mL of the filtrate add 2 mL of *ammonium chloride solution* and neutralise with a solution prepared by dissolving 2 g of *ammonium carbonate* and 2 mL of 6M *ammonia* in sufficient *water* to produce 20 mL; no precipitate is produced. Add *disodium hydrogen phosphate solution*; a white, crystalline precipitate is produced which is insoluble in 6M *ammonia*.
B. The precipitate retained in test A yields the reaction characteristic of *aluminium salts*, Appendix VI.
C. The filtrate obtained in test A yields the reactions characteristic of *sulfates*, Appendix VI.

TESTS

Neutralising capacity

Disperse a quantity containing the equivalent of 0.8 g of anhydrous magaldrate in 70 mL of water, heat to 37° and mix for 1 minute. Maintain the temperature at 37° and, while stirring continuously, add from a pipette 30 mL of *1M hydrochloric acid VS*. Stir for 15 minutes and, over a period not exceeding 5 minutes, titrate the excess acid with *1M sodium hydroxide VS* to a pH of 3.5 which is stable for a period of 10 to 15 seconds. Not more than 12 mL of *1M sodium hydroxide VS* is required.

Magnesium hydroxide

Not less than 49.2% and not more than 66.6% of the content of anhydrous magaldrate when determined by the following method. Mix a quantity of the oral suspension containing the equivalent of 1 g of magaldrate in 30 mL of *2M hydrochloric acid* and add sufficient *water* to produce 100 mL (solution A). Dilute 10 mL of this solution to 200 mL with *water*. Add, while stirring, 1 g of *ammonium chloride*, 20 mL of *triethanolamine*, 10 mL of *ammonia buffer pH 10.9* and 0.4 mL of *mordant black 11 solution*. Titrate with 0.05M *disodium edetate VS* until a blue colour is obtained. Repeat the procedure without the

substance being examined. The difference between the titrations represents the amount of disodium edetate required. Each mL of 0.05M *disodium edetate VS* is equivalent to 2.916 g of $Mg(OH)_2$.

Aluminium hydroxide

Not less than 32.1% and not more than 45.9% of the stated content of anhydrous magaldrate when determined by the following method. Dilute 10 mL of solution A obtained in the test for Magnesium hydroxide with 20 mL of *water*. Add 25 mL of 0.05M *disodium edetate VS*, mix, allow to stand for 5 minutes and add 20 mL of *acetate buffer pH 4.4*, 60 mL of *ethanol (96%)* and 2 mL of a 0.026% w/v solution of *dithizone* in *ethanol (96%)*. Titrate with *0.05M zinc sulfate VS* until a bright pink colour is obtained. Repeat the procedure without the substance being examined. The difference between the titrations represents the amount of disodium edetate required. Each mL of 0.05M *disodium edetate VS* is equivalent to 3.90 g of $Al(OH)_3$.

Microbial contamination

Carry out a quantitative evaluation for Enterobacteria and certain other Gram-negative bacteria, Appendix XVI B1. 0.01 mL of the preparation gives a negative result, Table 1 (most probable number of bacteria per gram fewer than 10^2).

ASSAY

To a quantity of the oral suspension containing the equivalent of 3 g of anhydrous magaldrate add 100 mL of *1M hydrochloric acid VS* and mix using a magnetic stirrer to achieve dissolution. Titrate the excess acid with *1M sodium hydroxide VS* to pH 3, determined potentiometrically. Repeat the procedure without the preparation being examined. The difference between the titrations represents the amount of hydrochloric acid required. Each mL of *1M hydrochloric acid VS* is equivalent to 35.40 mg of $Al_5Mg_{10}(OH)_{31}(SO_4)_2$.

LABELLING

The quantity of the active ingredient is stated in terms of the equivalent amount of anhydrous magaldrate.