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

Co-magaldrox Oral Suspension

General Notices

Magnesium Hydroxide and Aluminium Hydroxide Oral Suspension

Action and use

Antacid.

DEFINITION

Co-magaldrox Oral Suspension is a suspension containing Magnesium Hydroxide and Dried Aluminium Hydroxide in a suitable flavoured vehicle. The amount of dried aluminium hydroxide is adjusted to give the required content of Al_2O_3.

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

Content of magnesium hydroxide, $Mg(OH)_2$

90.0 to 110.0% of the stated amount.

Content of Al_2O_3

45.4 to 58.8% of the stated amount of dried aluminium hydroxide.

IDENTIFICATION

A. Mix 5 mL with 10 mL of 2M *hydrochloric acid*, add 5 drops of *methyl red solution* and heat to boiling. Add 6M *ammonia* until the solution becomes yellow, continue boiling for 2 minutes and filter. To 1 mL of the filtrate add 1 mL of 6M *ammonia* and 1 mL of 2M *ammonium chloride*; no precipitate is produced. Add 0.25M *disodium hydrogen orthophosphate*; a white, crystalline precipitate is produced which is insoluble in 6M *ammonia*.
B. To 5 mL add 10 mL of 2M *hydrochloric acid*. The solution yields the reaction characteristic *of aluminium salts*, Appendix VI.

TESTS

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 I (most probable number of bacteria per gram fewer than 10^2).

ASSAY

For Al_2O_3

To a weighed quantity containing 1.5 g of dried aluminium hydroxide add 20 mL of *water*, stir and slowly add 10 mL of *hydrochloric acid*. Heat gently, if necessary, to aid solution, cool, filter, wash the filter well with *water*, dilute the combined filtrate and washings to 200 mL with *water* and mix. Reserve a portion of the solution for the Assay for magnesium hydroxide. To 10 mL add 20 mL of *water* and, with continuous stirring, 25 mL of 0.05M *disodium edetate VS* followed by 20 mL of a mixture of equal volumes of 2M *ammonium acetate* and 2M *acetic acid*. Heat near the boiling point for 5 minutes, cool, add 50 mL of *absolute ethanol* and 3 mL of a freshly prepared 0.025% w/v solution of *dithizone* in *absolute ethanol*. Titrate the excess of disodium edetate with *0.05M zinc sulfate VS* until the colour of the solution changes from greenish blue to reddish violet. Each mL of 0.05M *disodium edetate VS* is equivalent to 2.549 mg of Al_2O_3. Determine the *weight per mL* of the suspension, Appendix V G, and calculate the percentage content of Al_2O_3, weight in volume.

For magnesium hydroxide

To a volume of the solution reserved in the Assay for Al_2O_3 containing about 40 mg of magnesium hydroxide add 200 mL of *water* and 20 mL of *triethanolamine* and stir. Add 10 mL of *ammonia buffer pH 10.9* and cool the solution to between 3° and 4° by immersion in iced water. Titrate the cooled solution with 0.05M *disodium edetate VS* using *mordant black 11 solution* as indicator. Each mL of 0.05M *disodium edetate VS* is equivalent to 2.916 mg of $Mg(OH)_2$. Using the weight per mL of the suspension, calculate the percentage content of $Mg(OH)_2$, weight in volume.

STORAGE

Co-magaldrox Oral Suspension should not be allowed to freeze.