



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

Magaldrate



General Notices

(Ph. Eur. monograph 1539)

$\text{Al}_5\text{Mg}_{10}(\text{OH})_{31}(\text{SO}_4)_2 \cdot x\text{H}_2\text{O}$ 1097 (anhydrous substance) 74978-16-8

Action and use

Antacid.

Preparation

Magaldrate Oral Suspension

Ph Eur

DEFINITION

Magaldrate is composed of aluminium and magnesium hydroxides and sulfates. Its composition corresponds approximately to the formula $\text{Al}_5\text{Mg}_{10}(\text{OH})_{31}(\text{SO}_4)_2 \cdot x\text{H}_2\text{O}$.

Content

90.0 per cent to 105.0 per cent (dried substance).

It contains a variable quantity of water.

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Practically insoluble in water and in ethanol (96 per cent). It is soluble in dilute mineral acids.

IDENTIFICATION

- A. Dissolve 0.6 g in 20 mL of [3 M hydrochloric acid R](#), add about 30 mL of [water R](#) and heat to boiling. Adjust to pH 6.2 with [dilute ammonia R1](#), continue boiling for a further 2 min, filter and retain the precipitate and the filtrate. To 2 mL of the filtrate add 2 mL of [ammonium chloride solution R](#) and neutralise with a solution prepared by dissolving 2 g of [ammonium carbonate R](#) and 2 mL of [dilute ammonia R1](#) in 20 mL of [water R](#); no precipitate is produced. Add [disodium hydrogen phosphate solution R](#); a white, crystalline precipitate is produced which does not dissolve in [dilute ammonia R1](#).
- B. The precipitate retained in identification test A gives the reaction of aluminium ([2.3.1](#)).
- C. The filtrate retained in identification test A gives reaction (a) of sulfates ([2.3.1](#)).

TESTS

Soluble chlorides

Maximum 3.5 per cent.

To 0.5 g add 25 mL of [dilute nitric acid R](#) and shake until completely dissolved. Add 10.0 mL of [0.1 M silver nitrate](#) and 2 mL of [ferric ammonium sulfate solution R2](#) as indicator. Titrate with [0.1 M ammonium thiocyanate](#), shaking vigorously until a persistent brownish-red colour is obtained.

1 mL of [0.1 M silver nitrate](#) is equivalent to 3.545 mg of Cl.

Soluble sulfates

Maximum 1.9 per cent.

Disperse 0.5 g in 25 mL of [water R](#), boil for 5 min, cool, dilute to 25.0 mL with [water R](#), mix and filter. To 2.5 mL of the filtrate, add 30 mL of [water R](#), neutralise to [blue litmus paper R](#) with [hydrochloric acid R](#), add 3 mL of [1 M hydrochloric acid](#), 3 mL of a 120 g/L solution of [barium chloride R](#) and dilute to 50 mL with [water R](#). Mix and allow to stand for 10 min. Any opalescence in the solution is not more intense than that in a standard prepared at the same time in the same manner using 1 mL of [0.01 M sulfuric acid](#) instead of 2.5 mL of filtrate.

Sulfates

16.0 per cent to 21.0 per cent (dried substance).

Dissolve 0.875 g in a mixture of 5 mL of [glacial acetic acid R](#) and 10 mL of [water R](#) and dilute to 25.0 mL with [water R](#). Prepare a chromatographic column of 1 cm in internal diameter containing 15 mL of [cation-exchange resin R](#) (150-300 µm), previously washed with 30 mL of [water R](#). Transfer 5.0 mL of the solution to be examined to the column and elute with 15 mL of [water R](#). To the eluate add 5 mL of a 53.6 g/L solution of [magnesium acetate R](#), 32 mL of [methanol R](#) and 0.2 mL of [alizarin S solution R](#). Add from a burette about 4.0 mL of [0.05 M barium chloride](#), add a further 0.2 mL of [alizarin S solution R](#) and slowly complete the titration until the yellow colour disappears and a violet-red tinge is visible.

1 mL of [0.05 M barium chloride](#) is equivalent to 4.803 mg of SO₄.

Aluminium hydroxide

32.1 per cent to 45.9 per cent (dried substance).

Dissolve 0.800 g in 10 mL of [dilute hydrochloric acid R](#), heating on a water-bath. Cool and dilute to 50.0 mL with [water R](#). To 10.0 mL of this solution, add [dilute ammonia R1](#) until a precipitate begins to appear. Add the smallest quantity of [dilute hydrochloric acid R](#) needed to dissolve the precipitate and dilute to 20 mL with [water R](#). Carry out the complexometric titration of aluminium ([2.5.11](#)).

1 mL of [0.1 M sodium edetate](#) is equivalent to 7.80 mg of $\text{Al}(\text{OH})_3$.

Magnesium hydroxide

49.2 per cent to 66.6 per cent (dried substance).

Dissolve 0.100 g in 2 mL of [dilute hydrochloric acid R](#) and transfer to a 500 mL conical flask with the aid of [water R](#). Dilute to 200 mL with [water R](#), add 20 mL of [triethanolamine R](#) with shaking, 10 mL of [ammonium chloride buffer solution pH 10.0 R](#) and about 50 mg of [mordant black 11 triturate R](#). Titrate with [0.1 M sodium edetate](#) until the colour changes from violet to pure blue.

1 mL of [0.1 M sodium edetate](#) is equivalent to 5.832 mg of $\text{Mg}(\text{OH})_2$.

Sodium

Maximum 0.10 per cent.

Atomic absorption spectrometry ([2.2.23, Method I](#)).

Test solution Weigh 2.00 g into a 100 mL volumetric flask, place in an ice-bath, add 5 mL of [nitric acid R](#) and swirl to mix. Allow to warm to room temperature and dilute to 100 mL with [water R](#). Filter, if necessary, to obtain a clear solution. Dilute 10.0 mL of the filtrate to 100.0 mL with [water R](#).

Reference solutions Prepare the reference solutions using [sodium standard solution \(200 ppm Na\) R](#), diluted as necessary with [dilute nitric acid R](#).

Source Sodium hollow-cathode lamp.

Wavelength 589 nm.

Atomisation device Air-acetylene flame.

Loss on drying (2.2.32)

10.0 per cent to 20.0 per cent, determined on 1.000 g by drying in an oven at 200 °C for 4 h.

ASSAY

To 1.500 g add 50.0 mL of [1 M hydrochloric acid](#). Titrate the excess hydrochloric acid with [1 M sodium hydroxide](#) to pH 3.0, determining the end-point potentiometrically ([2.2.20](#)). Carry out a blank titration.

1 mL of [1 M hydrochloric acid](#) is equivalent to 35.40 mg of $\text{Al}_5\text{Mg}_{10}(\text{OH})_{31}(\text{SO}_4)_2$.