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

Magnesium Trisilicate Hydrate

General Notices

Magnesium Trisilicate

(Ph. Eur. monograph 0403)

Action and use

Antacid.

Preparations

Magnesium Trisilicate Mixture

Compound Magnesium Trisilicate Chewable Tablets

Compound Magnesium Trisilicate Oral Powder

Ph Eur

DEFINITION

It has a variable composition corresponding approximately to $Mg_2Si_3O_8,xH_2O$.

Content

— *magnesium oxide* (MgO; M_r 40.30): minimum 29.0 per cent (ignited substance);

— *silicon dioxide* (SiO_2; M_r 60.1): minimum 65.0 per cent (ignited substance).

CHARACTERS

Appearance

White or almost white powder.

Solubility

Practically insoluble in water and in ethanol (96 per cent).

IDENTIFICATION

A. 0.25 g gives the reaction of silicates (2.3.1).
B. 1 mL of solution S (see Tests) neutralised with *dilute sodium hydroxide solution R* gives the reaction of magnesium (2.3.1).

TESTS

Solution S

To 2.0 g add a mixture of 4 mL of *nitric acid R* and 4 mL of *distilled water R*. Heat to boiling with frequent shaking. Add 12 mL of *distilled water R* and allow to cool. Filter or centrifuge to obtain a clear solution and dilute to 20 mL with *distilled water R*.

Alkalinity

To 10.0 g in a 200 mL conical flask, add 100.0 g of *water R* and heat on a water-bath for 30 min. Allow to cool and make up to the initial mass with *water R*. Allow to stand and filter or centrifuge until a clear liquid is obtained. To 10 mL of this liquid add 0.1 mL of *phenolphthalein solution R*. Not more than 1.0 mL of *0.1 M hydrochloric acid* is required to change the colour of the indicator.

Water-soluble salts

Maximum 1.5 per cent.

In a platinum dish, evaporate to dryness on a water-bath 20.0 mL of the liquid obtained in the test for alkalinity. The residue, ignited to constant mass at 900 ± 50 °C, weighs a maximum of 30 mg.

Chlorides (2.4.4)

Maximum 500 ppm.

Dilute 0.5 mL of solution S to 15 mL with *water R*. Prepare the standard using a mixture of 5 mL of *chloride standard solution (5 ppm Cl) R* and 10 mL of *water R*.

Sulfates (2.4.13)

Maximum 0.5 per cent.

Dilute 0.3 mL of solution S to 15 mL with *distilled water R*.

Loss on ignition

17 per cent to 34 per cent, determined on 0.5 g by ignition to constant mass at 900 ± 50 °C in a platinum crucible.

Acid-absorbing capacity

Suspend 0.25 g in *0.1 M hydrochloric acid*, dilute to 100.0 mL with the same acid and allow to stand for 2 h in a water-bath at 37 ± 0.5 °C, with frequent shaking. Allow to cool. To 20.0 mL of the supernatant add 0.1 mL of *bromophenol blue solution R* and titrate with *0.1 M sodium hydroxide* until a blue colour is obtained. The acid-absorbing capacity is not less than 100.0 mL of *0.1 M hydrochloric acid* per gram.

ASSAY

Magnesium oxide

To 1.000 g in a 200 mL conical flask, add 35 mL of *hydrochloric acid R* and 60 mL of *water R* and heat in a water-bath for 15 min. Allow to cool, filter, wash the conical flask and the residue with *water R* and dilute the combined filtrate and washings to 250.0 mL with *water R*. Neutralise 50.0 mL of the solution with *strong sodium hydroxide solution R* (about 8 mL). Carry out the complexometric titration of magnesium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 4.030 mg of MgO.

Silicon dioxide

To 0.700 g add 10 mL of *dilute sulfuric acid R* and 10 mL of *water R*. Heat for 90 min on a water-bath with frequent shaking, replacing the evaporated water. Allow to cool, then filter the supernatant through an ashless filter paper (diameter 7 cm). Wash the residue in the container with 3 quantities, each of 5 mL, of hot *water R*, then transfer it to the filter and wash it with hot *water R* until 1 mL of the filtrate remains clear after the addition of 0.05 mL of *dilute hydrochloric acid R* and 2 mL of *barium chloride solution R1*. Incinerate the filter and its contents in a platinum crucible, then ignite the residue (SiO_2) at 900 ± 50 °C to constant mass.

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristics may be relevant for magnesium trisilicate hydrate used as a lubricant in tablets and capsules.

Particle-size distribution (*2.9.31*)

Specific surface area (*2.9.26, Method I*)