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

Heavy Magnesium Oxide

General Notices

(Ph. Eur. monograph 0041)

MgO 40.30 *1309-48-4*

Action and use

Antacid; osmotic laxative.

Ph Eur

DEFINITION

Content

98.0 per cent to 100.5 per cent of MgO (ignited substance).

CHARACTERS

Appearance

Fine, white or almost white powder.

Solubility

Practically insoluble in water. It dissolves in dilute acids with at most slight effervescence.

IDENTIFICATION

A. Untapped bulk density (*2.9.34*): minimum 0.25 g/mL.
B. Dissolve about 15 mg in 2 mL of *dilute nitric acid R* and neutralise with *dilute sodium hydroxide solution R*. The solution gives the reaction of magnesium (*2.3.1*).
C. Loss on ignition (see Tests).

TESTS

Solution S

Dissolve 5.0 g in a mixture of 30 mL of *distilled water R* and 70 mL of *acetic acid R*, boil for 2 min, allow to cool and dilute to 100 mL with *dilute acetic acid R*. Filter, if necessary, through a previously ignited and tared porcelain or silica filter crucible of suitable porosity to give a clear filtrate. Keep the residue for the test for substances insoluble in acetic acid.

Appearance of solution

Solution S is not more intensely coloured than reference solution B_3 (*2.2.2, Method II*).

Soluble substances

Maximum 2.0 per cent.

To 2.00 g add 100 mL of *water R* and boil for 5 min. Filter whilst hot through a sintered-glass filter (40) (*2.1.2*), allow to cool and dilute to 100 mL with *water R*. Evaporate 50 mL of the filtrate to dryness and dry at 100-105 °C. The residue weighs a maximum of 20 mg.

Substances insoluble in acetic acid

Maximum 0.1 per cent.

Any residue obtained during the preparation of solution S, washed, dried and ignited at 600 ± 50 °C, weighs a maximum of 5 mg.

Chlorides (*2.4.4*)

Maximum 0.1 per cent.

Dilute 1 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*)

Maximum 1.0 per cent.

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

Calcium (*2.4.3*)

Maximum 1.5 per cent.

Dilute 1.3 mL of solution S to 150 mL with *distilled water R*. 15 mL of the solution complies with the test.

Iron (*2.4.9*)

Maximum 0.07 per cent.

Dissolve 0.15 g in 5 mL of *dilute hydrochloric acid R* and dilute to 10 mL with *water R*. Dilute 1 mL of the solution to 10 mL with *water R*.

Loss on ignition

Maximum 8.0 per cent, determined on 1.00 g at 900 ± 25 °C.

ASSAY

Dissolve 0.320 g in 20 mL of *dilute hydrochloric acid R* and dilute to 100.0 mL with *water R*. Using 20.0 mL of the solution, 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.

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 heavy magnesium oxide used as filler in oral solid dosage forms.

Particle-size distribution (*2.9.31* or *2.9.38*)

Bulk density of powders (*2.9.34*)