

Magnesium Oxide

1 Nonproprietary Names

BP: Heavy magnesium oxide and Light magnesium oxide
JP: Magnesium oxide
PhEur: Magnesii oxidum ponderosum and Magnesii oxidum leve
USP: Magnesium oxide
See Section 8.

2 Synonyms

Calcined magnesia; E530; *MagGran MO*; magnesia; magnesia usta; periclase.

3 Chemical Name and CAS Registry Number

Magnesium oxide [1309-48-4]

4 Empirical Formula Molecular Weight

MgO 40.30

5 Structural Formula

MgO

6 Functional Category

Tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium oxide is used as an alkaline diluent in solid-dosage forms. It is also used as a food additive and as an antacid, either alone or in conjunction with aluminum hydroxide. Magnesium oxide is additionally used as an osmotic laxative and a magnesium supplement in deficiency states.

8 Description

Two forms of magnesium oxide exist: a bulky form termed light magnesium oxide and a dense form termed heavy magnesium oxide. The USP 25 defines both forms in a single monograph, while other pharmacopeias have separate monographs for each form. For the heavy variety, 15 g occupies a volume of about 30 mL; for the light variety, 20 g occupies a volume of about 150 mL as defined by the USP 25.

Both forms of magnesium oxide occur as fine, white, odorless powders. They possess a cubic crystal structure.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for magnesium oxide.

Test	JP 2001	PhEur 2002	USP 25
Identification	+	+	+
Loss on ignition	≤ 10.0%	≤ 8.0%	≤ 10.0%
Color of solution	—	+	—
Free alkali and soluble salts	+	—	≤ 2.0%
Soluble substances	—	≤ 2.0%	—
Acid-insoluble substances	≤ 0.1%	≤ 0.1%	≤ 0.1%
Arsenic	≤ 10 ppm	≤ 4 ppm	—
Calcium	—	≤ 1.5%	≤ 1.1%
Calcium oxide	+	—	—
Carbonate	+	—	—
Heavy metals	≤ 40 ppm	≤ 30 ppm	≤ 20 µg/g
Iron	≤ 500 ppm	≤ 0.07%	≤ 0.05%
Chloride	—	+	—
Heavy magnesium oxide	—	≤ 0.1%	—
Light magnesium oxide	—	≤ 0.15%	—
Fluoride	≤ 0.08%	—	—
Sulfate	—	≤ 1.0%	—
Assay	≥ 96.0%	98.0–100.5%	96.0–100.5%

10 Typical Properties

Acidity/alkalinity: pH = 10.3 (saturated aqueous solution)

Boiling point: 3600°C

Melting point: 2800°C

Particle size distribution: 99.98% less than 45 µm in size (light magnesium oxide).

Refractive index: 1.732

Solubility: soluble in dilute acids and ammonium salt solutions; very slightly soluble in pure water (solubility is increased by carbon dioxide); practically insoluble in ethanol (95%).

Specific gravity: 3.581 g/cm³ at 25°C

11 Stability and Storage Conditions

Magnesium oxide is stable at normal temperatures and pressures. However, it forms magnesium hydroxide in the presence of water. Magnesium oxide is hygroscopic and rapidly absorbs water and carbon dioxide on exposure to the air, the light form more readily than the heavy form.

The bulk material should be stored in an airtight container in a cool, dry place.

12 Incompatibilities

Magnesium oxide is a basic oxide and as such can react with acidic compounds in the solid state to form salts such as Mg(ibuprofen)₂⁽¹⁾ or degrade alkaline-labile drugs. Adsorption of various drugs onto magnesium oxide has been reported, such as antihistamines,⁽²⁾ antibiotics (especially tetracyclines),⁽³⁾ salicylates,⁽⁴⁾ atropine sulfate,⁽⁵⁾ hyoscyamine hydrobromide,⁽⁵⁾ and anthranilic acid derivatives. Magnesium oxide can complex with polymers, e.g. *Eudragit RS*, to retard drug

release⁽⁶⁻⁸⁾ and can interact in the solid state with phenobarbitone sodium.⁽⁹⁾ Magnesium oxide has a negative effect on the stability of diazepam.⁽¹⁰⁾ Magnesium oxide can affect the bioavailability of trichlormethiazide⁽¹¹⁾ and antiarrhythmics.⁽¹²⁾

13 Method of Manufacture

Magnesium oxide occurs naturally as the mineral periclase. It may be manufactured by calcining either the mineral magnesite or magnesium hydroxide, which is obtained, by liming, from seawater or brine. Purification methods include crushing and size separation, heavy-media separation, and froth flotation. Magnesium oxide may also be produced by the thermal decomposition of magnesium chloride, magnesium sulfate, magnesium sulfite, nesquehonite, and the basic carbonate $5\text{MgO} \cdot 4\text{CO}_2 \cdot 5\text{H}_2\text{O}$. Purification is carried out by filtration or sedimentation.

14 Safety

Magnesium oxide is widely used in oral formulations as an excipient and as a therapeutic agent. Therapeutically, 250–500 mg is administered orally as an antacid and 2–5 g as an osmotic laxative. Magnesium oxide is generally regarded as a nontoxic material when employed as an excipient, although adverse effects, due to its laxative action, may occur if high doses are ingested orally.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Magnesium oxide may be harmful if inhaled, ingested, or absorbed through the skin in quantity and is irritating to the eyes and respiratory system. Gloves, eye protection, and a dust mask or respirator are recommended. In the US and UK, the long-term (8-hour TWA) occupational exposure limits for magnesium oxide, calculated as magnesium, are 10 mg/m^3 for total dust and 4 mg/m^3 for respirable dust.^(13,14) The short-term (15-minute) limit for respirable dust is 10 mg/m^3 .^(13,14)

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

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18 Comments

The EINECS number for magnesium oxide is 215-171-9.

19 Specific References

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20 General References

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21 Author

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22 Date of Revision

20 August 2002.