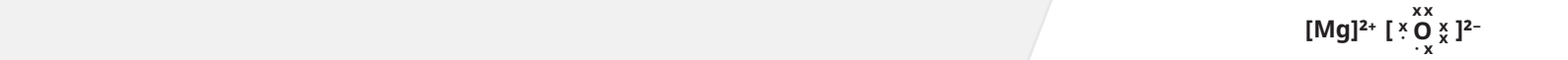
Technical Data Sheet

Magnesium oxide light

IP, Ph.Eur, USP



Applications

Magnesium oxide is used as an alkaline diluent in solid-dosage forms to modify the pH of tablets. It can be added to solid-dosage forms to bind excess water and keep the granulation dry.

General Information

Pharmacopeia Status	:	IP, Ph.Eur, USP
CAS No.	:	1309-48-4
EC No.	:	201-069-1
Appearance/Description	:	Fine, white or almost white amorphous powder.
Molecular Formula	:	MgO
Molecular Mass	:	40.30 g/mol

Marketed Formulation

- Cetirizine hydrochloride (Chewable) 10 mg tablets
- Clorazepate dipotassium 15 mg tablets
- Felodipine extended-release 5 mg tablets & many more...

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Control of elemental impurities as per ICH Q3D
- Control of Chloride (Cl), Calcium (Ca), Sulphate (SO4), Iron (Fe)
- Control of Arsenic (As)

Pack Mode

1 kg HDPE container

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 and dry place.

Safety and Handling Information

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.

Pharmaceutical Specifications

Description	Fine, white or almost white, amorphous powder, 15 gm occupies a volume of about 150 mL (USP, Ph.Eur, IP)
Solubility	Soluble in dilute acids with at most slight effervescence. Practically insoluble in water.; insoluble in alcohol (USP, Ph.Eur, IP)
Identification (Magnesium)	A white crystalline precipitate which is insoluble in 6 N ammonium hydroxide should form (USP, Ph.Eur)
Identification by Chemical test	Gives reaction (A) of magnesium salts (IP)
Identification A (Bulk density)	0.15 g/mL max. (Ph.Eur)
Appearance of solution	Solution should not more intensely coloured than reference solution B2 (Ph.Eur, IP)
Heavy metals	30ppm max. (IP)
Assay (Ignited substance)	98.0% - 100.5% (USP, Ph.Eur, IP)
Soluble substances/ Soluble salts	2.0% max. (USP, Ph.Eur, IP)
Substances insoluble in acetic acid	0.1% max. (IP, Ph.Eur)
Acid-Insoluble substance	NMT 0.1% (USP)
Free alkali and soluble salts: Free alkali	NMT 2.0 mL of the acid should consume (USP)
Chloride (Cl)	0.15% max. (Ph.Eur)
Chloride (Cl)	0.125% max. (IP)
Sulfates	1.0% max. (IP, Ph.Eur)
Arsenic	4 ppm max. (IP, Ph.Eur)
calcium	NMT 1.1% (USP)
Calcium (Ca)	1.5% max. (IP)
Iron	NMT 0.05% (USP, Ph.Eur)
Iron (Fe)	0.1% max. (IP)
Loss on ignition	NMT 8.0% (IP, USP, Ph.Eur)

Regulatory Information

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (oral capsules, tablets, and buccal). Included in non-parenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Non Hazardous

See the Material Safety Data Sheet on www.finarchemicals.com

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