Magnesium Aluminum Silicate

1 Nonproprietary Names

BP: Aluminium Magnesium Silicate
PhEur: Aluminium Magnesium Silicate
USP–NF: Magnesium Aluminum Silicate

2 Synonyms

Aluminii magnesii silicas; aluminosilicic acid, magnesium salt; aluminum magnesium silicate; *Carrisorb*; *Gelsorb*; *Magnabrite*; magnesium aluminosilicate; magnesium aluminum silicate, colloidal; magnesium aluminum silicate, complex colloidal; *Neusilin*; *Pharmasorb*; silicic acid, aluminum magnesium salt; *Veegum*.

3 Chemical Name and CAS Registry Number

Aluminum magnesium silicate [12511-31-8]
Magnesium aluminum silicate [1327-43-1]

4 Empirical Formula and Molecular Weight

Magnesium aluminum silicate is a polymeric complex of magnesium, aluminum, silicon, oxygen, and water. The average chemical analysis is conventionally expressed as oxides:

Silicon dioxide 61.1%
Magnesium oxide 13.7%
Aluminum oxide 9.3%
Titanium dioxide 0.1%
Ferric oxide 0.9%
Calcium oxide 2.7%
Sodium oxide 2.9%
Potassium oxide 0.3%
Carbon dioxide 1.8%
Water of combination 7.2%

5 Structural Formula

The complex is composed of a three-lattice layer of octahedral alumina and two tetrahedral silica sheets. The aluminum is substituted to varying degrees by magnesium (with sodium or potassium for balance of electrical charge). Additional elements present in small amounts include iron, lithium, titanium, calcium, and carbon.

6 Functional Category

Adsorbent; suspending agent; tablet and capsule binder; tablet and capsule disintegrant; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium aluminum silicate has been used for many years in the formulation of tablets, ointments, and creams. It is used in oral and topical formulations as a suspending and stabilizing agent either alone or in combination with other suspending agents.[1–3] The viscosity of aqueous dispersions may be greatly increased by combination with other suspending agents, such as xanthan gum, owing to synergistic effects; *see* Xanthan Gum. In tablets, magnesium aluminum silicate is used as a binder and disintegrant in conventional or slow-release formulations, and solid self-emulsifying drug delivery systems.[4–7] *See* Table I. It has also been investigated for use with chitosan in nanocomposite tablet film coatings.[8]

Magnesium aluminum silicate may cause bioavailability problems with certain drugs; *see* Section 12.

Table I: Uses of magnesium aluminum silicate.

Use	Concentration (%)
Adsorbent	10–50
Binding agent	2–10
Disintegrating agent	2–10
Emulsion stabilizer (oral)	1–5
Emulsion stabilizer (topical)	2–5
Suspending agent (oral)	0.5–2.5
Suspending agent (topical)	1–10
Stabilizing agent	0.5–2.5
Viscosity modifier	2–10

8 Description

The USP 40–NF 35 S1 describes magnesium aluminum silicate as a blend of colloidal montmorillonite and saponite that has been processed to remove grit and nonswellable ore components. Four types of magnesium aluminum silicate are defined: types IA, IB, IC, and IIA. These types differ according to their viscosity and ratio of aluminum and magnesium content; *see* Table II.

The PhEur 9.2 describes magnesium aluminum silicate (aluminium magnesium silicate) as a mixture of particles with colloidal particle size of montmorillonite and saponite, free from grit and nonswellable ore.

Magnesium aluminum silicate occurs as off-white to creamy white, odorless, tasteless, soft, slippery small flakes, or as a fine, micronized powder. Flakes vary in shape and size from about 0.3 × 0.4 mm to 1.0 × 2.0 mm and about 25–240 µm thick. Many flakes are perforated by scattered circular holes 20–120 µm in diameter. Under dark-field polarized light, innumerable bright specks are observed scattered over the flakes. The powder varies from 45 to 297 µm in size.

Table II: Magnesium aluminum silicate types defined in the USP34–NF29 S1.

Type	Viscosity (mPa s)	Al content/Mg content
IA	225–600	0.5–1.2
IB	150–450	0.5–1.2
IC	800–2200	0.5–1.2
IIA	100–300	1.4–2.8

9 Pharmacopeial Specifications

See Table III.

Table III: Pharmacopeial specifications for magnesium aluminum silicate.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Viscosity (5% w/v suspension)	–	*See* Table II
Microbial limits	$\leq 10^3$ cfu/g	$\leq 10^3$ cfu/g
pH (5% w/v suspension)	9.0–10.0	9.0–10.0
Acid demand	–	+
Loss on drying	≤8.0%	≤8.0%
Arsenic	≤3 ppm	≤3 µg/g
Lead	≤15 ppm	≤15 µg/g
Assay for Al and Mg content	95.0–105.0	+