Pharmacopoeias. In *Eur.* (see p.vii) and *Int.* Also in *USNF*.

Ph. Eur. 6.2 (Alginic Acid). A mixture of polyuronic acids composed of residues of D-mannuronic and L-guluronic acids extracted from algae belonging to the Phaeophyceae. A white or pale yellowish-brown, crystalline or amorphous powder. It swells in water. Very slightly soluble or practically insoluble in alcohol; practically insoluble in organic solvents; dissolves in solutions of alkali hydroxides.

USNF 26 (Alginic Acid). A hydrophilic colloidal carbohydrate extracted with dilute alkali from various species of brown seaweeds (Phaeophyceae). A white to yellowish-white, odourless or practically odourless, fibrous powder. Insoluble in water and in organic solvents; soluble in alkaline solutions. pH of a 3% dispersion in water is between 1.5 and 3.5.

Propylene Glycol Alginate

E405; Propilenglicol, alginato de. Propane-1,2-diol Alginate.

ATC — A02BX13.

ATC Vet — QA02BX13.

Pharmacopoeias. In *USNF*.

USNF 26 (Propylene Glycol Alginate). A white to yellowish, practically odourless, fibrous or granular powder. Soluble in water, in solutions of dilute organic acids, and, depending on the degree of esterification, in hydroalcoholic mixtures containing up to 60% by weight of alcohol, to form stable, viscous colloidal solutions at a pH of 3.

Sodium Alginate

Algin; Alginato sódico; E401; Natrii alginas; Natrio alginatas; Natriumalginaatti; Natriumalginat; Nátrium-alginát; Natrium-alginát; Sodium, alginate de; Sodium Polymannuronate; Sodyum Aljinat.

CAS — 9005-38-3.

ATC — A02BX13.

ATC Vet — QA02BX13.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Sodium Alginate). It consists chiefly of the sodium salt of alginic acid. A white or pale yellowish-brown powder. Slowly soluble in water, forming a viscous, colloidal solution; practically insoluble in alcohol.

USNF 26 (Sodium Alginate). A yellowish-white, practically odourless, coarse or fine powder. Soluble in water, forming a viscous, colloidal solution; insoluble in alcohol, in chloroform, and in ether, in hydroalcoholic solutions in which the alcohol content is greater than 30% by weight, and in acids when the pH of the resulting solution becomes lower than about 3. Store in airtight containers.

Incompatibility. Incompatibilities of sodium alginate have been observed with acridine derivatives, methylrosanilinium chloride, phenylmercuric acetate and nitrate, calcium salts, alcohol in concentrations greater than 5%, and heavy metals. High concentrations of electrolytes cause an increase in viscosity until salting-out of sodium alginate occurs; salting-out occurs if more than 4% of sodium chloride is present.

Uses and Administration

Alginic acid and alginates such as propylene glycol alginate and sodium alginate are used in pharmaceutical manufacturing as suspending and thickening agents. They may be used as stabilisers for oil-in-water emulsions and as binding and disintegrating agents in tablets. Various grades are usually available commercially for different applications and yield solutions of varying viscosity. A reduction in viscosity has been said to occur following sterilisation by autoclaving of sodium alginate solutions.

Alginic acid and alginates (ammonium alginate, calcium alginate (p.1058), potassium alginate, propylene glycol alginate, and sodium alginate) are also used as emulsifiers and stabilisers in the food industry.

Alginic acid or the alginates, magnesium alginate and sodium alginate, are given, usually formulated with an antacid, in the management of gastro-oesophageal reflux disease (p.1696). Alginic acid or the alginate reacts with gastric acid to form a viscous gel (often termed a raft) that floats on top of the gastric contents. This raft then acts as a mechanical barrier to reduce reflux.

Alginic acid is also used, usually in the form of a mixed calcium-sodium salt, as a haemostatic and wound dressing; it is employed in the form of a fibre made into a dressing or packing material.

Preparations

BP 2008: Alginate Raft-forming Oral Suspension; Compound Alginate Antacid Oral Suspension.

Proprietary Preparations (details are given in Part 3)
Arg.: Nu-Gel Hidrogel con Alginato; ***Austral.:*** Kaltostat†; ***Canad.:*** Kaltostat; Restore CalciCare; Tegagen†; ***Fr.:*** Nu-Gel; ***Irl.:*** Kaltostat; ***Israel:*** Nu-Gel; ***Ital.:*** Flaminal; Kaltostat; Nu-Gel; ***NZ:*** Gaviscon; ***Port.:*** Biafine; ***Rus.:*** Alginatol (Альгинатол); Natalsid (Натальсид); ***S.Afr.:*** Gaviscon; Gaviscon Advance; Kaltostat; ***UK:*** Comfeel SeaSorb.

Multi-ingredient: ***Arg.:*** Comfeel SeaSorb†; Gaviscon†; Glicalox†; Mylanta Reflux; Reduciet; Rennie; Seasorb; ***Austral.:*** Gaviscon; Gaviscon Double Strength; Infant Gaviscon; Meracote†; Mylanta Heartburn Relief†; ***Austria:*** Rennie Duo; ***Belg.:*** Gastriphar; Gaviscon; Gaviscon Advance; ***Canad.:*** Carboflex†; Gastrifom; Gaviscon Heartburn Relief; Heartburn Relief†; Maalox HRF; ***Chile:*** Algicote; Gaviscon; ***Cz.:*** Alginete†; Gaviscon; ***Denm.:*** Gaviscon; ***Fin.:*** Gaviscon; ***Fr.:*** Gaviscon; Gavisconell; Hyalogran; Pseudophage; Release Ag; Topaal; Topalkan; ***Ger.:*** Gaviscon; Gaviscon Advance; Nu-Gel†; Recatol Algin; ***Hong Kong:*** Gaviscon; ***India:*** Acigon†; Gaviscon; Raftace; Visco; ***Irl.:*** Acidex; Algicon†; Gaviscon; Gaviscon Advance; Gaviscon Infant; Gaviscon Lemon; Pyrogastrone; Rennie Duo†; ***Israel:*** Algical Kalzarevet; Kaltocarb; Kaltostat; ***Ital.:*** Digeral†; Gastrotuss; Gaviscon; Gaviscon Advance; Silvercel; ***Malaysia:*** Gaviscon; Gaviscon Advance; ***Mex.:*** Algicon†; ***Neth.:*** Aciflux; Algicon; Gaviscon; Rennie Duo; Rennie Refluxine; ***Norw.:*** Gaviscon; ***NZ:*** Gaviscon; Mylanta Heartburn Relief; ***Pol.:*** Gealcid; ***Port.:*** Carboflex†; Kaltostat; Rennie Duo; ***S.Afr.:*** Gaviscon; Gelacid; Infant Gaviscon; ***Singapore:*** Gaviscon; Gaviscon Advance; ***Spain:*** Dolcopin; ***Swed.:*** Gaviscon; ***Switz.:*** Gaviscon†; Refluxine†; ***Turk.:*** Gaviscon; Rennie Duo; ***UK:*** Acidex; Algicon†; Bisodol Extra; Bisodol Heartburn Relief; Gastrocote; Gaviscon Advance; Gaviscon Cool; Gaviscon Double Action; Gaviscon Infant; Gaviscon†; Peptac; Pyrogastrone†; Raft-Eze; Rennie Duo; Setlers Heartburn & Indigestion Liquid; Topal; ***USA:*** Foamicon†; Gaviscon; Genaton; Pretts Diet Aid.

Aluminium Magnesium Silicate

Aliuminio-magnio silikatas; Alumiinimagnesiumsilikaatti; Aluminii magnesii silicas; Aluminium (silicate d') et de magnésium; Aluminiummagnesiumsilikat; Alumínium-magnézium-szilikát; Aluminosilicato magnésico; Křemičitan hořečnato-hlinitý; Magnesium Aluminium Silicate; Magnesium Aluminum Silicate; Saponite.

CAS — 1327-43-1; 12511-31-8.

Pharmacopoeias. In *Eur.* (see p.vii) and *Int.* Also in *USNF*. *USNF* also includes Magnesium Aluminosilicate and Magnesium Aluminometasilicate.

Ph. Eur. 6.2 (Aluminium Magnesium Silicate). A mixture of colloidal-size particles of montmorillonite and saponite, free from grit and nonswellable ore. Almost white powder, granules, or plates. Practically insoluble in water and in organic solvents; swells in water to form a colloidal dispersion. A 5% dispersion in water has a pH of 9.0 to 10.0.

USNF 26 (Magnesium Aluminum Silicate). A blend of colloidal montmorillonite and saponite that has been processed to remove grit and nonswellable ore components. There are several types, differing in viscosity and in ratio of aluminium content to magnesium content. It is an odourless, fine (micronised) powder, small cream to tan granules, or small flakes that are creamy when viewed on their flat surfaces and tan to brown when viewed on their edges. Insoluble in water and in alcohol; swells when added to water or glycerol. pH of a 5% suspension in water is between 9.0 and 10.0. Store in airtight containers.

USNF 26 (Magnesium Aluminosilicate). A synthetic material that contains 20.5 to 27.7% of magnesium oxide, 27.0 to 34.3% of aluminium oxide, and 14.4 to 21.7% of silicon dioxide, calculated on the dried basis. A white powder or granules having an amorphous structure. Practically insoluble in water and in alcohol; partially soluble in acids and alkalis. A 4% suspension in water has a pH of 8.5 to 10.5. Store at a temperature not exceeding 40° in airtight containers.

USNF 26 (Magnesium Aluminometasilicate). A synthetic material that contains 29.1 to 35.5% of aluminium oxide, 11.4 to 14.0% of magnesium oxide, and 29.2 to 35.6% of silicon dioxide, calculated on the dried basis. It exists in two forms, Type I-A and Type I-B. A white powder or granules having an amorphous structure. Practically insoluble in water and in alcohol; partially soluble in acids and alkalis. A 4% suspension in water has a pH of 6.5 to 8.5 (Type I-A) and 8.5 to 10.5 (Type I-B). Store at a temperature not exceeding 40° in airtight containers.

Uses

Aluminium magnesium silicate has a variety of pharmaceutical uses, including use as a suspending and thickening agent, as an emulsion stabiliser, and as a binder and disintegrating agent in tablets.

Other forms of aluminium magnesium silicate include an artificial hydrate known as almasilate (p.1705), which is used as an antacid, and attapulgite (p.1709), a purified native hydrated aluminium magnesium silicate that is highly adsorbent and is used in a wide range of products including fertilisers and pesticides. Activated attapulgite, which is attapulgite that has been carefully heated to increase its adsorptive capacity, is used in preparations for diarrhoea.

Preparations

Proprietary Preparations (details are given in Part 3)
Indon.: Neusilin.

Multi-ingredient: ***Denm.:*** Alkasid†; ***India:*** Digene; ***Indon.:*** Flatucid; Stomadon; ***Jpn:*** Cabe 2; ***Thai.:*** Diasgest; ***UAE:*** Alkasid.

Bentonite

Bentoniitti; Bentonit; Bentonita; Bentonitas; Bentonitum; E558; Mineral Soap; Soap Clay; Wilkinite.

CAS — 1302-78-9.

Pharmacopoeias. In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF*, which also includes a purified form.

Ph. Eur. 6.2 (Bentonite). A natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms may be replaced by other atoms such as magnesium and iron. A very fine, homogeneous, greyish-white powder with a more or less yellowish or pinkish tint. Practically insoluble in water and in aqueous solutions, but swells with a little water forming a malleable mass.

USNF 26 (Bentonite). A native, colloidal, hydrated aluminium silicate. A very fine, odourless, hygroscopic, pale buff or cream-coloured to greyish powder, free from grit. Insoluble in water, but swells to about 12 times its volume when added to water; insoluble in, and does not swell in, organic solvents. pH of a 2% suspension in water, mixed vigorously to facilitate wetting, is between 9.5 and 10.5. Store in airtight containers.

USNF 26 (Purified Bentonite). A colloidal montmorillonite that has been processed to remove grit and nonswellable ore components. An odourless, fine, micronised powder, or small flakes that are creamy when viewed on their flat surfaces and tan to brown when viewed on their edges. Insoluble in water and in alcohol. Swells when added to water or glycerol. pH of a 5% suspension in water is between 9.0 and 10.0. Store in airtight containers.

Uses

Bentonite absorbs water readily to form sols or gels, depending on its concentration. It is used in pharmaceutical manufacturing as a suspending and stabilising agent and as an adsorbent or clarifying agent. It is also used as an anticaking agent in the food industry.

Bentonite may be used as an oral adsorbent in paraquat poisoning (p.2047).

Preparations

USNF 26: Bentonite Magma.

Proprietary Preparations (details are given in Part 3)
Gr.: Bentonine†.

Multi-ingredient: ***Indon.:*** Stomagel; ***Malaysia:*** Clearasil Pimple Treatment; ***S.Afr.:*** Clearasil T; ***Singapore:*** Clearasil Pimple Treatment.

Carbomers

Acrylic Acid Polymers; Carbomera; Carbomères; Carbómeros; Carbopols; Carboxypolymethylene; Carboxyvinyl Polymers; Karbomeerit; Karbomerai; Karbomerek; Karbomerer; Karbomerler; Karbomery; Poliakrilic Asit; Polyacrylic Acid.

CAS — 9003-01-4; 54182-57-9.

NOTE. Carbomer is *BAN*, *USAN*, and *rINN*.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *Int. USNF* has separate monographs for a range of carbomers.

USNF also includes Carbomer Copolymer and Carbomer Interpolymer.

Ph. Eur. 6.2 (Carbomers). High-molecular-weight polymers of acrylic acid cross-linked with polyalkenyl ethers of sugars or polyalcohols. They are produced in several grades characterised by the viscosity of a defined solution. White or almost white, fluffy, hygroscopic powders. They swell in water and in other polar solvents after dispersion and neutralisation with sodium hydroxide solution. Store in airtight containers.

USNF 26 (Carbomer 934; Carbomer 934P; Carbomer 940; Carbomer 941; Carbomer 1342). Carbomers are high-molecular-weight polymers of acrylic acid cross-linked with allyl ethers of pentaerythritol. The viscosity of a neutralised aqueous dispersion for each carbomer is:

- Carbomer 934 (0.5%), 30 500 to 39 400 cP
- Carbomer 934P (0.5%), 29 400 to 39 400 cP
- Carbomer 940 (0.5%), 40 000 to 60 000 cP
- Carbomer 941 (0.5%), 4000 to 11 000 cP
- Carbomer 1342 (1.0%), 9500 to 26 500 cP

They are white, fluffy, hygroscopic powders having a slight characteristic odour. pH of a 1% dispersion in water is about 3. When neutralised with alkali hydroxides or with amines, they dissolve in water, in alcohol, and in glycerol. Store in airtight containers.

USNF 26 (Carbomer Copolymer). A high-molecular-weight copolymer of acrylic acid and a long chain alkyl methacrylate cross-linked with allyl ethers of polyalcohols. Different types of Carbomer Copolymer are characterised by the viscosity of a defined solution. Carbomer Copolymer does not constitute the official title when benzene is used in the manufacturing process, in which case the name will be Carbomer 1342 if it complies with the requirements of that monograph. Store in airtight containers at a temperature not exceeding 45°.

USNF 26 (Carbomer Interpolymer). A carbomer homopolymer or copolymer that contains a block copolymer of macrogol and a long chain alkyl acid ester. Different types of Carbomer Interpolymer are characterised by the viscosity of a defined solution. Store in airtight containers at a temperature not exceeding 45°.

Uses and Administration

Carbomers are used in pharmaceutical manufacturing as suspending agents, gel bases, emulsifiers, and binding agents in tablets.

Carbomers, in liquid gel formulations containing typically 0.2 or 0.3%, are used topically as tear substitutes in the management of dry eye (p.2140).

Preparations

BP 2008: Carbomer Eye Drops.

Proprietary Preparations (details are given in Part 3)
Arg.: Acrylarm; Lacryvisc†; Liposic; Refresh Gel; Siccafluid; Teargel†; Viscotears; ***Austral.:*** Poly Gel; Viscotears; ***Austria:*** AquaTears; Liposic; Tears Naturale; Vidisic; ***Belg.:*** Alcon Eye Gel; Lacrinorm; Liposic; Ocugel; Thilo Tears; Vidisic; ***Braz.:*** Refresh Gel; Vidisic†; Viscotears; ***Canad.:*** Lacrinorm†; Tear-Gel; ***Chile:*** Feels; Lacryvisc; Nicotears; Viscotears; ***Cz.:*** Lacryvisc†; Oftagel; Vidisic; ***Denm.:*** Oftagel; Viscotears; ***Fin.:*** Oftagel; Viscotears; ***Fr.:***