Stabilising and Suspending Agents

The stabilising and suspending agents described in this chapter have the property of increasing the viscosity of water when dissolved or dispersed. The rheological properties of the dispersions can vary widely from thin liquids to thick gels.

They have wide applications both in pharmaceutical manufacturing and in the food industry. As well as being used as thickening and suspending agents many are used in emulsions as stabilisers and in some cases as emulsifying agents; some are also used in the manufacture of tablets as disintegrants, binding and granulating agents, and for film or enteric coating.

Some are used in artificial tear and artificial saliva preparations which are used in the management of dry eye and dry mouth respectively. Those most commonly used are carbomers, cellulose ethers such as carmellose and hypromellose, polyvinyl alcohol, and povidone. Some, such as the alginates and methylcellulose, are also used in gastrointestinal disorders.

Dry eye

Dry eye is a chronic condition caused by instability of the tear film covering the eye; the tear film breaks up to leave dry spots rather than being maintained between blinks. Tears consist of a slightly alkaline fluid that is spread across the eye by blinking and is lost via the lachrymal ducts or by evaporation. Mucus secreted by the conjunctiva is also required to maintain tear film stability and dry eye can result from reduced production of either tears or conjunctival mucus. Reduced tear secretion is common in the elderly, but also occurs in some systemic disorders or as an adverse effect of drugs such as those, like tricyclic antidepressants, that have antimuscarinic effects. Tear film instability may also result from increased tear evaporation, for example due to corneal exposure in thyroid disease, or from lid, corneal, or other eye disorders.

The main symptoms of dry eye are discomfort, typically with a chronic gritty sensation, visual disturbances, and sometimes photophobia. If left untreated corneal ulceration and eventual loss of sight may occur. Keratoconjunctivitis sicca (corneal inflammation) may result from severe dry eye in Sjögren's syndrome (see below).

Treatment of dry eye is primarily symptomatic using 'artificial tears' preparations; eye drops containing hypromellose or other cellulose ethers (carmellose, hyetellose, methylcellulose), polyvinyl alcohol, or povidone are used. Carbomer, in liquid gel formulations, and ointments containing soft or liquid paraffins are also used. Ointments have a longer duration of action than drops, but tend to blur the vision and are most suitable for use at night. Drops should be used as frequently as required, up to hourly or more often if necessary. Frequent use of eye drops may cause sensitivity to the preservative, in which case preservative-free preparations should be considered. An alternative in patients needing very frequent instillation of drops is a slow-release ophthalmic insert of hyprolose. Punctal occlusion with gelatin rods or collagen implants is used diagnostically to block tear outflow and treatment by permanent occlusion may be considered. Mucus build-up due to reduced tear production may respond to topical mucolytics such as acetylcysteine or bromhexine. Topical immunosuppressants such as ciclosporin may be of benefit in some patients with keratoconjunctivitis sicca;[1] combination of topical ciclosporin with punctal occlusion has been tried.[2]

Sjögren's syndrome is an auto-immune inflammatory disease primarily affecting the lachrymal and salivary glands, and manifests as dry eye and dry mouth. It is often secondary to an auto-immune disorder such as rheumatoid arthritis.[3] Treatment is mainly symptomatic[4] using artificial tears and topical mucolytics for dry eye; dry mouth is treated with artificial saliva as outlined below. Oral pilocarpine may be of benefit for both dry eye and dry mouth;[5,6] systemic treatment with the mucolytic bromhexine has produced conflicting results.[7-9] Corticosteroids and immunosuppressants may have a role in patients with CNS involvement.[10]

1. Anonymous. Ophthalmic cyclosporine (Restasis) for dry eye disease. *Med Lett Drugs Ther* 2003; **45:** 42–3.
2. Roberts CW, *et al.* Comparison of topical cyclosporine, punctal occlusion, and a combination for the treatment of dry eye. *Cornea* 2007; **26:** 805–9.
3. Fox RI. Sjögren's syndrome. *Lancet* 2005; **366:** 321–31.
4. Oxholm P, *et al.* Rational drug therapy: recommendations for the treatment of patients with Sjögren's syndrome. *Drugs* 1998; **56:** 345–53.
5. Vivino FB, *et al.* Pilocarpine tablets for the treatment of dry mouth and dry eye symptoms in patients with Sjögren syndrome: a randomized, placebo-controlled, fixed-dose, multicenter trial. *Arch Intern Med* 1999; **159:** 174–81.
6. Tsifetaki N, *et al.* Oral pilocarpine for the treatment of ocular symptoms in patients with Sjögren's syndrome: a randomised 12 week controlled study. *Ann Rheum Dis* 2003; **62:** 1204–7.
7. Frost-Larsen K, *et al.* Sjögren's syndrome treated with bromhexine: a randomised clinical study. *BMJ* 1978; **i:** 1579–81.
8. Tapper-Jones LM, *et al.* Sjögren's syndrome treated with bromhexine: a reassessment. *BMJ* 1980; **280:** 1356.
9. Prause JU, *et al.* Lacrimal and salivary secretion in Sjögren's syndrome: the effect of systemic treatment with bromhexine. *Acta Ophthalmol (Copenh)* 1984; **62:** 489–97.
10. Rogers SJ, *et al.* Myelopathy in Sjögren's syndrome: role of nonsteroidal immunosuppressants. *Drugs* 2004; **64:** 123–32.

Dry mouth

Dryness of the mouth (xerostomia) resulting from decreased salivary secretion is often an adverse effect of therapy with drugs such as antimuscarinics, antihistamines, tricyclic antidepressants, and diuretics. Other causes include dehydration, anxiety, Sjögren's syndrome (see Dry Eye, above), and radiotherapy of the head and neck. Dry mouth can cause eating difficulties and lead to oral disease such as candidiasis, dental caries, and bacterial infections.[1,2] Where possible any underlying disorder should be treated first.

Frequent sips of fluids help to relieve dry mouth. Artificial saliva products are also important in the symptomatic treatment of dry mouth. They aim to mimic normal saliva and generally contain viscosity-increasing agents, such as mucins or cellulose derivatives such as carmellose,[3,4] as well as electrolytes, including fluoride; they seldom relieve symptoms for more than 1 or 2 hours. It may be possible to stimulate saliva production with sialogogues such as sugarless chewing gum or citrus products but the low pH of the latter can damage the teeth. Malic acid has also been used as a sialogogue.

A number of systemic therapies have also been tried. Pilocarpine is an effective sialogogue, increasing salivary production where some function remains,[5] and is used in dry mouth following radiotherapy; it may also be effective in Sjögren's syndrome or other causes of dry mouth. Adverse effects, particularly increased sweating, may, however, limit its use.[6] Carbachol has been suggested as an alternative to pilocarpine with a study[7] reporting comparable efficacy but less sweating. Anethole trithione and cevimeline have been used similarly. Amifostine is used for the prevention of dry mouth associated with radiotherapy.

1. Fox PC. Management of dry mouth. *Dent Clin North Am* 1997; **41:** 863–75.
2. Silvestre-Donat FJ, *et al.* Protocol for the clinical management of dry mouth. *Med Oral* 2004; **9:** 276–9.
3. Vissink A, *et al.* A clinical comparison between commercially available mucin- and CMC-containing saliva substitutes. *Int J Oral Surg* 1983; **12:** 232–8.
4. Duxbury AJ, *et al.* A double-blind cross-over trial of a mucin-containing artificial saliva. *Br Dent J* 1989; **166:** 115–20.
5. Wiseman LR, Faulds D. Oral pilocarpine: a review of its pharmacological properties and clinical potential in xerostomia. *Drugs* 1995; **49:** 143–55.
6. Davies AN, Shorthose K. Parasympathomimetic drugs for the treatment of salivary gland dysfunction due to radiotherapy. Available in The Cochrane Database of Systematic Reviews; Issue 3. Chichester: John Wiley; 2007 (accessed 23/06/08).
7. Joensuu H. Treatment for post-irradiation xerostomia. *N Engl J Med* 1994; **330:** 141–2.

Acacia

Acac.; Acaciae gummi; Akaasiakumi; Akaciagummi; Arabmézga; Arabská klovatina; E414; Goma arábiga; Gomme arabique; Gomme de Sénégal; Gum Acacia; Gum Arabic; Guma arabska; Gumiarabikas; Gummi Africanum; Gummi Arabicum; Gummi Mimosae.

CAS — 9000-01-5.

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

Ph. Eur. 6.2 (Acacia). The air-hardened gummy exudate from the trunk and branches of *Acacia senegal*, other species of *Acacia* of African origin, and *Acacia seyal*. Yellowish-white, yellow, or pale amber tears, sometimes with a pinkish tint. It is friable, opaque, frequently with a cracked surface, easily broken into irregular, whitish or slightly yellowish angular fragments with conchoidal fracture and a glassy and transparent appearance. Very slowly but almost completely soluble, after about 2 hours, in twice its mass of water leaving only a very small residue of vegetable particles; the liquid obtained is colourless or yellowish, dense, viscous, adhesive, translucent, and weakly acid to blue litmus paper. Practically insoluble in alcohol. Protect from light.

Ph. Eur. 6.2 (Acacia, Spray-dried; Acaciae Gummi Dispersione Desiccatum). It is obtained from a solution of acacia. Dissolves, rapidly and completely, after about 20 minutes, in twice its mass of water. The liquid obtained is colourless or yellowish, dense, viscous, adhesive, translucent, and weakly acid to blue litmus paper. Practically insoluble in alcohol. Protect from light.

USNF 26 (Acacia). The dried gummy exudate from the stems and branches of *Acacia senegal* (Leguminosae) or of other related African species of *Acacia*. Spheroidal tears or angular fragments of white to yellowish-white colour. It is translucent or somewhat opaque from the presence of numerous minute fissures. It is very brittle, the fractured surface is glassy and occasionally iridescent. It is also available as flakes, powder, granules, or as a spray-dried form. It is practically odourless. Insoluble in alcohol. Store in airtight containers.

Incompatibility. Incompatibilities of acacia have been reported with a number of substances including alcohol, aminophenazone, apomorphine, cresol, ferric salts, morphine, phenol, physostigmine, tannins, thymol, and vanillin. Acacia contains an oxidising enzyme that may affect preparations containing easily oxidised substances; the enzyme may be inactivated by heating at 100° for a short time.

Adverse Effects

Hypersensitivity reactions have occurred rarely after inhalation or ingestion of acacia.

Uses

Acacia is used in pharmaceutical manufacturing as a suspending and emulsifying agent, as a tablet binder, and in pastilles. It is often used with tragacanth.

It is used as an emulsifier and stabiliser in the food industry.

Preparations

USNF 26: Acacia Syrup.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Indon.:*** Norflam.

Agar

Agar-agar; Agaras; Colle du Japon; E406; Gelosa; Gélose; Japanese Isinglass; Layor Carang.

CAS — 9002-18-0.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Agar). Polysaccharides extracted from various species of Rhodophyceae algae, mainly those belonging to the genus *Gelidium*. It is prepared by treating the algae with boiling water; the extract is filtered while hot, concentrated, and dried. Colourless to pale yellow translucent strips, flakes, or powder; tough when damp but becoming more brittle on drying.

USNF 26 (Agar). The dried, hydrophilic, colloidal substance extracted from *Gelidium cartilagineum* (Gelidiaceae), *Gracilaria confervoides* (Sphaerococcaceae), and related red algae (Class Rhodophyceae). It usually consists of thin, membranous, agglutinated strips, but may occur in cut, flaked, or granulated forms. May be weak yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Odourless or has a slight odour. Insoluble in cold water; soluble in boiling water.

Uses and Administration

Agar is used as a suspending or thickening agent in pharmaceutical manufacturing and as an emulsifying and stabilising agent in the food industry.

It was formerly used similarly to methylcellulose (p.2145) as a bulk laxative. Preparations containing agar with liquid paraffin and phenolphthalein are available to treat constipation, but the relatively small amount of agar in these probably acts solely as an emulsion stabiliser.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Arg.:*** Agarol; Usar Fibras†; ***Austral.:*** Lexat†; ***Braz.:*** Agarol; Fenogar†; ***Chile:*** Agarol; ***Fr.:*** Pseudophage; ***India:*** Agarol†; ***Port.:*** Byl†; ***Switz.:*** Paragar; ***USA:*** Agoral; ***Venez.:*** Agarol†.

Alginic Acid

Acide alginique; Acidum alginicum; Algiinihappo; Algínico, ácido; Algino rūgštis; Alginsav; Alginsyra; Aljinik Asit; E400; Kyselina alginová; Polymannuronic Acid.

CAS — 9005-32-7.

ATC — A02BX13.

ATC Vet — QA02BX13.

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.:***