

solution measured at 20°. A white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Practically insoluble in hot water, in dehydrated alcohol, in acetone, and in toluene; dissolves in cold water forming a colloidal solution. A 1% w/w solution in water has a pH of 5.5 to 8.0.

USNF 26 (Hymetellose). A partly *O*-(methylated) and *O*-(2-hydroxyethylated) cellulose. Various grades are available, labelled with the viscosity of a 2% w/w solution measured at 20°. A white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Insoluble in hot water, in alcohol, in acetone, in ether, and in toluene; dissolves in cold water forming a colloidal solution. pH of a 1% w/w solution in water is between 5.5 and 8.0.

Uses

Hymetellose is used similarly to other cellulose ethers, such as methylcellulose (p.2145), as a pharmaceutical excipient.

Preparations

Proprietary Preparations (details are given in Part 3)

Austria: Cellobexon.

Multi-ingredient: **Fr.:** Pharmatex.

Hyprolose (rINN)

E463; Hidroksipropilceliuloz; Hidroxipropilcellulóz; Hidroxi-propilcellulosa; Hidroksipropilcelluloosa; Hydroxypropylcellulosa; Hydroxypropyl Cellulose; Hydroxypropylcellulose; Hydroxypropylcellulosum; Hydroxypropylcellulosa; Hyprolosum.

Гипролоза

CAS — 9004-64-2.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF* which has two separate monographs, for Hydroxypropyl Cellulose and for Low-substituted Hydroxypropyl Cellulose. **Ph. Eur. 6.2** (Hydroxypropylcellulose). A partially substituted 2-hydroxypropyl ether of cellulose. Various grades are available and may be distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% w/w solution measured at 20°. White or yellowish-white, granules or powder; hygroscopic after drying. Soluble in cold water, in dehydrated alcohol, in glacial acetic acid, in methyl alcohol, in propylene glycol, and in a mixture of 10 parts methyl alcohol and 90 parts dichloromethane, forming colloidal solutions; practically insoluble in hot water, in ethylene glycol, and in toluene; sparingly soluble or slightly soluble in acetone. A 1% w/w solution in water has a pH of 5.0 to 8.5.

USNF 26 (Hydroxypropyl Cellulose). A partially substituted poly(hydroxypropyl) ether of cellulose. When dried at 105° for 1 hour, it contains not more than 80.5% of hydroxypropoxy groups. It may contain not more than 0.60% of silica or other suitable antikicking agent. A white to cream-coloured, practically odourless, granular solid or powder, hygroscopic after drying. Soluble in cold water, in alcohol, in chloroform, and in propylene glycol, giving a colloidal solution; insoluble in hot water. pH of a 1% solution in water is between 5.0 and 8.0.

USNF 26 (Low-Substituted Hydroxypropyl Cellulose). It contains not less than 5.0% and not more than 16.0% of hydroxypropoxy groups. A white to yellowish-white, practically odourless, hygroscopic, fibrous or granular powder. Practically insoluble in dehydrated alcohol and in ether; dissolves in a solution of sodium hydroxide (1 in 10) and produces a viscous solution; swells in water, in sodium carbonate, and in 2N hydrochloric acid. pH of the suspension obtained by shaking 1.0 g with 100 mL of water is between 5.0 and 7.5. Store in airtight containers.

Adverse Effects

Hyprolase used as a solid ocular insert may result in blurred vision and ocular discomfort or irritation including hypersensitivity and oedema of the eyelids.

Hypersensitivity. Allergic contact dermatitis was reported in a patient, associated with the hyprolase present in the reservoir layer of a transdermal estradiol patch.¹

- Schwartz BK, Clendenning WE. Allergic contact dermatitis from hydroxypropyl cellulose in a transdermal estradiol patch. *Contact Dermatitis* 1988; **18**: 106–7.

Uses and Administration

Hyprolase is used in pharmaceutical manufacturing in the film coating of tablets, as a tablet excipient, as a thickener, and in microencapsulation. It is used as an emulsifier and stabiliser in the food industry.

Hyprolase is also used as a modified-release solid ophthalmic insert in the management of dry eye (p.2140).

Preparations

USP 31: Hydroxypropyl Cellulose Ocular System.

Proprietary Preparations (details are given in Part 3)

Austral.: Lacrisert†; **Canad.:** Lacrisert; **Fin.:** Lacrisert; **Fr.:** Lacrisert; **Neth.:** Lacrisert; **Norw.:** Lacrisert†; **Swed.:** Lacrisert; **USA:** Lacrisert.

Hypromellose (BAN, rINN)

E464; Hipromelozé; Hipromellóz; Hipromelosa; Hipromeloz; Hydroxypropyl Methylcellulose; Hydroxypropylmethylcellulose; Hypromellose; Hypromellos; Hypromellosum; Hypromelosa; Hypromelosa; Methyl Hydroxypropyl Cellulose; Methylcellulose Propylene Glycol Ether; Methylhydroxypropylcellulose; Methylhydroxypropylcellulosum.

Гипромелоза

CAS — 8063-82-9; 9004-65-3.

ATC — S01KA02.

ATC Vet — QS01KA02.

NOTE. HPRM is a code approved by the BP 2008 for use on single unit doses of eye drops containing hypromellose where the individual container may be too small to bear all the appropriate labelling information.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.*, and *US*.

Ph. Eur. 6.2 (Hypromellose). A mixed ether of cellulose containing a variable proportion of methoxy and 2-hydroxypropoxy groups. Various grades are available (see Labelling, below). A white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Dissolves in cold water, forming a colloidal solution; practically insoluble in hot water, in dehydrated alcohol, in acetone, and in toluene. A 1% w/w solution in water has a pH of 5.0 to 8.0.

USP 31 (Hypromellose). A methyl and hydroxypropyl mixed ether of cellulose. It contains methoxy and hydroxypropoxy groups conforming to the limits for the types 1828, 2208, 2906, and 2910, calculated on the dried basis (see Labelling, below). A white to slightly off-white fibrous or granular powder. Swells in water and produces a clear to opalescent, viscous, colloidal mixture; insoluble in dehydrated alcohol, in chloroform, and in ether.

Labelling. In Europe, grades of hypromellose are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% w/w solution measured at 20° (e.g. hypromellose 4500). In the USA, they are distinguished by appending a number in which the first 2 digits represent the approximate percentage content of methoxy groups, and the third and fourth digits the approximate percentage content of hydroxypropoxy groups.

Hypromellose Phthalate (BANM, rINNM)

Ftalát hipromeloz; Ftalato de hipromelosa; Hipromeliozės ftalatas; Hipromellóz-ftalát; Hydroxypropyl Methylcellulose Phthalate; Hypromelloosftalatti; Hypromellose, phthalate d'; Hypromellos-ftalát; Hypromellosi phthalas; Methylhydroxypropylcellulose Phthalate; Methylhydroxypropylcellulosi Phthalas.

Гипромеллозы Фталат

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

Ph. Eur. 6.2 (Hypromellose Phthalate). A monophthalic acid ester of hypromellose containing methoxy, 2-hydroxypropoxy, and phthalyl groups, calculated with reference to the anhydrous substance. White or slightly off-white, free-flowing flakes or a granular powder. Practically insoluble in water and in dehydrated alcohol; very slightly soluble in acetone and in toluene; soluble in a mixture of equal volumes of acetone and methyl alcohol, and of dichloromethane and methyl alcohol. Store in airtight containers.

USNF 26 (Hypromellose Phthalate). A monophthalic acid ester of hypromellose. It contains methoxy, hydroxypropoxy, and phthalyl groups. It contains 21.0 to 35.0% of phthalyl groups, calculated on the anhydrous basis. Store in airtight containers. A white, odourless, powder or granules. Practically insoluble in water, in dehydrated alcohol, and in hexane; produces a viscous solution in a mixture of dehydrated alcohol and acetone (1:1), or in a mixture of methyl alcohol and dichloromethane (1:1); dissolves in 1N sodium hydroxide. Store in airtight containers.

Labelling. Different grades of hypromellose phthalate in the USA are distinguished by appending a number in which the first 2 digits represent the approximate percentage content of the methoxy groups, the next 2 digits the approximate percentage content of hydroxypropoxy groups, and the last 2 digits the approximate percentage content of the phthalyl groups. Another system of nomenclature involves appending a number which indicates the pH value ($\times 10$) at which the polymer dissolves in aqueous buffer solutions; letters such as S or F may also be used to indicate grades of high molecular-weight or small particle size respectively.

Uses and Administration

Hypromellose has properties similar to those of methylcellulose (below). It is used in pharmaceutical manufacturing for film-coating tablets, as a tablet binder, as a modified-release matrix, and as an emulsifier, suspending agent, and stabiliser in topical gels and ointments. Hypromellose may also be used as an emulsifier and stabiliser in the food industry.

Hypromellose phthalate is used to provide enteric coating for tablets and granules, for the preparation of modified-release granules, and as a coating to mask the unpleasant taste of some tablets.

Hypromellose is widely used clinically in ophthalmic solutions; it is preferred to methylcellulose since mucilages of hypromel-

lose have greater clarity and usually contain fewer undispersed fibres. Hypromellose is used to prolong the action of medicated eye drops and, either alone or with other viscosity-increasing agents, in artificial tears preparations for the management of dry eye (p.2140); solutions containing 0.3 to 1% of hypromellose are commonly used. Solutions for contact lens care (p.1622) and for lubricating artificial eyes contain similar concentrations. Hypromellose is also used intra-ocularly, usually as a 2% solution, as an adjunct in ophthalmic surgery (below) and concentrations of up to 2.5% may be used topically to protect the cornea during gonioscopy procedures.

Hypromellose has been included in artificial saliva preparations used in the management of dry mouth (p.2140), but other drugs are usually preferred.

Ophthalmic surgery. Intra-ocular hypromellose may be used as a visco-elastic agent to protect the eye during surgery. In cataract extraction it is used to maintain the anterior chamber and to coat the intra-ocular lens to facilitate its implantation. Although intra-ocular hypromellose is generally considered to be well tolerated, some¹ have reported an increased incidence of pupil abnormalities (non-reactive semi-dilated pupils) after such use; others² did not confirm this. There has also been a report³ of corneal opacities in a number of patients after use of intra-ocular hypromellose.

- Tan AKK, Humphry RC. The fixed dilated pupil after cataract surgery—is it related to intraocular use of hypromellose? *Br J Ophthalmol* 1993; **77**: 639–41.
- Eason J, Seward HC. Pupil size and reactivity following hydroxypropyl methylcellulose and sodium hyaluronate. *Br J Ophthalmol* 1995; **79**: 541–3.
- Newton JN, *et al.* Corneal opacities after cataract surgery with hypromellose. *Lancet* 2000; **355**: 290.

Preparations

BP 2008: Hypromellose Eye Drops;

USP 31: Hypromellose Ophthalmic Solution.

Proprietary Preparations (details are given in Part 3)

Arg.: Artelac; Cool Tears; Gentel; Lacrisif†; Lagrima Dor†; Natura Lagrimas; Oftalook Plus; **Austral.:** Gentel Lubricant; Isopto Tears†; Methopt†; **Austria:** Artelac; Okuzell; Proscica; **Belg.:** Artelac; Isopto Tears; **Braz.:** Artelac†; Filmcel; Gentel; Lubrik†; **Canad.:** Eyleube; Gentel; Isopto Tears; Lacril; Visine Advance True Tears; Visine Contact Lens; **Chile:** Gentel; **Cz.:** Isopto Tears†; Lacrisyn†; **Denm.:** Artelac; **Fin.:** Artelac; Isopto Alkaline; Isopto Plain; **Fr.:** Artelac; **Ger.:** Artelac; Berberil Dry Eye; Cellugel; Celofalt; Gentel; HPMC-Optalt†; Methocel; Sic-Optalt; Sicca-Stuln†; **Gr.:** Lubrilac; Vidilac; **Hong Kong:** Blueye; Eye Glo Moist; Gentel; Isopto Tears; Lac-Oph; Methocel†; **Hung.:** Artelac†; Humalac B; Lacrisyn†; **India:** Hyprosol; Moisol; Nova Vizol; Occu System†; Sanvisc; **Indon.:** Gentel; **Ir.:** Artelac; Isopto Alkaline; Isopto Plain; **Israel:** Adato-Cel†; Gentel; Ocucot; **Ital.:** Gel 4000; Gentel; Lacrimil†; Lacrisif; Lacrisol; Methocel; **Malaysia:** Cellugel; Eye Glo Moist; **Mex.:** Artelac; Celulose; Filmexil†; Gentel; Luvistar; Meticel; **Norw.:** Artelac; **NZ:** Gentel; Methopt; **Philipp.:** Artelac; Gentel; Methopt; **Pol.:** Artelac; **Port.:** Artelac; Davilose; Hidroclif; **Rus.:** Defislez (Дедислэз); Lacrisif (Лакрисиф); Lacrisyn (Лакрисин); **S.Afr.:** Cellugel; Methocel; Spersatear; Viscotran; **Singapore:** Eye Mo Moist†; Gentel; Lacrisif†; Methocel†; **Spain:** Acucolens; Artific; **Swed.:** Artelac; Isopto Plain; **Switz.:** Isopto Tears; Methocel; **Thai.:** Gentel; Isopto Tears; Lac-Oph; Natarac; Opsil Tears; Simoph Tears†; **Turk.:** Lacrisif; **UK:** Artelac; Brolene Cool Eyes; Isopto Alkaline; Isopto Plain; **USA:** Artificial Tears; Entrocel; Gentel; Gonak; Goniosoft; Goniosol; Isopto Plain; Isopto Tears; Lacril; Ocucot; Tearsol; Tears Again MC; Ultra Tears; **Venez.:** Celofalt†; Gentel.

Multi-ingredient: **Arg.:** Alcon Lagrimas; Irix Lagrimas; Kalopsis Lagrimas; Oxysept Comfort†; Phoenix Lagrimas; Solucion Oral; Tears Naturale; Visine Lagrimas; **Austral.:** Bion Tears; Blink-N-Clean; Gentel Moisturising; Opti-Free Comfort†; Poly-Tears; Tears Naturale; Visine True Tears†; **Austria:** Lacrisic; **Belg.:** Alcon Adequad; Lacrystat; Tears Naturale; **Braz.:** Lacribell; Lacrima Plus; Lacrima†; Opti-Tears; Trisorb; **Canad.:** Artificial Tears; Bion Tears; Moisture Drops†; Tears Naturale; Tears Naturale Forte; **Chile:** Lagrimas Artificiales; Nicio Drops; Nicotears; Novo-Tears; Tears Naturale; **Cz.:** Tears Naturale; **Denm.:** Dacriosol; **Ger.:** Gellipur; Isopto Naturale; Lacrisic; Oculotect; **Gr.:** Tears Naturale; **Hong Kong:** Bion Tears; Tears Naturale Forte; Visine for Contacts; **Hung.:** Dacrolux; Tears Naturale; **Indon.:** Gentel; Isotic Tearin; Tears; Tears Naturale II; **Ir.:** Ilube; Tears Naturale; **Israel:** Tears Naturale; **Ital.:** Dacriosol; Hamamilli†; Ipragocet†; Tirs; **Malaysia:** Bion Tears; Dacrolux; Tears Naturale; **Mex.:** Lacrima Plus; Naphacel; Naphtears; Naturalag; Tears Naturale; **Neth.:** Duratears; **Norw.:** Tears Naturale; **NZ:** Poly-Tears; Tears Naturale; **Philipp.:** Gentle Tears; Tears Naturale; Visine Refresh; **Pol.:** Tears Naturale; **Port.:** Tears Naturale†; **Rus.:** Tears Naturale (Слезя Натуральная); **S.Afr.:** Moisture Drops†; Tears Naturale; **Singapore:** Bion Tears; Dacrolux†; Tears Naturale; **Spain:** Dacrolux; Humectant; Tears Humectant; **Swed.:** Bion Tears; **Switz.:** Tears Naturale; **Thai.:** Bion Tears; Tears Naturale; **Turk.:** Dacrolux; Tears Naturale; **UK:** Ilube; Tears Naturale; Uvistat Eye Drops; **USA:** Bion Tears; Clear Eyes CLR; Lacri-Tears; LubriTears; Maximum Strength Allergy Drops; Moisture Drops; Nature's Tears; Ocucot; Tears Naturale; Tears Renewed; Visine Pure Tears; Visine Tears; **Venez.:** Gentel; Optifresh.

Magnesium Silicate

E553(a); Silicato de magnesio.

CAS — 1343-88-0.

ATC — A02AA05.

ATC Vet — QA02AA05.

NOTE. The code E553(a) has also been applied to magnesium trisilicate.

Pharmacopoeias. In *Jpn.* Also in *USNF*.

USNF 26 (Magnesium Silicate). A compound of magnesium oxide and silicon dioxide. It contains not less than 15.0% of magnesium oxide and not less than 67.0% of silicon dioxide, calculated on the ignited basis. It is a fine, white, odourless powder, free from grittiness. Insoluble in water and in alcohol. It is readily decomposed by mineral acids. pH of a well-mixed 10% suspension in water is between 7.0 and 10.8.

Uses

Magnesium silicate is used in the food industry and in pharmaceutical manufacturing as an anticaking agent.

Preparations

Proprietary Preparations (details are given in Part 3)

Port.: Acnol Free.

Multi-ingredient: **Braz.:** Cutisanol; **Fr.:** ZeaSor; **Port.:** Mucaft.

Methylcellulose (*riINN*)

E461; Méthylcellulose; Methylcellulosum; Methylcellulosa; Metilcelulioz; Metilcellulóz; Metilcellulosa; Metylcellulosa; Metyloce-luloza; Metylcelluloosa.

Метилцеллюлоза

CAS — 9004-67-5.

ATC — A06AC06.

ATC Vet — QA06AC06.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.* and *US*. **Ph. Eur. 6.2** (Methylcellulose). A cellulose having some of the hydroxyl groups in the form of the methyl ether. Various grades of methylcellulose are available and are distinguished by appending a number indicating the apparent viscosity in millipascal seconds of a 2% w/w solution at 20°. It is a white, yellowish-white, or greyish-white powder or granules; hygroscopic after drying. Practically insoluble in hot water, in dehydrated alcohol, in acetone, and in toluene; dissolves in cold water, forming a colloidal solution. A 1% w/w solution in water has a pH of 5.0 to 8.0.

USP 31 (Methylcellulose). A methyl ether of cellulose. When dried at 105° for 2 hours, it contains 27.5 to 31.5% of methoxy groups. It is a white, fibrous powder or granules. It swells in water and produces a clear to opalescent, viscous, colloidal suspension; insoluble in alcohol, in chloroform, and in ether; soluble in glacial acetic acid and in a mixture of equal volumes of alcohol and chloroform. Its aqueous suspensions are neutral to litmus.

Incompatibility. Incompatibilities of methylcellulose have been reported with a number of compounds including chlorocresol, hydroxybenzoates, and phenol. Large amounts of electrolytes increase the viscosity of methylcellulose mucilages owing to salting-out of the methylcellulose; in very high concentrations of electrolytes, the methylcellulose may be completely precipitated.

Adverse Effects

Large quantities of methylcellulose may temporarily increase flatulence and distension and there is a risk of intestinal obstruction. Oesophageal obstruction may occur if compounds such as methylcellulose are swallowed dry.

Precautions

Methylcellulose and other bulk-forming agents should not be given to patients with intestinal obstruction or conditions likely to lead to intestinal obstruction. They should be taken with sufficient fluid to prevent faecal impaction or oesophageal obstruction, and should not be taken immediately before going to bed. Methylcellulose should not be used in infective bowel disease.

Interactions

Bulk laxatives such as methylcellulose lower the transit time through the gut and could affect the absorption of other drugs.

Uses and Administration

The various grades of methylcellulose are widely used in pharmaceutical manufacturing as emulsifying, suspending, and thickening agents and as binding, disintegrating, and coating agents in tablet manufacturing. Low-viscosity grades are preferred for use as emulsifying agents as the surface tension produced is lower than with the higher-viscosity grades. Low-viscosity grades may also be used as suspending or thickening agents for liquid oral dosage forms and solutions of methylcellulose may be used as replacements for sugar-based syrups or other suspension bases. For thickening topically applied products such as gels and creams a high-viscosity grade is usually used. In tablet technology low- or medium-viscosity grades are used as binding agents while high-viscosity grades act as tablet disintegrants by swelling on contact with the disintegration medium. For tablet coating, highly substituted low-viscosity grades are usually used. Methylcellulose may also be included in modified-release tablet formulations.

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

Methylcellulose is used clinically as a bulk-forming agent. Medium- or high-viscosity grades are used as bulk laxatives in the treatment of constipation (p.1693); by taking up moisture they increase the volume of the faeces and promote peristalsis. Methylcellulose is usually given in an oral dosage of up to 6 g daily in divided doses, taken with plenty of fluid. In the UK, the *BNFC* recommends a dose of 1 g twice daily for children aged from 7 to 12 years. Methylcellulose is also given in similar doses but with a minimum amount of water for the control of diarrhoea (p.1694) and for the control of faecal consistency in ostomies. It is also used in the management of diverticular disease (p.1695). Methylcellulose has also been used as an aid to appetite control in the management of obesity (p.2149) but there is little evidence of efficacy.

Solutions of high-viscosity grade methylcellulose (usually 0.5 to 1%) have been used as a vehicle for eye drops, as artificial tears, and in contact lens care, but hyromellose (above) is now generally preferred for this purpose.

Preparations

BP 2008: Methylcellulose Granules; Methylcellulose Tablets;

USP 31: Methylcellulose Ophthalmic Solution; Methylcellulose Oral Solution; Methylcellulose Tablets.

Proprietary Preparations (details are given in Part 3)

Austria: Bulk; **Fr.:** Dacryolamess; **Ir.:** Celevac; **Ital.:** Lacrimart; **Malaysia:** Methocel; **Spain:** Muciplasma; **UK:** Celevac; **USA:** Citrucel; Murocel.

Multi-ingredient: **Austral.:** Bioglan 3B Beer Belly Buster; Citri Slim+Trim; Le Trim-BM; Neo-Trim Fibre; Parachoc; Pro-Shape; **Braz.:** Kolanty; Kolanty DMP; **S.Afr.:** Kolanty; Medigel; Merasyn.

Pectin

E440 (amidated pectin or pectin); Pectina; Pektin.

CAS — 9000-69-5.

ATC — A07BC01.

ATC Vet — QA07BC01.

Pharmacopoeias. In *US*.

USP 31 (Pectin). A purified carbohydrate product obtained from the dilute acid extract of the inner portion of the rind of citrus fruits or from apple pomace; it consists mainly of partially methoxylated polygalacturonic acids. A yellowish-white, almost odourless, coarse or fine powder. Almost completely soluble in 1 in 20 of water, forming a viscous, opalescent, colloidal solution which flows readily and is acid to litmus; practically insoluble in alcohol or in diluted alcohol and in other organic solvents. It dissolves more readily in water if first moistened with alcohol, glycerol, or simple syrup, or if mixed with 3 or more parts of sucrose. Store in airtight containers.

Interactions

Bulk-forming agents such as dietary fibre lower the transit time through the gut and may affect the absorption of other drugs.

Lipid regulating drugs. Pectin, used as a source of fibre, with a lipid-lowering diet and *lovastatin*, has resulted in a paradoxical increase in low-density lipoprotein (LDL)-cholesterol in patients with hypercholesterolaemia. It was believed the pectin reduced the absorption of lovastatin from the gut.¹

1. Richter WO, *et al.* Interaction between fibre and lovastatin. *Lancet* 1991; 338: 706.

Uses and Administration

Pectins are used as emulsifiers and stabilisers in the food industry. They are non-starch polysaccharide constituents of dietary fibre (see under Dietary Role in Bran, p.1713).

Pectin is an adsorbent and bulk-forming agent and is present in multi-ingredient preparations for the management of diarrhoea, constipation, and obesity. Pectin has also been tried for reducing or slowing carbohydrate absorption in the dumping syndrome (p.1695).

Preparations

Proprietary Preparations (details are given in Part 3)

Braz.: Kaogel; **Fr.:** Arhemapectine Antihemorragique; Hydrocoll.

Multi-ingredient: **Arg.:** Bismuto con Pectina; Crema De Bismuto; Endomica; Mucobase; Opodert; **Austral.:** Betaine Digestive Aid; Bioglan 3B Beer Belly Buster; Bioglan Psylli-Mucil Plus; Bioglan Zellulean with Escin; Bis-Pectin; Citri Slim+Trim; Diarcalm; Diareze; Donnagel; Kaomagma with Pectin; Orabase; Orahesive; PC Regulax; Pro-Shape; Stomahesive; **Austria:** Diarhones; **Belg.:** Tanalene; **Braz.:** Atalint; Atapec; Enterobi-on; Kaomagma; Kaopectin; Parenterin; Sanadiant; **Canad.:** Orabase; Orahesive; Tegaserol; **Chile:** Enterol; Furazolidona; **Fr.:** Gelopectose; **Ger.:** Diarhones; Kaoprompt-H; **Gr.:** Kaopectate; **Hong Kong:** Enterocin Compound; Uni-Kaotin; **Indon.:** Andikap; Arcapac; Diagit; Entrogard; Kaopectate; Licopec; Neo Diaform; Neo Diastop; Neo Entrostop; Neo Kaocitin; Neo Kaolana; Neo Kaominal; Neo Koniform; **Ir.:** Kaopectate; Orabase; **Israel:** Kaopectin; Kapectin Forte; Orabase; **Ital.:** Cruscasohn; Streptomagma; **Malaysia:** Beakopectin; Kaopectate; **Mex.:** Ameban; Caopecfar; Colfur; Contefur; Corazul; Depofin; Dia-Par Compuesto; Diabacomp Compuesto; Estibal; Exofur; Facetin-D; Farpectol; Furoxona CP; Fuzoty; Hidromagma; Isocar; K-Omiston; Kaomycin; Kaopectate; Kapec-furan; Kediar; Lactopectin; Neokap; Neoxil; Olam; Optazol; Quimefuran; Suyodit; Tapzol con Neomycin; Treda; Trilor; Yodozona; **NZ:** Orabase; **Port.:** Cloranpectina; Varhesive; **S.Afr.:** Betapac; Bipectinol; Biskapac; Chloropect; Collodene; Enterolyte; Gastropect; Granuflex; Granugel; Kantrexil; Kao; Kaopectin; Kaostate; Orabase; Pectin-K; Pectrolyte; **Singapore:** Beakopectin; Kaopectate; **Spain:** Dextrice; Estrep-toenterol; **Switz.:** HEC; **Thai:** Biodan; Carbonpectate; Cenopec; Di-Su-Frone; Difuran; Disento PF; Furasin; Furopectin; Kaopactal; Med-Kafu-zone; **Turk.:** Streptomagma; **UAE:** Kaplin; **UK:** Goodpops; KLN; Orabase; Orahesive; Stomahesive; **USA:** K-C; Kao-Paverin; Kao-Spen; Kaodene Non-Narcotic; Surets Herbal; **Venez.:** Kaopcon; Kaopectate; Klincosak; Micyn-2; Mycin-2; Parepectolin; Pec-Kao; Sendafur; Strediazin c Atapul-guita; Streptomagma.

Polyethylene Oxide

Polietileno, óxido de.

Pharmacopoeias. In *USNF*.

USNF 26 (Polyethylene Oxide). A nonionic homopolymer of ethylene oxide, represented by the formula (OCH₂CH₂)_n, in which n represents the average number of oxyethylene groups (about 2000 to over 100 000). It is obtainable in several grades, varying in viscosity profile in an aqueous isopropyl alcohol solution. It may contain not more than 3% of silicon dioxide. A white to off-white powder. Miscible with water; freely soluble in ace-

tonitrile, in dichloromethane, in ethylene dichloride, and in trichloroethylene; insoluble in aliphatic hydrocarbons, in ethylene glycol, in diethylene glycol, and in glycerol. Store in airtight containers. Protect from light.

Uses

Polyethylene oxide is used as a tablet binder and as a suspending and thickening agent in pharmaceutical preparations. Polyethylene oxide has been used in hydrogel wound dressings.

Preparations

Polyvinyl Acetate

Poli(vinil-acetát); Polivinilacetatas; Poly(acétate de viny); Poly(vinylacetat); Polyvinyl-acetát; Polyvinyls Acetas; Poly(vinylis acetas); Poly(vinylisetaatti).

CAS — 9003-20-7.

Pharmacopoeias. In *Eur.* (see p.vii). *Eur.* also includes a 30% dispersion.

Ph. Eur. 6.2 (Poly(vinyl acetate)). A white or almost white powder or colourless granules or beads. Practically insoluble in water; soluble in alcohol; freely soluble in ethyl acetate. It is hygroscopic and swells in water. It softens at temperatures above 40° to 50°.

Ph. Eur. 6.2 (Poly(Vinyl Acetate) Dispersion 30 per cent). A dispersion in water of polyvinyl acetate having a mean relative molecular mass of about 450 000. It may contain povidone and a suitable surface-active agent, such as sodium laurilsulfate, as stabilisers.

An opaque, white or almost white, slightly viscous liquid. Miscible with water and with alcohol. It is sensitive to spoilage by microbial contaminants. Store at a temperature of 5° to 30°.

Polyvinyl Acetate Phthalate

Polivinilo, acetato ftalato de.

Pharmacopoeias. In *USNF*.

USNF 26 (Polyvinyl Acetate Phthalate). A reaction product of phthalic anhydride and a partially hydrolysed polyvinyl acetate. It contains 55.0 to 62.0% of phthalyl groups, calculated on an anhydrous acid-free basis. It is a free-flowing white powder that may have a slight odour of acetic acid. Insoluble in water, in chloroform, and in dichloromethane; soluble in alcohol and in methyl alcohol. Store in airtight containers.

Uses

Polyvinyl acetate phthalate is a viscosity-modifying agent that is used in the manufacture of enteric coating for tablets. Polyvinyl acetate is used in tablet coating; it is also widely used as a glue.

Polyvinyl Alcohol

Alcohol polivinílico; Alcohol Polyvinylus; Alkohol polivinylowy; Polivinil Alkol; Polivinil-alkohol; Polivinilo alkoholis; Poly(alcohol vinylicus); Poly(alcool vinylique); Polyvinylalkohol; Poly(vinylalkohol); Poly(vinylalkoholi).

CAS — 9002-89-5.

Pharmacopoeias. In *Eur.* (see p.vii) and *US*.

Ph. Eur. 6.2 (Poly(Vinyl Alcohol)). It is obtained by polymerisation of vinyl acetate followed by partial or complete hydrolysis of polyvinyl acetate in the presence of catalytic amounts of alkali or mineral acids. Various grades are available and they differ in their degree of polymerisation and their degree of hydrolysis, which determine the physical properties of the different grades. They are characterised by the viscosity and the ester value of the substance. The mean relative molecular mass lies between 20 000 and 150 000. The viscosity is 3 to 70 millipascal seconds. The ester value, which characterises the degree of hydrolysis, is not greater than 280.

Polyvinyl alcohol occurs as a yellowish-white powder or translucent granules. Soluble in water; slightly soluble in dehydrated alcohol; practically insoluble in acetone. A 4% solution in water has a pH of 4.5 to 6.5.

USP 31 (Polyvinyl Alcohol). A synthetic resin represented by the formula (CH₂CHOH)_n, where the average value of n is 500 to 5000. It is prepared by 85 to 89% hydrolysis of polyvinyl acetate. White to cream-coloured, odourless, granules or powder. Freely soluble in water at room temperature; solution may be effected more rapidly at somewhat higher temperatures. pH of a 4% solution in water is between 5.0 and 8.0.

Uses and Administration

Polyvinyl alcohol is a nonionic surfactant that is used in pharmaceutical manufacturing as a stabilising agent and as a viscosity-increasing agent and lubricant.

Polyvinyl alcohol has also been used in the preparation of jellies that dry rapidly when applied to the skin to form a soluble plastic film.

Polyvinyl alcohols of various grades are used for a wide variety of industrial applications.

Polyvinyl alcohol has been used to increase the viscosity of ophthalmic preparations thus prolonging contact of the active ingredient with the eye. It is included in artificial tears preparations

The symbol † denotes a preparation no longer actively marketed