Aqualarm; Civigel; Gel-Larmes; Lacrinorm; Lacryvisc; Liposic; Siccafluid; Ger.: Arufil C. Liposic; Liquigel; Siccapos; Thilo-Tears; Vidisic; Visc-Ophtal; Gr.: Dacrio Gel; Liposic; Tear dropst; Thilogel; Viscoter; Hong Kong: Lacryvisc; Liposic; Viscotears; Hung.: Oftagel; Viscoter; Hong Kong: Lacryvisc; Liposic; Viscotears; Ind.: Dacriogel; Droppel; Lacrigel; Lacrigel; Lacrinorm; Lipovisc; Siccafluid; Viscotirs; Molaysia: Vidisic; Mex.: Conforgel; Lacrinorm; Liposic; Siccafluid; Thilo-Tears; Vidisic; Norw.: Oftagel; Viscotears; NZ: Viscotears; Philipp.: Lacryvisc; Lipolin; Siccafluid; Vidisic; Pol.: Oftagel; Othpara, Vidisic; Port.: Lacryvisc; Lipolin; Siccafluid; Vidisic; Rus.: Oftagel; Othpara, Vidisic; Port.: Lacryvisc; Liposic; Siccafluid; Viscotears; Switz.: Lacrinorm; Lacryvisc; Siccafluid; Viscotears; Swed.: Oftagel; Viscotears; Switz.: Lacrinorm; Lacryvisc; Siccafluid; Viscotears; Thdi: Lacryvisc; Vidisic; Turk.: Lacryvisc; Siccapos; Thilo-Tears; Viscotears; UK: Gel Fears; Liposic; Liquivisc; Viscotears; Vernez.: Acrylarm; Lacryvisc; Siccafluid; Viscotears; UR: Gel Fears; Liposic; Liquivisc; Viscotears; Vernez.: Acrylarm; Lacryvisc; Siccafluid; Viscotears; Vernez.: Acrylarm; Lacryvisc; Siccafluid; Viscotears; Vernez.: Acrylarm; Lacryvisc; Siccafluid; Viscotears; Vernez.: Acrylarm; Lacryvisc; Genezal Moisturising: Chile:

Multi-ingredient: Arg.: Latlas; Austral.: Genteal Moisturising: Chile: Gelsolets; Cz.: Hypotears; Hong Kong: Clinac OC; Hypotears†; Indon.: Genteal; Oculotect; H.I.: Liposic; Ital.: Dropyal; Pol.: Oculotect; Port.: Hidratante VC; Switz.: Lacrycon; USA: Maxilube; Venez.: Genteal.

Carmellose (rINN)

Carboxymethylcellulose; Carmellosum; Carmelosa; CMC; E466. Кармеллоза

CAS = 9000-11-7

Pharmacopoeias. In Jpn.

Carmellose Calcium (rINNM)

Calcii Carmellosum; Calcium Carboxymethylcellulose; Carboxymethylcellulose Calcium; Carmellose calcique; Carmellosum calcicum; Carmellosum Calcium; Carmelosa cálcica; Karmeliozės kalcio druska; Karmelloosikalsium; Karmelloskalcium; Karmellóz-kalcium; Karmelosa vápenatá sůl.

Кальций Кармеллоза CAS = 90.50-0.4-8.

Pharmacopoeias. In Eur. (see p.vii) and Jpn. Also in USNF. Ph. Eur. 6.2 (Carmellose Calcium). A white or yellowish-white, hygroscopic powder. It swells in water to form a suspension; practically insoluble in alcohol, in acetone, and in toluene. Store in airtight containers.

USNF 26 (Carboxymethylcellulose Calcium). A white to yellowish-white, hygroscopic powder. It swells in water to form a suspension; practically insoluble in alcohol, in acetone, in chloroform, in ether, and in benzene, pH of a 1% suspension in water is between 4.5 and 6.0. Store in airtight containers.

Carmellose Sodium (BAN, rINNM)

Carboxymethylcellulose Sodium; Carboxymethylcellulosum Natricum; Carmellose sodique; Carmellosum natricum; Carmelosa sódica; Cellulose Gum; E466; Karmeliozės natrio druska; Karmelloosinatrium; Karmellosnatrium; Karmellóz-nátrium; Karmelosa sodná sůl; Karmeloza sodowa; Natrii Carmellosum; SCMC; Sodium Carboxymethylcellulose; Sodium Cellulose Glycollate.

Натрий Кармеллоза CAS - 9004-32-4.

Pharmacopoeias. In Eur. (see p.vii), Int., Jpn, and US. Eur. and USNF also include low-substituted carmellose sodium. USNF also includes Carboxymethylcellulose Sodium 12. Eur also includes a mixture of microcrystalline cellulose with

carmellose sodium.

Ph. Eur. 6.2 (Carmellose Sodium). A white or almost white, hygroscopic granular powder. It has a sodium content of 6.5 to 10.8% calculated on the dry substance. Easily dispersed in water forming colloidal solutions; practically insoluble in dehydrated alcohol, in acetone, in ether, and in toluene. A 1% colloidal solution in water has a pH of 6.0 to 8.0.

Ph. Eur. 6.2 (Carmellose Sodium, Low-substituted; Carmellosum Natricum, Substitutum Humile). It contains not less than 2.0% and not more than 4.5% of sodium, calculated with reference to the dried substance. A white or almost white powder or short fibres. It swells in water to form a gel; practically insoluble in dehydrated alcohol, in acetone, and in toluene. A 1% suspension in water has a pH of 6.0 to 8.5.

Ph. Eur. 6.2 (Microcrystalline Cellulose and Carmellose Sodium). A colloid-forming, powdered mixture of microcrystalline cellulose with 5 to 22% of carmellose sodium. It contains 75 to 125% of the nominal amount of carmellose sodium, calculated with reference to the dried substance. A white or off-white, coarse or fine powder. Dispersible in water producing a white, opaque colloidal dispersion; practically insoluble in organic solvents and in dilute acids. pH of a 2% dispersion in water is 6 to 8. USP 31 (Carboxymethylcellulose Sodium). A white to creamcoloured, hygroscopic powder or granules. It contains not less than 6.5% and not more than 9.5% of sodium, calculated on the dried basis. Easily dispersed in water to form colloidal solutions; insoluble in alcohol, in ether, and in most other organic solvents. pH of a 1% solution in water is between 6.5 and 8.5. Store in airtight containers.

USNF 26 (Low-Substituted Carboxymethylcellulose Sodium). It has a sodium content of 2.0 to 4.5%, calculated on the dried basis. A white or almost white powder or short fibres. Practically insoluble in alcohol, in acetone, and in toluene. It swells in water

to form a gel. pH of a 1% suspension in water is between 6.0 and 8.5. Store in airtight containers

USNF 26 (Carboxymethylcellulose Sodium 12). A colourless or white to off-white, odourless, powder or granules. Water solubility depends on degree of substitution (easily dispersed in water at all temperatures, forming a clear, colloidal solution). Insoluble in alcohol, in acetone, in ether, and in toluene. It has a sodium content of 10.4 to 12.0%, calculated on the dry substance. Store in airtight containers.

Incompatibility. Incompatibilities of carmellose sodium have been reported with strongly acidic solutions, with soluble salts of iron and some other metals, and with xanthan gum.

Croscarmellose Sodium (USAN)

Carmellosum natricum conexum; Croscarmellose sodique; Croscarmelosa sódica; Crosslinked Carboxymethylcellulose Sodium; E468; Kroskarmeliozės natrio druska; Kroskarmelloosi natrium; Kroskarmellosnatrium; Kroskarmelosa sodná sůl; Kroskarmeloza sodowa; Kroszkarmellóz-nátrium; Modified Cellulose Gum.

Pharmacopoeias. In Eur. (see p.vii) and Jpn. Also in USNF. Ph. Eur. 6.2 (Croscarmellose Sodium). A cross-linked polymer of carmellose sodium. A white or greyish-white powder. Practically insoluble in dehydrated alcohol, in acetone, and in toluene. A 1% suspension in water has a pH of 5.0 to 7.0.

USNF 26 (Croscarmellose Sodium). The sodium salt of a crosslinked partly O-(carboxymethylated) cellulose. A white, freeflowing powder. Partially soluble in water; insoluble in alcohol, in ether, and in other organic solvents. pH of a dispersion containing 1 g mixed with 100 mL of water for 5 minutes is between 5.0 and 7.0.

Uses and Administration

Carmellose calcium and carmellose sodium have a variety of pharmaceutical uses, including use as suspending, thickening, and emulsifying agents, and as disintegrants, binders, and coating agents in tablets. Carmellose sodium is also used as an emulsifier or stabiliser in the food industry. Croscarmellose sodium is used as a tablet disintegrant

Carmellose sodium is used topically as an ingredient of protective preparations for stoma care, in the management of wounds, and for the mechanical protection of oral and perioral lesions, such as mouth ulceration (p.1700). It is also used, in concentrations of up to 1%, in artificial saliva preparations for the treatment of dry mouth (p.2140), and in eye drops for the management of dry eye (p.2140).

Carmellose sodium given orally absorbs water and acts as a bulkforming agent; the volume of faeces is increased and peristalsis promoted. It is used in the treatment of constipation (p.1693). Carmellose sodium has been included in preparations to control appetite in the management of obesity (p.2149) but there is little evidence of efficacy. For precautions to be observed with bulkforming agents, see under Methylcellulose, p.2145.

Preparations

BP 2008: Carmellose Sodium Eye Drops; USP 31: Carboxymethylcellulose Sodium Paste; Carboxymethylcellulose Sodium Tablets.

Proprietary Preparations (details are given in Part 3)

Proprietary Preparations (details are given in Part 3)

Arg.: Aqua Lent Lagrima†, Aqua Lent Lubricante; Aquacel; Aucic; Cellufresh; Celluvisc†; Comfeel; Comfeel Plus Transparente; Natura Fresh; NuDerm Hidrocoloide; Refresh Liquigel; Refresh Tears; Austral: Aquacel†,
Cellufresh; Celluvisc, Refresh Liquigel; Refresh Tears Plus†, Austral: Celluvisc; Belg.: Gelilact; Braz.: Cellufresh; Ecoflim; Fresh Tears; Lacrifim; Sallvan;
Canad: Aquacel†; Refresh Celluvisc; Refresh Liquigel; Refresh Plus; Refresh Fars; Calcufluid; Demm.: Celluvisc; Fin: Celluvisc; Fin: Aquacel; Askina Biofilm†; Biatain; Celluvisc; Clip Ampoules; Clip Brulures; Comfeel; Hydrocoll; Physiotulle; Sureskin; Urgomed; Urgotul; Ger.: Algoplaque; Alione; Cellufresh; Celluvisc; Celluvisc; Comfeel Plus Transparenter; Physiotulle; Urgotul; Gr.: Celluficid; Celluvisc; Hong Kong: Refresh; In.: Celluvisc; Israel: Refresh Tears; Ital.: Cellufresh; Celluvisc; Lacrilens; Malaysia: Refresh Plus†; Refresh Tears; Mex.: Cellu Celluvisc, Larcinens, Malaysia: Refresh Plust; Refresh Tears; Mex.: Celluvisc; Novafix Ultra Fuerte; Refresh Liquigel; Refresh Tears; Mex.: Celluvisc; Novafix Ultra Fuerte; Refresh Liquigel; Refresh Tears Thera Tears; Neth.: Celluvisc; NZ: Cellufresh; Celluvisc; Refresh Tears Plus; Philipps: Cellufresh; Celluvisc; Cornfeet; Askina Biofilm†; Celluvisc; Celluvisc; Cornfeet; Refresh Liquigel; Refresh Tears; Singopore: Cellufresh; Celluvisc; Kefresh Tears; Spain: Cellufresh; Celluvisc; Kescofissh; Celluvisc; Switz.: Celluflicit; Celluvisc; Thai.: Celluvisc; Cornfeet; Celluv fresh; Celluvisc; **UK:** Celluvisc; Comfeel; Intrasite; Physiotulle; **USA:** Celluvisc; Clear Eyes for Dry Eyes; Optive; Refresh Plus; Refresh Tears; Tears Again; TheraTears; **Yenez.:** Refresh Liquigel; Refresh Tears.

Again; TheraTears; Venez.: Refresh Liquigel; Refresh Tears.

Multi-ingredient: Arg.: Comfeel Plus; Comfeel Purilon; Comfeel SeaSorb; Humectante Bucal; Mucobase; Purilon; Razagleda Plus; Seasorb;
Austral.: Aquae; Orabase; Orahesive; Sološite; Stomahesive; Austria:
Glandosane; Sialin; Braz.: Chofranina; Canad.: Appedrine; Carboflex;
Orabase; Orahesive; Salivart; Tegasorb; Chile: Delgadol Fibra; K.C.M.C.;
Novafix Extra Fuerte; Reducform-F. Salivart; Cz.: Alginete; Spofax; Fr.:
Altreet Ag, Arniva; Aquacal Ag, Artisiai, Askina Sorb; Batain Argent; Cellosorb; Clip Hemo; Intrasite; Melgisorb; Purilon; Release Ag; Seasorb; Urgosorb; Urgotul S.Ag, Ger.: Cellosorb; Comfeel Plus; Glandosane; LaryPhary; Nu-Gel; Purilon; Recatol Algin; SeaSorb Soft; Hong Kong: Aquae;
Glandosane; Salivart; India: Digene; Int.: Orabase; Israel: Orabase; Ital.:
Laxvita; Switz.: Glandosane; Stomahesive; Port.: Askina Sorb; Carbase; Spain:
Laxvita; Switz.: Glandosane; Thal.: Bisolax; Emulay; Glandosane; Ukcane; Ukcane Pretts Diet Aid; Salivart; Seprafilm; Surgel; Venez.: Klincosal; Novafix; Polan-

Carrageenan

Carrageenanum; Carrageenin; Carragenina; Carraghénanes; Carraghénates; Chondrus Extract; E407; Irish Moss Extract. CAS — 9000-07-1 (carrageenan); IIII4-20-8 (κ -carrageenan); 9064-57-7 (λ -carrageenan).

Pharmacopoeias. In Fr. Also in USNF.

USNF 26 (Carrageenan). The hydrocolloid obtained by extraction with water or aqueous alkali from some members of the class Rhodophyceae (red seaweeds). It consists chiefly of a mixture of the ammonium, calcium, magnesium, potassium, and sodium sulfate esters of galactose and 3,6-anhydrogalactose copolymers. The prevalent copolymers in the hydrocolloids are kcarrageenan, ι-carrageenan, and λ-carrageenan.

A yellowish or tan to white, coarse to fine, practically odourless, powder. Soluble in water at 80° forming a viscous, clear or slightly opalescent solution that flows readily. It disperses more readily in water if first moistened with alcohol, with glycerol, or with a saturated solution of glucose in water. Store in airtight containers at a temperature of 8° to 15°.

Uses and Administration

Carrageenan is used in pharmaceutical manufacturing and the food industry as a suspending and gelling agent.

It has been used as a bulk-forming laxative to treat constipation; for precautions to be observed with bulk-forming laxatives, see under Methylcellulose, p.2145. Carrageenan is also included in topical preparations for the symptomatic relief of anorectal disorders. A gel containing carrageenan has been investigated as a topical microbicide.

A degraded form of carrageenan was formerly used in gastrointestinal disorders but it was associated with lesions in animals and is no longer used.

Irish moss (Chondrus crispus), a source of carrageenan, is used in herbal medicine.

 \Diamond Refined non-degraded carrageenan and furcellaran, a similar extract from Rhodophyceae that is included in the specifications for food-grade carrageenan, have generally been considered safe for use as food additives, although this may not be the case with degraded and 'semi-refined' forms.1 However, in the UK the Food Advisory Committee has recommended that carrageenan should not be permitted as an additive for infant formulas because of the possibility of immunological consequences after absorption from the immature gut.² Carrageenans affect the immune system of experimental animals after parenteral or oral use, and small amounts of food-grade carrageenan cross the intestinal epithelium in rats and are taken up by gut-associated lymphoid tissue.3

- FAO/WHO. Evaluation of certain food additives and contami-nants: twenty-eighth report of the joint FAO/WHO expert com-mittee on food additives. WHO Tech Rep Ser 710 1984.
- MAFF. Food Advisory Committee: report on the review of the use of additives in foods specially prepared for infants and young children. FdAC/REP/12. London: HMSO, 1992.
- MAFF. Food Advisory Committee: report on the review of the emulsifiers and stabilisers in food regulations. FdAC/REP/11. London: HMSO, 1992.

Proprietary Preparations (details are given in Part 3) Austria: Coreine

Multi-ingredient: Austral.: Bonningtons Irish Moss; Austria: Anoreine; Anoreine mit Lidocain; Cz.: Titanoreine†; Fr.: Anoreine; Titanoreine; Titanoreine Lidocaine; Ger.: Saseem; Ital.: Resource Gelificata; NZ: Bonningtons Irish Moss; Pol.: Tytanoreina†; Spain: Titanorein; Switz.: Flogecyl; Titanoreine†; UK: Fam-Lax Senna.

Cellacefate (BAN, rINN)

CAP; Celacefát; Celacefat; Celacefato; Celiuliozès acetatas-ftalatas; Cellacéfate; Cellacefatum; Cellacephate; Cellulosaacetatftalat; Cellulose, acétate phtalate de; Cellulose Acetate Phthalate; Cel-Iulosi acetas phthalas: Cellulosum Acetylphthalicum: Cellulózacetát-ftalát; Celophthalum; Selluloosa-asetaattiftalaatti.

Целлацефат

CAS — 9004-38-0.

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

Ph. Eur. 6.2 (Cellulose Acetate Phthalate: Cellacefate BP 2008) Cellulose in which some of the hydroxyl groups are acetylated (21.5 to 26.0%) and some are phthalylated (30.0 to 36.0%), both calculated with reference to the anhydrous, acid-free substance. A hygroscopic, white or almost white, free-flowing powder or colourless flakes. Practically insoluble in water, in dehydrated alcohol, and in dichloromethane; freely soluble in acetone; soluble in diethylene glycol; it dissolves in dilute solutions of alkalis. Store in airtight containers.

USNF 26 (Cellacefate). A reaction product of phthalic anhydride and a partial acetate ester of cellulose. It contains 21.5 to 26.0% of acetyl groups, and 30.0 to 36.0% of phthalyl(o-car-

boxy-benzoyl) groups, calculated on the anhydrous, acid-free basis. A white, free-flowing powder that may have a slight odour of acetic acid. Insoluble in water and in alcohol; soluble in acetone and in dioxan. Store in airtight containers.

Uses

Cellacefate is unaffected by immersion in acid media in the stomach but softens and swells in intestinal fluid. It is used in pharmaceutical manufacturing as an enteric-coating material for tablets and capsules, usually with a plasticiser. Films of cellacefate are reported to be permeable to some ionic substances such as ammonium chloride and potassium iodide, and such substances require a sealing coat.

Cellulose

Celulosa.

Description. Cellulose is an unbranched polysaccharide poly mer consisting of 1,4-β-linked glucopyranose units. It is the chief constituent of fibrous plant material.

Dispersible Cellulose (BAN)

Cellulose microcristalline et carmellose sodique; Cellulosum microcristallinum et carmellosum natricum; Celulosa dispersable; Microcrystalline Cellulose and Carboxymethylcellulose Sodium; Microcrystalline Cellulose and Carmellose Sodium.

Pharmacopoeias. In Br. Also in USNF.

BP 2008 (Dispersible Cellulose). An odourless or almost odourless, white or off-white, coarse or fine powder consisting of a colloid-forming attrited mixture of microcrystalline cellulose and carmellose sodium. Disperses in water to produce a white, opaque dispersion or gel; practically insoluble in organic solvents and in dilute acids. Store at a temperature between 8° and

USNF 26(Microcrystalline Cellulose and Carboxymethylcellulose Sodium). A colloid-forming, attrited mixture of microcrystalline cellulose and carmellose sodium. A white to off-white, odourless, coarse to fine, powder. It swells in water, producing, when dispersed, a white, opaque dispersion or gel; insoluble in organic solvents and in dilute acids. Store in airtight containers in a dry place, and at a temperature not exceeding 40°.

Microcrystalline Cellulose

Celiuliozė, mikrokristalinė; Cellulosa Microgranulare; Cellulosa, mikrokristallin; Cellulose Gel; Cellulose microcristalline; Cellulosum microcristallinum; Cellulosum Microcrystallinum; Cellulosum Microristallinum; Celulosa microcristalina; Celulosa mikrokrystalická; Celuloza mikrokrystaliczna; Crystalline Cellulose; E460; Mikrokristályos cellulóz; Selluloosa, mikrokiteinen. CAS - 9004-34-6.

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

Eur also includes a mixture of microcrystalline cellulose with carmellose sodium.

Ph. Eur. 6.2 (Cellulose, Microcrystalline). A purified, partly depolymerised cellulose, prepared by treating alpha-cellulose, obtained as a pulp from fibrous plant materials, with mineral acids. It is a white or almost white, fine or granular powder, Practically insoluble in water, in dehydrated alcohol, in acetone, in toluene, in dilute acids, and in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid obtained from a 12.5% mixture in water after 20 minutes of shaking is 5.0 to 7.5.

Ph. Eur. 6.2 (Microcrystalline Cellulose and Carmellose Sodium). A colloid-forming, powdered mixture of microcrystalline cellulose with 5 to 22% of carmellose sodium. It contains 75 to 125% of the nominal amount of carmellose sodium, calculated with reference to the dried substance. A white or off-white, coarse or fine powder. Dispersible in water producing a white, opaque colloidal dispersion; practically insoluble in organic solvents and in dilute acids. pH of a 2% dispersion in water is 6 to 8. USNF 26 (Microcrystalline Cellulose). A purified, partially depolymerised cellulose, prepared by treating alpha-cellulose, obtained as a pulp from fibrous plant material, with mineral acids. It is a fine, white or almost white powder consisting of free-flowing, nonfibrous particles. Insoluble in water, in dilute acids, and in most organic solvents; practically insoluble in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid obtained from a 12.5% mixture in water after 20 minutes of shaking is between 5.0 and 7.5. Store in airtight containers.

Powdered Cellulose

Celiuliozės milteliai; Cellulosapulver; Cellulose en poudre; Cellulose Powder; Cellulosi pulvis; Cellulózpor; Celulosa en polvo; Celulosový prášek; E460; Selluloosajauhe

Pharmacopoeias. In Eur. (see p.vii) and Jpn. Also in USNF. Ph. Eur. 6.2 (Cellulose, Powdered). A purified mechanically disintegrated cellulose prepared from alpha-cellulose obtained as a pulp from fibrous plant materials. It is a white or almost white, fine or granular powder. Practically insoluble in water, in dehydrated alcohol, in acetone, in toluene, in most organic solvents, and in dilute acids; slightly soluble in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid of an 11.1% mixture in water is between 5.0 and 7.5 one hour after preparation.

USNF 26 (Powdered Cellulose). A purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from fibrous plant materials. It is a white or almost white powder. Exhibits degrees of fineness ranging from a free-flowing, dense powder to a coarse, fluffy, nonflowing material. Insoluble in water, in nearly all organic solvents, and in dilute acids; slightly soluble in sodium hydroxide solution (1 in 20). The pH of the supernatant liquid of an 11.1% mixture in water is between 5.0 and 7.5 one hour after preparation. Store in airtight containers.

Uses and Administration

Powdered cellulose and microcrystalline cellulose are used in pharmaceutical manufacturing as tablet binders and disintegrants and as capsule and tablet diluents. These two forms of cellulose are also used in the food industry. Dispersible cellulose (which also contains some carmellose sodium) forms a thixotropic gel with water and is used pharmaceutically as a suspending and thickening agent.

Various forms of cellulose have been included in preparations used in the management of constipation and obesity. Cellulose is also used in adsorbent powder preparations used for skin disorders including hyperhidrosis.

Preparations

Proprietary Preparations (details are given in Part 3) *Ital.*: Fibrasan; **UK**: Nasaleze; Sterigel; **USA**: Unifiber.

Multi-ingredient: Arg.: Usar Fibras†; ZeaSorb; Austral.: ZeaSorb; Candd.: ZeaSorb; Chile: ZeaSorb†; Cz.: Systogen†; Fr.: Gelopectose; Hydroclean; ZeaSorb; Irl.: ZeaSorb; Israel: Celluspan; Thai.: ZeaSorb; UK:

Ceratonia

Carob Bean Gum; Carob Gum; Cerat.; Ceratonia Gum; E410; Goma de garrofín; Gomme de Caroube; Guma z nasion Carobe; Locust Bean Gum.

CAS — 9000-40-2. ATC — A07XA02. ATC Vet — QA07XA02.

Uses

Ceratonia consists of the endosperms separated from the seeds of the locust bean tree, Ceratonia siliqua (Leguminosae). It is used as a thickening agent and stabiliser in the food industry.

Preparations

Proprietary Preparations (details are given in Part 3) Austria: Arobon; Irl.: Carobel; Ital.: Arobon; Switz.: Nestargel; UK: Carobel; Nestargel.

Multi-ingredient: Austria: China-Eisenwein; Belg.: Kestomatine Baby†; Fr.: Gumilk; Indon.: Polysilane; Switz.: Kestomatine Bebet.

Dextrates (USAN)

CAS - 39404-33-6.

Pharmacopoeias. In USNF.

USNF 26 (Dextrates). A purified, anhydrous or hydrated, mixture of saccharides obtained by the controlled enzymatic hydrolysis of starch. Free-flowing, porous, white, odourless, spherical granules consisting of aggregates of microcrystals. Freely soluble in water (heating increases its solubility in water); soluble in dilute acids and alkalis and in basic organic solvents such as pyridine; insoluble in the common organic solvents. pH of a 20% solution in water is between 3.8 and 5.8. Store in a dry place at a temperature of 8° to 15°.

Uses

Dextrates is used as a capsule and tablet diluent and as a tablet binding agent.

Ethylcellulose (rINN)

Cellulose Ethyl Ether; E462; Éthylcellulose; Ethylcellulosum; Ethylcelulosa; Etilceliuliozė; Etilcellulóz; Etilcelulosa; Etylcellulosa; Etyyliselluloosa. Этилцеллюлоза

CAS — 9004-57-3.

Pharmacopoeias. In Chin., Eur. (see p.vii), and Int. Also in

 $\textbf{Ph. Eur. 6.2} \ (\textbf{Ethylcellulose}). \ A \ partly \ \textit{O-ethylated cellulose}. \ It$ contains 44 to 51% of ethoxy (-OC₂H₅) groups, calculated on the dried basis. A white to vellowish-white, odourless or almost odourless, powder or granular powder. Solutions of ethylcellulose may show a slight opalescence. Practically insoluble in water, in glycerol (85%), and in propylene glycol; soluble in dichloromethane and in a mixture of 20 parts alcohol and 80 parts toluene (w/w); slightly soluble in ethyl acetate and methyl alco-

USNF 26 (Ethylcellulose). A partly O-ethylated cellulose. It contains 44.0 to 51.0% of ethoxy groups, calculated with reference to the dried substance. A free-flowing white to light tan powder. Its aqueous suspensions are neutral to litmus. Insoluble in water, in glycerol, and in propylene glycol. Ethylcellulose containing less than 46.5% of ethoxy groups is freely soluble in chloroform, in methyl acetate, in tetrahydrofuran, and in mixtures of aromatic hydrocarbons with alcohol; ethylcellulose containing 46.5% or more of ethoxy groups is freely soluble in alcohol, in chloroform, in ethyl acetate, in methyl alcohol, and in toluene.

Ethylcellulose is used as a binder in tablets and as a coating material for tablets, granules, and microcapsules. It is also used as a

Preparations

USNF 26: Ethylcellulose Aqueous Dispersion.

Gastric Mucin (BAN)

Mucina gástrica.

Uses and Administration

Gastric mucin is a high-molecular-weight glycoprotein precipitated by alcohol (60%) after digestion of hogs' stomach linings by pepsin and hydrochloric acid. It is used in artificial saliva formulations for dry mouth (p.2140) as an oral spray containing 3.5% or as lozenges.

Preparations

Proprietary Preparations (details are given in Part 3) Ger.: Saliva medac; Neth.: Saliva Orthana.

Multi-ingredient: UK: Saliva Orthana.

Hyetellose (INN)

Hidroksietilceliuliozė; Hidroxietilcellulóz; Hidroxietilcelulosa; Hydroksietyyliselluloosa; Hydroksyetyloceluloza; Hydroxietylcellulosa; Hydroxyethyl Cellulose; Hydroxyéthylcellulose; Hydroxyethylcellulose; Hydroxyethylcellulosum; Hyétellose; Hyetellosum: Hvetelosa.

Гиетэллоза

CAS - 9004-62-0.

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

Pharmacopoeias. In Eur. (see p.vii) and Int. Also in USNF. **Ph. Eur. 6.2** (Hydroxyethylcellulose). A partially substituted 2-hydroxyethyl ether of cellulose. Various grades are available and are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% solution measured at 25°. A white, yellowish-white, or greyish-white, powder or granules. Soluble in cold or hot water, forming colloidal solutions; practically insoluble in alcohol, in acetone, and in toluene. A 1%

solution in water has a pH of 5.5 to 8.5. USNF 26 (Hydroxyethyl Cellulose). A partially substituted poly(hydroxyethyl) ether of cellulose. It is available in several grades, varying in viscosity and degree of substitution, and some grades are modified to improve their dispersion in water. It may contain suitable anticaking agents. A white to light tan, practically odourless, hygroscopic, powder. Soluble in cold or hot water, giving a colloidal solution; practically insoluble in alcohol and in most organic solvents, pH of a 1% solution in water is between 6.0 and 8.5

Uses and Administration

Hyetellose is used in pharmaceutical manufacturing as a thickener and stabiliser and as a tablet coating and binding agent. It is present in lubricant preparations for dry eye (p.2140), contact lens care (p.1622), and dry mouth (p.2140).

Preparations

Proprietary Preparations (details are given in Part 3) Austral.: Rohto Zi Contact†; Ger.: Lacrigel; Israel: V-Tears; USA: Comfort

ars; Gonioscopic; TearGard. Multi-ingredient: Arg.: Hidratage!; Austral.: Minims Artificial Tears†; Fr.: Premicia; Ger.: Lubrikano; Nu-Gel†; Irl.: Minims Artificial Tears; Israel: V-Crima; Turk.: Gleitgelen; UK: Minims Artificial Tears; USA: Biotene with

HEMC; Hidroxietilmetilcelulosa; Hydroxyethyl Methylcellulose; Hydroxyethylmethylcellulose: Hymétellose: Hymetellosum: Methylhydroxyethylcellulose; Méthylhydroxyéthylcellulose; Methylhydroxyethylcellulosum; Metilhidroksietilceliuliozė; Metilhidroxietilcellulóz; Metylhydroxietylcellulosa; Metyylihydroksietyyliselluloosa.

Гимэтеллоза

CAS = 9032-42-2

Hymetellose (rINN)

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

Ph. Eur. 6.2 (Methylhydroxyethylcellulose; Hydroxyethylmethylcellulose BP 2008). A partially substituted ether of cellulose containing methoxyl and 2-hydroxyethyl groups. Various grades are available and are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds of a 2% w/w