

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

Cellacéfate 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 cellacéfate are reported to be permeable to some ionic substances such as ammonium chloride and potassium iodide, and such substances require a sealing coat.

## Cellulose

Cellulosa.

**Description.** Cellulose is an unbranched polysaccharide polymer consisting of 1,4- $\beta$ -linked glucopyranose units. It is the chief constituent of fibrous plant material.

### Dispersible Cellulose (BAN)

Cellulose microcristalline et carmellose sodique; Cellulosum microcristallinum et carmellose natricum; Celulosa dispersable; Microcristalline Cellulose and Carboxymethylcellulose Sodium; Microcristalline 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 microcristalline 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 15°.

**USNF 26** (Microcristalline Cellulose and Carboxymethylcellulose Sodium). A colloid-forming, attrited mixture of microcristalline 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°.

### Microcristalline Cellulose

Celuliozè, mikrokristalinè; Cellulosa Microgranulare; Cellulosa, mikrokristallin; Cellulose Gel; Cellulose microcristalline; Cellulosum microcristallinum; Cellulosum microcristallinum; Cellulosum Microristallinum; Celulosa microcristalina; Celulosa mikrokristalica; Celuloza mikrokristaliczna; 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 microcristalline cellulose with carmellose sodium.

**Ph. Eur. 6.2** (Cellulose, Microcristalline). 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** (Microcristalline Cellulose and Carmellose Sodium). A colloid-forming, powdered mixture of microcristalline 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** (Microcristalline 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

Celuliozès miltellai; Cellulosapulver; Cellulose en poudre; Cellulose Powder; Cellulosi pulvis; Cellulózpor; Celulosa en polvo; Celulosový prášek; E460; Selluloosajahu.

**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 microcristalline 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; Stengel; **USA:** Unifiber.

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

## Ceratonia

Carob Bean Gum; Carob Gum; Cerat; Ceratonia Gum; E410; Goma de garrofin; 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.:** Nestagel; **UK:** Carobel; Nestagel.

**Multi-ingredient:** **Austria:** China-Eisenwein; **Belg.:** Kestomatine Baby†; **Fr.:** Gumik; **Indon.:** Polysilane; **Switz.:** Kestomatine Bebe†.

## Dextrates (USAN)

Dextratos.

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; Ethylcellulosa; Etilceluliozè; Etilcellulóz; Etilcellulosa; Etylcellulosa; Etyliselluloosa.

ЭТИЛЦЕЛЛЮЛОЗА

CAS — 9004-57-3.

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

**Ph. Eur. 6.2** (Ethylcellulose). A partly *O*-ethylated cellulose. It contains 44 to 51% of ethoxy (–OC<sub>2</sub>H<sub>5</sub>) groups, calculated on the dried basis. A white to yellowish-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 alcohol.

**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.

### Uses

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

### 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 medic; **Neth.:** Saliva Orthana.

**Multi-ingredient:** **UK:** Saliva Orthana.

## Hyetellose (rINN)

Hidroksietilceluliozè; Hidroksietilcellulóz; Hidroksietilcellulosa; Hidroksietyliselluloosa; Hidroksyetylcelluloza; Hydroxyethylcellulosa; Hydroxyethyl Cellulose; Hydroxyethylcellulose; Hydroxyethylcellulose; Hydroxyethylcellulosum; Hyétellose; Hyetellosum; Hyetelloza.

ГИЕТАЛЛОЗА

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** (Hydroxyethyl Cellulose). 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 Tears; Gonioscopic; TearGard.

**Multi-ingredient:** **Arg.:** Hidratagel; **Austral.:** Minims Artificial Tears†; **Fr.:** Premicia; **Ger.:** Lubrikano; Nu-Gel†; **Irl.:** Minims Artificial Tears; **Israel:** V-Crma; **Turk.:** Gleitgelin; **UK:** Minims Artificial Tears; **USA:** Biotene with Calcium; Optimoist.

## Hymetellose (rINN)

HEMC; Hidroksietilmetilcellulosa; Hydroxyethyl Methylcellulose; Hydroxyethylmethylcellulose; Hymétellose; Hymetellosum; Méthylhydroxyéthylcellulose; Méthylhydroxyethylcellulose; Methylhydroxyethylcellulosum; Metilhidroksietilceluliozè; Metilhidroksietilcellulóz; Methylhydroxyethylcellulosa; Methylhydroksyetyliselluloosa.

ГИМЭТЕЛЛОЗА

CAS — 9032-42-2.

**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