







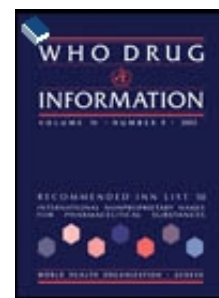


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Naming of excipients: future challenges

Paper prepared for the <INN Expert Group discussion by Professor Witold Wieniawski, Polish Pharmacopoeia Commission, Warsaw and Dr Wai Keung Chui, Department of Pharmacy, National University of Singapore.

Activities of the INN Programme have focused on selecting names for active pharmaceutical substances used in human and veterinary medicine while expanding only incidentally to other types of substances and products used directly or indirectly for health purposes. The rules governing the allocation of INNs are specifically adapted to indicate the therapeutic activity of a single substance and these rules may not be appropriate for naming of other types of products. However, over the years, the success of the Programme has led to requests for expansion into other areas, especially in cases where divergence in naming practices creates difficulties for international cooperation. One possible area highlighted for expansion is the naming of excipients.

At present, the naming of excipients is carried out with regard to chemical composition. Existing approaches to assigning names may include trivial (traditional) names, systematic chemical (IUPAC) names, or International Nonproprietary Names (INNs). Options available for the selection of excipient names include one-word names with syllables indicating specific properties of the substance, or an alphanumeric system.

The International Pharmaceutical Excipients Council (IPEC) has defined pharmaceutical excipients as any substance, other than the pharmacologically active ingredient, that has been appropriately evaluated for safety and is included in a drug delivery system to:

- (i) facilitate the process of manufacturing of the medicinal product;
- (ii) protect, support or enhance the stability and bioavailability of the active ingredient;
- (iii) aid in the identification of the finished product;
- (iv) enhance any other attribute of the overall safety and efficacy of the medicinal product during storage or use.

The INN Programme has already named those pharmaceutical substances that may serve a dual purpose as excipients or as pharmacologically active ingredients. INNs have also been assigned to a few specific groups of polymeric excipients such as cellulose derivatives, macrogols, macrogol esters, sorbitan esters, macrogol-sorbitan-fatty acid polymers, polysiloxanes, and poloxamers.

A considerable number of inorganic or simple organic substances are used as excipients. They are usually designated by short systematic names established according to the rules of the International Union of Pure and

Applied Chemistry (IUPAC) or by traditional (trivial) names. The same applies to many excipients of plant or mineral origin designated by traditional names. In the case of active substances, the INN Programme avoids a formal recognition of such names, especially if they were in use before the INN Programme came into being. The adoption of such names (or their modified versions) occurs only when there are compelling reasons for such an action. This is done, for example, when the systematic name is considered too long or requires the use of locants or stereodesignators for proper identification of the substance. A comparable situation exists in the case of excipients. If the INN Programme is expanded to include this group of products, it will be necessary to decide whether to adopt a similar policy.

Groups of excipients

The repertoire of excipients available for the manufacture of different dosage forms may be broadly divided into either inorganic or organic substances. The table set out on pages 298-307 gives a brief description of each excipient category and use.

When considering the establishment of a system for naming excipients several approaches may be taken into account. Until now, the INN programme has used the same approach for excipients as that used for selecting INNs for active pharmaceutical substances, i.e. a single word to designate a substance or a group of substances. When a group name is given, the word is usually followed by an Arabic number to describe a distinguishing property of the individual member of the group. This requires the establishment of specific rules for individual groups of substances.

INNs for active substances are selected with regard to their use by physicians in prescribing. For that reason, they cannot be cumbersome and the one-word approach is preferred whenever possible. Names have to be distinctive in spelling and sound and to differ from each other to avoid confusion. They also have to differ from existing trademarks, to avoid infringement of intellectual property rights. The INN programme avoids selecting names for old substances that have well established traditional (trivial) names or names devised according to the rules of chemical nomenclature.

Some of these considerations may also apply to excipients but will need to be modified. Names of excipients are not used by physicians or by the general public but mainly by pharmacy technologists and drug regulatory authorities. For that reason, INNs for excipients use the numbers as part of an excipients name, an approach that is not in use for active substances. A unique system for naming excipients will therefore be needed if the programme is faced with the daunting task of uniformly naming the several hundreds of substances and products currently in use.

One possible system is to retain one-word names composed of syllables each with a specific meaning. A similar system exists at present for naming mono-clonal antibodies. This permits the description, in one or two words, of several properties of the product. The drawbacks of the system are that names are polysyllabic, difficult to pronounce, and sometimes quite similar.

Another possible system would be a straightforward alphanumeric code system. Such systems exist in related areas, such as the Colour Index numbering system. For example, CI 16255 for Ponceau 4R; CI 45430 for erythrosine or the European Union food additives nomenclature E 124 for Ponceau 4R; E127 for erythrosine. Similar types of designations (type name, plus a number) are used for excipients by some large-scale manufacturers of these materials. Depending on the number of digits in the numerical part, the system would permit any type of classification to be included, the description (definition) of the substance could contain any desired type of information.

The majority of excipients are mixtures, even if some of them (like inorganic salts and sugars) are essentially homogenous substances. This creates a specific difficulty as any substance (or a product) designated by a name has to be properly characterized (defined). Whereas the definition of a homogenous chemical substance is usually straightforward (even if sometimes rather cumbersome for substances of a complex structure), a definition of a mixture is more complicated. It has to include either the designation of the components and of their amounts (e.g. percentage), or provide information on its other properties which will distinguish it in an unequivocal manner.

Various situations exist among non-homogenous excipients. Natural products are usually heterogenous (e.g. vegetable oils contain mixtures of fatty acids), synthetic polymeric materials may consist of mixtures of homologues with differing molecular mass distribution, some polymer constructs are also mixtures of individual products which may differ in the amounts of components each contains. In all such cases, it is necessary to decide on the type of elements that have to be included in the definition, so that the product can be described properly.

An additional difficulty in defining a product (or a member of a group of substances) is related to the existence of different grades of purity of excipients, usually depending on intended use. There is also the question of whether functionality related properties of excipients should be included in definitions and to what extent.

Excipient nomenclature: some examples

Inorganic Substances

MINERAL ACIDS, BASES AND SALTS

Mineral acids are widely used in diluted form as an acidifying agent in a variety of pharmaceutical and food preparations. A commonly used mineral acid is hydrochloric acid.

Mineral salts are water-soluble and may be used as excipients for various reasons. Many of the salts used in pharmacy are calcium salt, sodium salt or potassium salt. Mineral salts may be added to a pharmaceutical preparation to:

- (a) serve as a buffer solution to maintain stability of the active ingredient
- (b) provide an ideal ionic strength for stabilisation of the active ingredient
- (c) provide an ideal isotonicity for ophthalmic and parenteral preparations
- (d) act as an effervescent

Some examples of salts that are used as excipients in pharmaceutical preparations include sodium carbonate, sodium phosphate, sodium chloride, sodium bisulphite, calcium carbonate, calcium bisul-phite, calcium sulphate, potassium bicarbonate and potassium phosphate.

Current Nomenclature Approach

Either the chemical names or trivial names are used for this group of substances. In some cases, there are different names assigned to the same substance by different pharmacopeias.

Examples:

BP	USP	PhEur
Anhydrous Disodium Hydrogen Phosphate, Disodium Hydrogen Phosphate Dihydrate, Disodium Hydrogen Phosphate Dodecahydrate (Lat.)	Dibasic sodium phosphate(anhydrous, dihydrate, heptahydrate, dodecahydrate)	Disodium Phosphate, Anhydrous, Disodium Phosphate Dihydrate, Disodium Phosphate Dodecahydrate (Eng.), Dinatrii phosphas anhydricus, dihydricus, dodecahydricus
Heavy Magnesium Carbonate, Light Magnesium Carbonate	Magnesium carbonate (anhydrous, hydrate)	Magnesium Carbonate Heavy, Magnesium Carbonate Light(Eng.), Magnesii subcarbonas ponderous, Magnesii subcar- bonas levis (Lat.)
Anhydrous Calcium Hydrogen Phosphate, Calcium Hydrogen	Dibasic calcium phosphate (anhydrous, hydrogen phosphate, dihydrate (Eng.)	Calcium hydrogen phosphate, anhydrous, Calcium (Eng.) Calcii

Phosphate (= dihydrate)	dihydrate)	hydrogenophosphas anhydricus, Calcii hydrogenophosphas dihydricus (Lat.)
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Calcium Carbonate	Calcium carbonate	Calcium Carbonate (Eng.) Calcii carbonas (Lat.)
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SILICAS

Silicon dioxide (SiO₂) is widely used in the manufacture of pharmaceuticals, cosmetics and food products. It is used as an adsorbent, anticaking agent, glidant, suspending agent, tablet disintegrant and viscosity-increasing agent.

Current Nomenclature Approach

Trivial names or chemical names have been adopted by different pharmacopeias.

Examples:

BP	USPNF	PhEur
Colloidal Anhydrous Silica	Colloidal silicon dioxide	Colloidal anhydrous silica (Eng.), Silica colloidalis anhydrica (Lat.)

SILICATES (NATURAL, SYNTHETIC)

Silicates are complexes or salts of silicic acid. They may be naturally occurring or synthetic. Silicates are commonly employed as excipients in the production of pharmaceuticals as an adsorbent, stabilising agent, suspending agent or viscosity-increasing agent.

Bentonite (Al₂O₃.4SiO₂.H₂O) is a naturally occurring hydrated aluminium silicate used primarily in the formulation of suspensions, gels and sols.

Kaolin (Al₂O₃.2SiO₂.2H₂O) also a naturally occurring native hydrated aluminium silicate is used in the preparation of both oral and topical preparations.

Magnesium Aluminium Silicate is a complex that is made up of a three-lattice layer of octahedral alumina and two tetrahedral silica sheets. It is used in the formulation of tablets, ointment and creams.

Magnesium trisilicate (Mg₂Si₃O₈.xH₂O) is mainly used as a glidant in the manufacture of solid oral dosage forms.

Current Nomenclature Approach

Trivial names have been adopted by pharmacopeias.

Examples:

BP	USPNF	PhEur
Aluminium Magnesium Silicate	Magnesium aluminum silicate	Aluminium Magnesium silicate (Eng.) Aluminii magnesii silicas (Lat.)

Organic Substances

Homogenous Substances

MONOALCOHOLS, ETHERS, CARBOXYLIC ACIDS AND PHENOLS (INCLUDING ANTIOXIDANTS AND PRESERVATIVES)

Monoalcohols are short chain aliphatic alcohols that possess only one hydroxyl group. Ethanol is commonly used as a solvent; in addition, it is also employed for its antimicrobial preservative property and its ability to enhance penetration of drugs through the skin. Isopropyl alcohol is used both as a disinfectant and solvent.

Dimethyl ether is a liquefied gas which, when exposed to atmospheric pressure, will undergo vaporisation, hence it is commonly employed as an aerosol propellant.

Organic acids such as ascorbic acid, benzoic acid, citric acid, fumaric acid, lactic acid, malic acid and tartaric acid are widely used as antioxidants or preservatives to prevent degradation of the active ingredient.

Current Nomenclature Approach

Trivial names and chemical names have been adopted as non-proprietary names in some pharmacopeias.

Examples:

BP	USP/USPNF	PhEur
Ethanol (96%)	Alcohol	Ethanol (96 per cent) (Eng.) Ethanolum (96 per centum) (Lat.)
Chlorobutanol, Anhydrous Chlorobutanol(viously Chlorbutol, Anhydrous Chlorbutol)	Chlorobutanol (anhydrous, hemihydrate)	Chlorobutanol anhydrous, Chlorobutanol hemihydrate(Eng.) Chlorobutanolum anhydri- cum, Chlorobutanolum hemihydricum (Lat.)
Racemethol	Menthol	Menthol, racemic (Eng.) Mentholum racemicum (Lat.)
Ethyl hydroxybenzoate	Ethylparaben	Ethyl parahydroxybenzoate (Eng.) Ethylis parahydroxyben-zoas (Lat.)
Phenoxyethanol	-	Phenoxyethanol (Eng.) Phenoxyethanolum (Lat.)
Benzyl Alcohol	Phenylethyl alcohol	Benzyl alcohol (Eng.) Alcohol benzylicus (Lat.)

MONOSACCHARIDES AND DISACCHARIDES

Monosaccharide, like dextrose, is used as a tablet and capsule diluent, a sweetening agent as well as a tonicity agent. Glucose is often used as a coating agent, a sweetening agent or a tablet binder. Disaccharide like lactose is commonly used as a tablet or capsule filler. Sucrose is a good sweetening agent, a filler, a viscosity-increasing agent and a sugar-coating agent.

Current Nomenclature Approach

Trivial names or chemical names are used.

Examples:

BP	USP/USPNF	PhEur
Anhydrous Glucose (= monohydrate) anhydricum, Gluco-	Dextrose (anhydrous, monohydrate)	Glucose anhydrous, Glucose monohydrate (Eng.) Glucosum sum monohydricum (Lat.)

DIOLS AND POLYOLS

Hydrocarbons that consist of two or more hydroxyl groups are called diols and polyols respectively. Glycerol, for example, is used as an emollient, a humectant or a plasticizer. Sometimes the hydroxyl groups are sourced to give a range of esters that are commonly used as non-ionic emulsifying agents (eg. glyceryl monooleate, glyceryl palmitostearate). Some diols and polyols are used as sweetening agents

Current Nomenclature Approach

Both trivial names and chemical names have been used.

Example:

BP USP/USPNF PhEur

Glycerol Glycerin Glycerolum

SWEETENING AGENTS

Sweetening agents are added to a formulation to mask the unpalatable taste of some medicine. There are a few sweetening agents that are commonly used in pharmaceuticals. These include mannitol, xylitol, saccharin, sucrose, sorbitol and aspartame.

Current Nomenclature Approach

The trivial names of these sweetening agents are used.

Natural Substances

VEGETABLE OILS

Vegetable oils are natural oils that are usually obtained directly from the seeds of a plant. Pharmaceutically, appropriately processed vegetable oils are used as vehicle or solvent for drugs. Some of the widely used vegetable oils are peanut oil, soybean oil, corn oil, canola oil, cottonseed oil and sesame oil. Sometimes, oil can be hydrogenated to give special quality, e.g. hydrogenated castor oil that is used either as an extended release agent, a stiffening agent or a tablet or capsule lubricant.

Current Nomenclature Approach

Trivial names are commonly used.

Examples:

BP USP/USPNF PhEur

Arachis oil Peanut oil Arachidis oleum

FATS

Fats are solid or semi-solid fatty substances. They are usually obtained from animal sources. The most commonly used fat in the manufacture of ointment or cream is lanolin.

Current Nomenclature Approach

The trivial name is used. Different names are used for lanolin depending on the literature.

BP USP/USPNF PhEur

Wool fat Lanolin Adeps lanae

FATTY ACIDS AND THEIR SALTS AND ESTERS

Fatty acids are long chain aliphatic carboxylic acids. They can be converted into salts and esters chemically and are used as emulsifying agents or tablet/capsule lubricants. Some of the commonly used fatty acids and derivatives are stearic acid and its sodium, magnesium, calcium and zinc salts; oleic acid; palmitic acid; sodium stearyl fumarate; ethyl oleate, glyceryl monooleate, isopropyl palmitate etc. This group also includes products obtained by partial esterification of a fatty acid with sorbitol and its mono and di-anhydrides, known as Spans®.

Current Nomenclature Approach

Trivial names are used for aliphatic fatty acids and their derivatives. INN names are given to sorbitan esters.

Examples:

INN	USPNF	PhEur
Sorbitan laurate	Sorbitan monolaurate	Sorbitan laurate
Sorbitan palmitate	Sorbitan monopalmitate	Sorbitan palmitate
Sorbitan trioleate	Sorbitan trioleate	Sorbitan trioleate

Polymeric Materials

NATURAL HOMOPOLYMERS

STARCHES

Starches are obtained from different sources and can be modified differently to give a range of different physicochemical properties and usages. There are starch, sterilizable starch, pregelatinised starch and sodium starch glycolate. Starch is often used as a disintegrant in tablets or capsules. It is also a main ingredient in dusting powder.

Current Nomenclature Approach

Trivial names are given to describe starch variety.

Examples:

BP	USP/USPNF	PhEur
Maize Starch, Potato Starch, Rice Starch, Tapioca Starch, Wheat Starch	Starch (corn, potato, tapioca, wheat)	Corn starch, Potato starch, Rice starch, Wheat starch (Eng.)

Maydis amyllum, Solani amyllum, Oryzae amyllum, Triticum amyllum(Lat.)

Pregelatinised starch -(Pregelatinised Maize Starch) Pregelatinised starch Pregelatinised starch (Eng.) Amyllum pregelificatum (Lat.)

DEXTRINS

Dextrin is starch that is partially hydrolysed. Cyclodextrins are cyclic oligosaccharide with at least 6 D-(+)-glucopyranose units attached by a (1-> 4) glucoside bonds. There are 3 types of cyclodextrins, namely α , β , and γ -cyclodextrins. β -cyclo-dextrin yields cyclodextrin of different physicochemical properties. Examples of the sourced β -cyclodextrins are dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, 2-hydroxyethyl- β -cyclodextrin, 2-hydroxypropyl- β -cyclodextrin and 3-hydroxypropyl- β -cyclodextrin.

Current Nomenclature Approach

INN Systematic name

alfadex α -cyclodextrin

betadex β -cyclodextrin

CELLULOSES

Cellulose is obtained from plant materials and has been sourced and processed into various forms for a wide range of applications. These include powdered cellulose, microcrystalline cellulose (obtained by partial depolymerization of cellulose), carboxymethylcellulose calcium/sodium, cellulose acetate phthalate, ethylcellulose, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, etc. These different types of cellulosic derivatives are used as stabilising agent, suspending agent, disintegrating agent for tablets and capsules, viscosity increasing agent.

CELLULOSE ESTERS

Current Nomenclature Approach

The present INN approach for naming cellulose esters is the following:

- (i) esters with one acidic residue: a two-word name (= INN approach)
- (ii) esters with several different acidic residues: a one word name with a cell- prefix and -ate suffix.

Examples:

INN Definition

Cellulose acetate(INNM)

Cellacefate cellulose acetate phthalate

CELLULOSE ETHERS

Current Nomenclature Approach

Present INN approach for naming cellulose ethers is to create a one word name with an -ellose suffix. For esters of cellulose ethers with one acidic residue - a two-word name (= INN approach), e.g. hypromellose phthalate.

Examples:

INN	USP	Systematic name
Hyprolose		Hydroxypropylcellulose
Hypromellose		Hydroxypropylmethylcellulose as USP
Carmellose	Carboxymethylcellulose	
Hyetellose		Hydroxyethylcellulose
Methylcellulose *		Cellulose methyl ether

** retained as well-established name*

MODIFIED CELLULOSE ETHERS

Current Nomenclature Approach

Present INN approach for naming modified cellulose ethers is to create a one word name with an -ellose suffix.

INN	Systematic name
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Croscarmellose	Cross-linked carboxymethylcellulose
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PROTEINS

Proteins are macromolecules of polypeptides and are often derived from animal or human sources. Albumin is the smallest plasma protein that is used commonly as a stabilising agent in injectables. Gelatin is a mixture of purified protein fraction obtained either by partial acid hydrolysis or alkaline partial hydrolysis of animal collagen. Gelatin is used as coating agent, film former and gelling agent.

Current Nomenclature Approach

Trivial names are used.

Example:

BP	USP/USPNF	PhEur
Gelatin - types A, B	Gelatin - types A, B	Gelatin (Eng.) Gelatinum (Lat.) - types A, B

Synthetic homopolymers

POLYETHYLENE GLYCOLS

Polyethylene glycols (PEGs) are widely used in a variety of pharmaceutical formulations including parenteral, topical, ophthalmic, oral and rectal preparations.

Current Nomenclature Approach

The nomenclature adopted indicates the molecular mass of the polymer.

Example:

INN	Definition
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Macrogol	polyethylene glycol of general formula $H-(OCH_2CH_2)_n-OH$, where n varies from 3 to 225 appropriately. Each macrogol name is followed by a number corresponding approximately to its average molecular mass
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BP	USP/USPNF	PhEur
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Macrogol	Polyethylene glycol	Macrogol (Eng.) Macrogolum (Lat.)
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POLYETHYLENE GLYCOL ESTERS

Polyethylene glycol esters are used as surfactants (emulsifying agents).

Current Nomenclature Approach

The nomenclature adopted indicates the molecular mass of the polymer.

Example:

INN	Definition
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Macrogol	monoester derived from a polyethylene glycol and a fatty acid of general formula $H-(OCH_2CH_2)_n-OOCR$. esters Each macrogol ester name is followed by a number corresponding approximately to the average molecular mass of the polyethylene glycol portion, e.g. macrogol laurate 600, macrogol oleate 600, macrogol stearate 400, 600, 1000 and 2000
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INN	USAN NF
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Macrogol Stearate 400	Polyoxyl 8 Stearate
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Macrogol Stearate 2000	Polyoxyl 40 Stearate
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POLYMETHYLACRYLATES

Polymethylacrylates are methylacrylic acid copolymers. This group includes a fully polymerised copolymer of methylacrylic acid and copolymers of acrylic or methyl-acrylic esters. There are 3 types of polymethyl-acrylates (type A, B and C) that are defined according to the methylacrylic acid content and solution viscosity. Polyacrylates are primarily used in oral capsule and tablet formulations as film coating agents.

Current Nomenclature Approach

Trivial names are used.

Examples:

BP	USP/USPNF	PhEur
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- Ammonio methacrylate copolymer-

Methacrylic Acid - Methyl Methacrylate Copolymer (1:1) Methacrylic acid copolymer- type A Methacrylic Acid - Methyl Methacrylate Copolymer (1:1)

Methacrylic Acid - Methyl Methacrylate Copolymer (1:2) Methacrylic acid copolymer- type B Methacrylic Acid - Methyl Methacrylate Copolymer (1:2)

- Methacrylic acid copolymer- type C -

POLYVINYL ALCOHOL

Polyvinyl alcohol is a polymer that can be represented by the empirical formula of $(C_2H_4O)_n$, in which the average value of n lies between 500-5000. Various grades with different viscosities and molecular weights are commercially. It is used primarily in topical pharmaceutical formulations, particularly in ophthalmic products.

Current Nomenclature Approach

Trivial names are adopted.

SILICONES

Silicones are used in barrier creams and as lubricants.

Current Nomenclature Approach

INN	Definition
Dimeticone	poly (dimethylsiloxane) - each name is followed by a number referring to the viscosity of the substance

Dimeticone 20 viscosity of 17.0 to 23.0 centistokes

Dimeticone 350 viscosity of 330 to 370 centistokes

Heteropolymers and mixtures

Natural heteropolymers

GUMS AND RESINS

Gums are formed upon injury of the plant or as a result of unfavourable conditions, such as drought, by the breakdown of cell walls. Gums upon hydrolysis will yield a mixture of sugars and uronic acids. Resins are complex mixtures of resin acids, resin alcohols, resin phenols and esters. Gums and resins are used pharmaceutically as emulsifying agents, stabilizing agents and suspending agents. Some examples include: guar gum, acacia and xantha gum.

Current Nomenclature Approach

Trivial names, frequently indicating botanical origin, are used.

WAXES

Waxes are natural mixtures containing appreciable quantities of esters derived from higher monohydric alcohols of methyl alcohol series combined with fatty acids. Waxes include products such as carnauba wax, microcrystalline wax, white wax, yellow wax and spermaceti wax.

Current Nomenclature Approach

Trivial names are used.

Synthetic and semisynthetic heteropolymers

POLYETHYLENEGLYCOL-POLYPROPYLENEGLYCOL COPOLIMERS

Polyethylenglycol-polypropylenglycol copolymers are used as ointment bases, suppository bases, tablet binders, emulsifying agents, tablet coating agents, may be also used as solubilizers and stabilizers.

Current Nomenclature Approach

Example:

INN	Definition
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	Poloxamer α -hydro- ω - hydroxypoly (oxyethylene) poly (oxypropylene) poly (oxyethylene) block copolymer; Each poloxamer name is followed by a number, e.g. poloxamer 188, 331, 407, etc. The first two digits multiplied by 100 correspond to the approximate average molecular mass of the poly (oxypropylene) portion; the third digit multiplied by 10 corresponds to the percentage by weight of the poly (oxyethylene) portion
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POLYETHYLENEGLYCOL-SORBITAN-FATTY ACID POLYMERS

Heteropolymers of polyoxyethylene, cyclic sorbitol anhydrides and fatty acids, known as Tweens®, are used as surfactants.

Current Nomenclature Approach

INN	Definition
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	Polysorbate poly (oxyethylene) derivative of cyclic sorbitol anhydrides with a fatty acid
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Examples:

INN	Definition
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	Polysorbate 20 polyethylene 20 sorbitan* monolaurate
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	Polysorbate 55 polyethylene 20 sorbitan* tristearate
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	Polysorbate 85 polyethylene 20 sorbitan* trioleate
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*polyoxyethylene 20 sorbitan corresponds to tris(polyethylene glycol 300) sorbitan ethers

CROSS-LINKED STARCHES

Microspheres produced by reaction of partially hydrolysed starch with epichlorhydrin are degradable by amylose. They are used as carriers in modified release dosage forms.

Current Nomenclature Approach

Examples:

INN	Definition
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Amilomer	Microspheres produced by reaction of partially hydrolysed starch with epichlorhydrin; half-life < 120 min. The name is followed by a hyphenated numerical code in which the number preceding the hyphen indicated the half-life in minutes and that following the hyphen indicates the mean diameter of the microspheres in μm ; e.g amilomer 25-45 has a half life of 25 min. and a mean diameter of 45 μm
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Cadexomer	Microspheres produced by reaction of partially hydrolysed starch with epichlorhydrin; half-life > 120 min. The name is followed by a number referring to the mean diameter in μm of the microspheres; e.g cadexomer 110
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Eldexomer	Microspheres produced by reaction of partially hydrolysed starch with epichlorhydrin; half-life > 120 min. The name is followed by a number referring to the mean diameter in μm of the microspheres; e.g eldexomer 60
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CROSS-LINKED POLYMERS OF ACRYLIC ACID AND CARBOHYDRATES

Polymers of acrylic acid cross-linked with allyl ethers of sucrose are used as emulsifying and thickening agents.

Current Nomenclature Approach

Examples:

INN	Definition
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Carbomer	Polymer of acrylic acid cross-linked with allyl sucrose
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